

Confidentiality and Record Keeping

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The purpose of this section is to review issues associated with confidentiality for patients receiving substance abuse treatment.

Specific Federal regulations govern disclosure of a patient's identity and treatment information, and states may have further such regulations.

Title 42, Part 2, Code of Federal Regulations [42 CFR Part 2]

Knowledge of these statutes is important for those providing substance abuse treatment as the rules may apply to their practice.

Outline for This Talk

I. History and Purpose

II. Scope of the law

III. General rules

IV. Exceptions and EHR

V. HIPAA

VI. Summary

Introduction

Genesis in two statutes of the early 1970s

Implemented by regulations from HEW in 1975

Revised by HHS in 1987 (42 CFR Part 2)

Congress reaffirmed and reorganized the two statutes into a single act

Rationale for Development of Confidentiality Statutes Specific to Those Seeking Substance Abuse Treatment

The logic behind these regulations is that persons with substance abuse problems are more likely to seek and succeed at treatment if they know their need for treatment will not be disclosed unnecessarily

Scope of the Law

Overview

Restricts disclosure and use of patient-identifying information

Patient-identifying information is anything that reveals a person is receiving, has received, or has applied for substance abuse treatment

Cannot disclose participation in substance abuse treatment – but can disclose identity under some circumstances

Scope of the Law

Application

**Regulations apply to holders, recipients,
and seekers of patient-identifying
information**

**Individual/program can't release
information except as authorized by the
patient or as permitted by regulations**

Scope of the Law

Application (continued)

Anyone who receives information can't re-disclose without patient consent or as authorized by regulations, and may not use it except for certain purposes

Anyone seeking information can't compel its disclosure except as permitted by regulations

Scope of the Law

Strictness of Regulations

Federal confidentiality regulations more strict than most other confidentiality rules

They apply whether the individual:

- **Seeking the information already has it**
- **Is seeking it for judicial or administrative proceedings**
- **Is a law enforcement or other government official**
- **Has a subpoena or a search warrant**
- **Is the spouse, parent, relative, employer, or friend**

Scope of the Law

Consequences of Violating or Disregarding

Criminal penalty

**For a program, could lose license or
certification**

Patients may sue

Scope of the Law

Conflicts with State Laws

State laws or regulations can be more restrictive than federal regulations, but they can't reduce the restrictions contained in federal regulations

General Rules: Definitions of Terms in Statutes

Patient

Anyone who has applied for or received a diagnostic examination or interview, treatment, or referral for treatment at a drug or alcohol program

Applicants for services are covered even if they fail to show for their initial appointment, or elect to not follow up with treatment

Includes current, former, and deceased patients

General Rules: Definition of Terms in Statutes

Programs

Definition of a program: federally assisted organizations and individual practitioners (DOs, MDs, NPs, PAs, psychologists, Social Workers and others)

General Rules

Programs (continued)

Federal assistance:

- Operated by the Federal government**
- Certified for Medicaid reimbursement**
- Receiving Federal block grant funds**
- Licensed by the Federal government**
- Exempt from paying taxes**

General Rules

Programs (continued)

What programs (including individual practitioners) do:

Specialize in providing, in whole or in part, individualized alcohol or drug abuse diagnosis, treatment, or referral for treatment

General Rules

Programs (continued)

Location of programs (and individual practitioners): free standing, part of a larger organization (in a hospital, part of a larger clinic)

Staff in the program subject to

Confidentiality Rules: part- and full-time employees; volunteers; student interns; former staff; executive, administrative, clinical and support staff

General Rules

Disclosure

Communication that directly or indirectly identifies someone as being, having been in, or having applied for substance abuse treatment

Occurs when a program or practitioner:

discloses patient's record;

allows an employee to testify about a patient's treatment;

allows a receptionist to confirm that a person is a patient in the program;

uses identifying stationery;

discloses anecdotal information

Disclosure: Exceptions

- **Internal communications**
- **Consent**
- **Anonymous or non-patient identifying information**
- **Qualified service organization agreement**
- **Crimes on premises or against personnel**

Disclosure: Exceptions

- **Medical emergencies**
- **Mandated reports**
- **Research**
- **Audit and evaluation**
- **Court orders ****

Disclosure: Exceptions

Internal Communications

- **Can occur within a program/office or with an entity having direct administrative control, if information is needed**
- **Staff can share information with each other, supervisors**
- **Staff of the hospital's record-keeping or billing department**

Disclosure: Exceptions

With Patient Consent

Patient can authorize specific disclosures

The patient's consent must be in writing

Consent must contain:

- name of patient
- name of disclosing program
- purpose of disclosure
- who is to receive
- exact information to be released
- that patient understands he/she can revoke consent at any time
- revocation can be oral
- date/condition under which consent expires
- date signed
- patient's signature

Disclosure: Exceptions

Consent (continued)

- **Program (or office) has to receive a copy of the patient's consent before responding to request**
- **Disclosures must include a written notice prohibiting re-disclosure**
- **The re-disclosure prohibition must be sent to recipient even when disclosure is made orally**

Disclosure: Exceptions

Anonymous or Non-patient Identifying Information

Disclosure may reveal a patient's name, address, telephone number without violating regulations when it does not reveal the nature of the services received by the patient or provided by the program

Disclosure: Exceptions

Qualified Service Organization Agreement

- Program or office can disclose to QSO without consent
- QSO: a person or agency that provides services that the program/office itself does not provide (e.g., data processing, dosage preparation, vocational counseling)
- QSO must be qualified to communicate with the program/office (i.e., written agreement)

Disclosure: Exceptions

Qualified Service Organization Agreement

- Program or office may freely communicate with QSO only the information needed by QSO
- Program or office can enter into such an agreement only if QSO offers service the program/office does not offer
- Program/office doesn't have to inform patients about QSOs

Disclosure: Exceptions

Crimes on Premises or Against Personnel

- **Regulations permit a program or office to release patient identifying information to the police if a patient commits or threatens to commit a crime on the premises or against program/office staff**
- **Can give name, address, last known location**
- **Can't report patient's other crimes**

Disclosure: Exceptions

Medical Emergencies

- **Medical emergency: situation posing immediate threat to health of the patient and requiring immediate medical intervention**
- **Information can be released to medical personnel who need to treat the condition**
- **This exception cannot be used to release information to family or non-medical personnel**

Disclosure: Exceptions

Mandated Reports

States require reporting of cases of child abuse or neglect (to child welfare authorities)

Can report such cases to the state (including in writing), but regulations continue to apply regarding patient's records

Disclosure: Exceptions

Research

- **Program or individual practitioner may allow a researcher to have access to patient records**
- **Program director/ individual practitioner must verify researcher qualified, protocol protects records, patient identification will not be re-disclosed**
- **Research protocol needs outside review**

Disclosure: Exceptions

Audit and Evaluation

- **May be conducted by regulatory agencies; funders; private third-party payers; private peer review organizations**
- **Time-limited activity for audit or evaluation**
- **Can't re-disclose information except pursuant to a court order or to determine Medicaid/Medicare compliance**

Disclosure: Exceptions

Court Orders

A federal, state, or local court may authorize a program or individual practitioner to make a disclosure of confidential patient identifying information only after following certain procedures and making certain determinations

A subpoena, search warrant, or arrest warrant is not sufficient by itself to require or permit disclosure, even if signed by a judge

Disclosure: Exceptions

Court Orders

- All court proceedings must remain confidential unless the patient requests otherwise
- The court must find “good cause” before it orders the disclosure

Disclosure: Exceptions

Court Orders

If information sought is a “confidential communication,” it may not be disclosed unless the disclosure:

- is necessary to protect against threat to life/serious bodily harm;

- is necessary to investigate or prosecute an extremely serious crime;

- is connected with a proceeding in which the patient has already presented evidence concerning the confidential communication

Electronic Health Records EHR

The issues of 42 CFR Part 2 and HIPPA in the IHS and Tribal Electronic Health Record is still pending. The IHS EHR was built from the Veteran's Administration Electronic Health Record. The VA is specifically exempted from the 42 CFR Part 2. The IHS is NOT exempted. We will continue to work to adhere with the existing regulations for privacy and confidential care but the regulations may change in the future. The practitioner is responsible to be aware of the law.

HIPAA and Substance Abuse Treatment

HIPAA: Health Insurance Portability and Accountability Act (1996) became effective on April 14, 2003, providing national standards for protecting health information.

It is important to be aware of HIPAA for all patients in treatment (not just those with a substance abuse disorder)

HIPAA and Substance Abuse Treatment

HIPAA shifts control of health information from providers to patients (to a great degree)

Covers providers who transmit health information electronically (essentially everyone)

Key feature of HIPAA is the definition of “Protected Health Information” (PHI) – individually identifiable information (e.g., name, date of birth, Social Security Number)

HIPAA and Substance Abuse Treatment

HIPAA establishes rules regarding PHI (for example, regarding patient notification, protection of information, disclosure, and research)

These rules are, in some ways, a movement toward the substance abuse confidentiality regulations (i.e., making general confidentiality regulations more like those used in substance abuse treatment programs)

HIPAA and Substance Abuse Treatment

Important for the physician to be familiar with HIPAA, and how it impacts their treatment and office practices

Maintaining the standards for confidentiality of substance abuse treatment is very consistent with the requirements of HIPAA.

Confidentiality: Summary

Confidentiality regarding treatment for substance use disorders is more stringent than typical regulations for doctor-patient relationship

Disclosure of information requires special consent of patient; other circumstances may allow disclosure

Be familiar with regulations for confidentiality, and be prepared for requests of records

Medical Recordkeeping

Medical Record Keeping

The medical record is the ongoing narrative of a patient's healthcare and memorializes the past history for purposes of continuity of current and future treatment.

Remember: if it isn't written down, it didn't happen.

Treatment for substance abuse is confidential. The medical record is a legal document which takes on different importance when a controlled substance – such as buprenorphine – is used in the treatment of substance abuse.

This section reviews aspects of medical record keeping as they apply to treatment of patients with a substance abuse disorder.

Outline for This Talk

- I. Overview to the medical record**
- II. The history portion of the record**
- III. Treatment plan**
- IV. Documentation and buprenorphine**
- V. Documentation scrutiny**
- VI. Alteration of records**
- VII. Storage of records**
- VIII. Summary**

Overview to the Medical Record

The medical record should document

- **Initial diagnosis and treatment plan information**
 - **Complete history**
 - **Physical examination results**
- **On-going history and physical examination**
- **Comparisons with initial presentation for progress or regression (with corresponding modifications, if needed, in the treatment plan)**
- **Assessment of pharmacological efficacy**
- **Lab tests and results**
- **Consults**
- **Compliance with treatment plan**
- **Urine and blood drug screening: Collection and results**
- **Medications prescribed**
- **Inventory and dispensing of controlled substances**

History Portion of the Record

Attention should be paid to documenting:

- Social supports and living arrangements
- Employment status
- Addiction and treatment history of patient and close family members

History Portion of the Record

Particular attention should be paid to documenting:

Whether the patient has current medical or psychiatric conditions, and treatment status

How the patient intends to pay for treatment (especially if his or her insurance company is not to be billed)

Treatment Plan

Treatment Plan portion of the medical record should document:

- Diagnoses and how determined
- Treatment goals
- Determination of medication to be used
- How medication will be used
- Psychosocial services needed/recommended
- Signature of patient and provider

Documentation and Buprenorphine

When planning to prescribe buprenorphine for opioid dependence treatment, it is important to document:

- Evidence showing patient is opioid dependent (including physical signs/symptoms, urine toxicology results)**
- Length and severity of patient's opioid dependence**
- Number, type, and intensity of previous treatments for opioid dependence**
- Any legal consequences to the patient because of opioid use**

Documentation and Buprenorphine

Prior to starting the patient on buprenorphine, obtain and document the patient's consent

Document each of the elements of informed consent:

- Adequate information given
- Patient competent to process information
- Patient given opportunity to ask questions
- Consent given freely and voluntarily

Documentation and Buprenorphine

As a part of informed consent, document that you have:

- Notified the purpose of the treatment
- Identified the agent to be used, what it does
- Explained contraindications to use of the medication
- Provided any special warnings, adverse reactions, side effects, drug interactions

Documentation and Buprenorphine

As a part of informed consent, document that you have:

- Discussed dependence, withdrawal**
- Discussed alternative treatments**
- Determined who else can know about the treatment**

Access to Records

- To encourage patients to seek treatment, Federal regulation protects the identity of patients who receive treatment for alcoholism or drug abuse by limiting access to their medical records.
- A specific release of information from the patient is required for release
- Some agencies can obtain access to records:
 - Department of Justice (DOJ):
 - Department of Health and Human Services (HHS):
 - Food and Drug Administration (FDA)
 - Substance Abuse and Mental Health Services Administration (SAMHSA)
 - Drug Enforcement Administration (DEA)
 - Federal Bureau of Investigation (FBI)
 - U.S. Attorney Offices

Documentation Scrutiny

Pertinent federal regulations include:

Confidentiality and disclosure of records

**Storage and dispensing controlled
substances in an office setting**

Writing of prescriptions

Documentation Scrutiny

Pertinent state regulations:

State regulations vary from state to state

Typically modeled on federal template

Can be more stringent than federal regulations

Subpoena may be required

Documentation Scrutiny

Insurance companies

May seek to review medical records to determine the medical necessity of treatment provided

Alteration of Records

Records can be legitimately changed under certain conditions

- Words crossed out (not erased)
- Date and initials of writer entered at correction site
- New or changed information inserted

Investigators and attorneys are trained to detect aberrations

Alteration of Records

Absence of words or information is construed as never existing

Controlled substance records are more likely to be scrutinized due to addiction and diversion

Storage of Records

Must keep available for at least 2 years

**Can be kept at a central location (but
must notify DEA)**

**Must be kept in a locked, secure place
when not in use**

Storage of Buprenorphine

- **Buprenorphine must be stored in the physician's office**
- **Buprenorphine must be stored under locked conditions**
- **Tracking record must be maintained that provides information on who received buprenorphine and quantity of drug dispensed**

Summary

Documentation and immaculate record keeping are extremely important – for the well being of both the patient and the physician.

The record is a legal document that may be reviewed by outside agencies.