



Applying Federal Substance Abuse Confidentiality Regulations to Behavioral Health Settings

Charles H. Smith, PhD

Regional Administrator - Region VIII

Substance Abuse Mental Health Services Administration

U.S. Department of Health & Human Services



Confidentiality & Trust

- *Privacy is not an area for compromise.*
- *Confidentiality should never be a shortcut.*
- *Security should not be a second thought or an afterthought.*



Why Confidentiality?

- Reduce negative attitudes
- Fostering trust
- Preserving privacy
- Encouraging help-seeking behavior
- It is an important, but not absolute, legal and ethical principle
- Balance between a patients legitimate desire to maintain privacy of sensitive information and permitting sharing of information that will improve treatment or public health or safety

Privacy Regulations

- Not meant to prevent information sharing but to set the standards for how to share
- Federal laws are a baseline, states may adopt more strict regulations
- Most states have laws that are stricter than HIPPA, few have laws that are stricter than Part 2
- State laws vary widely, presenting challenges for developing unified policy solutions or solutions that work across states, also difficult for technology vendors to develop functionality

SAMHSA: Civil Rights Protections

SAMHSA works to protect the rights of the most vulnerable individuals with mental and/or substance use disorders by ensuring they are treated with dignity

- Americans with Disabilities Act (ADA)
- Olmstead Act
- Protection and Advocacy for Individuals with Mental Illness (PAIMI) Program

5

SAMHSA: Medical Records Privacy & Confidentiality

SAMHSA supports standards that protect personal health information and advances standards on behavioral health records privacy, consent, and sharing.

- Health Insurance and Portability and Accountability Act of 1996 (HIPAA)
- Alcohol and Drug Abuse Patient Records Privacy Law (42 CFR Part 2)

6

Substance Abuse Confidentiality Regulations (42 CFR Part 2)

Federal Law, developed in early 1970's, updated in 1986 and 1992 to:

- Guarantee strict confidentiality of information about persons receiving alcohol and drug prevention and treatment services.
- Strongly protect people who are at risk for or seek or have been in treatment for alcohol and drug problems (stigma, social and/or criminal persecution, treatment noncompliance/avoidance)

U.S. Department of Health and Human Services

- Primary responsibility for the regulation

7

42 CFR Part 2

- The purpose of the statute and regulations prohibiting disclosure of records relating to substance abuse treatment, except with the patient's consent or a court order after good cause is shown, is **to encourage patients to seek substance abuse treatment without fear that by doing so their privacy will be compromised.**



Source: State of Florida Center for Drug-Free Living, Inc., 842 So.2d 177 (2003) at 181.

Applicability

- Applies to: Federally assisted individual or entity that “holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or treatment referral”
- Unit within a general medical facility that holds itself out as providing diagnosis, treatment or treatment referral
- Medical personnel in a general medical facility whose primary function is the provision of alcohol or drug abuse diagnosis, treatment or referral for treatment and who are identified as such providers.

What types of providers are covered programs under 42 CFR Part 2 (“Part 2”)?

To be a “program” that falls under 42 CFR Part 2, an individual or entity must be federally assisted and hold itself out as providing, and provide, alcohol or drug abuse diagnosis, treatment or referral for treatment (42 CFR § 2.11).

What types of providers are covered programs under 42 CFR Part 2 (“Part 2”)?

A program is “federally assisted,” if it is...

1. Authorized, licensed, certified, or registered by the Federal government; or
2. Receives Federal funds in any form, even if the funds do not directly pay for the alcohol or drug abuse services; or
3. Assisted by the Internal Revenue Service through a grant of tax exempt status or allowance of tax deductions for contributions; or
4. Authorized to conduct business by the Federal government (e.g., certified as a Medicare provider, authorized to conduct methadone maintenance treatment, or registered with the Drug Enforcement Agency (DEA) to dispense a controlled substance used in the treatment of alcohol or drug abuse); or
5. Operated directly by the Federal government.

11

What types of providers are covered programs under 42 CFR Part 2 (“Part 2”)?

A different definition of a “program” applies when services are provided by a specialized unit or staff within a general medical facility (or ‘mixed use’ facility). A general medical facility has a Part 2 program if:

1. There is “an identified unit within a medical facility which holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment;” OR
2. There are “medical personnel or other staff in a general medical facility whose primary function is the provision of alcohol or drug abuse diagnosis, treatment or referral for treatment and who are identified as such providers.” (42 CFR § 2.11(b),(c))

12

What types of providers are covered programs under 42 CFR Part 2 (“Part 2”)?

Most Substance Use Disorder Treatment programs are “federally assisted”; however...

- For-profit programs/private practitioners that do not receive federal assistance (e.g., private health insurance or self-pay) are not covered by 42 CFR Part 2.
 - Unless the State licensing or certification agency requires those programs or private practitioners to comply with Part 2. Check State laws for guidance.
- Clinicians, who use a controlled substance (e.g., benzodiazepines, methadone or buprenorphine) for detoxification or treatment of a substance use disorder, require a federal DEA registration and are subject to Part 2 (DEA license)
 - A physician who does not use a controlled substance for treatment and does not otherwise meet the definition of a Part 2 program is not subject to Part 2.

13

Is a Mental Health Program a “Federally Assisted” program under 42 CFR Part 2

A mental health program is a covered program if...

1. there is an identified unit within the facility or program which holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment; or
2. there are medical personnel or other staff in the mental health program or facility whose primary function is the provision of alcohol or drug abuse diagnosis, treatment or referral for treatment and who are identified as such providers. (42 CFR § 2.11 (b), (c))

14

What patients, and which records and information, are protected by 42 C.F.R Part 2?

Under 42 CFR § 2.11:

- “Patient” means “any individual who has applied for or been given diagnosis or treatment for alcohol or drug abuse at a federally assisted program.”
- “Records” mean “any information, whether recorded or not, relating to a patient received or acquired by a federally assisted alcohol or drug program.”

15

What patients, and which records and information, are protected by 42 C.F.R Part 2?

The Part 2 regulations “impose restrictions upon the disclosure and use of alcohol and drug patient records which are maintained in connection with the performance of any federally assisted alcohol and drug abuse program.” (42 CFR § 2.3(a))

The restrictions on disclosure apply to any information disclosed by a Part 2 program that “...would identify a patient as an alcohol or drug abuser ...” (42 CFR § 2.12(a) (1))

16

Disclosure

- Patient consent must be obtained before sharing information from a substance use disorder treatment facility that is subject to 42 CFR Part 2
- Disclosure:
 - “A communication of patient identifying information, the affirmative verification of another person’s communication of patient identifying information, or the communication of any information *from the record* of a patient...” (42 CFR 2.11)
 - Even acknowledging that an individual is (or was) a patient at a Part 2 facility is a breach of the regulations

Source: 42 CFR Part 2

Limited Disclosure Exceptions Without Patient Consent :

- Medical emergencies
- Child abuse reporting
- Crimes on program premises/against program personnel
- Communications with a qualified service organization of information needed by the organization to provide services to the program
- Research
- Court order
- Audits and evaluations

Revocation of Consent

“The written consent must state that it is revocable upon the passage of a specified amount of time or the occurrence of a specified, ascertainable event. The time or occurrence upon which consent becomes revocable may be no later than the final disposition of the conditional release or other action in connection with which consent is given.”

Source: 42 CFR Part 2

Restrictions on Redislosure and Use

“A person who receives patient information under this section may redisclose and use it only to carry out that person’s conditional release or other action in connection with which the consent was given.”



Source: 42 CFR Part 2

Disclosure of Information

Does 42 CFR Part 2 permit the disclosure of information without a patient's consent for the purposes of treatment, payment, or health care operations?

- Unlike HIPAA, which generally permits the disclosure of protected health information without patient consent or authorization for the purposes of treatment, payment, or health care operations, Part 2, with limited exceptions (i.e., medical emergencies and audits and evaluations), requires patient consent for such disclosures (42 CFR §§ 2.3, 2.12, 2.13).

21

Disclosure of Information

Patient Consent is not required when information is exchanged within a Part 2 program (e.g., SUD treatment agency) or between a Part 2 program and an entity that has direct administrative control over the program (42 CFR § 2.12(c)(3)).

Patient information may not be exchanged among all of the programs and personnel that fall under the umbrella of the entity that has administrative control over the Part 2 program.

- A Qualified Service Organization Agreement (QSOA) would be required to enable information exchange without patient consent in this situation.

22

Qualified Service Organization Agreement

Under Part 2, can a Qualified Service Organization Agreement (QSOA) be used to facilitate communication between a Part 2 program & an HIO?

- **Yes.** A QSOA under Part 2, which is similar ,but not identical to a business associate agreement under §§ 164.314(a) and 164.504(e) of the HIPAA Security and Privacy Rules, is a mechanism that allows for disclosure of information between a Part 2 program and an organization that provides services to the program, such as an HIO.
- Examples of services that an HIO might provide include
 - Holding and storing patient data,
 - Receiving and reviewing requests for disclosures to third parties, AND
 - Facilitating the electronic exchange of patients' information through the HIO network.

23

Qualified Service Organization Agreement

The HIO may also communicate with the Part 2 program and share information it receives from the program back with the program.

Patient consent is not needed to authorize such communications between the HIO and Part 2 program when a QSOA is in place between the two.

24

Health Information Exchange

May information protected by Part 2 be made available to an HIO for electronic exchange?

Yes. Information protected by 42 CFR Part 2 may only be made available to an HIO for exchange if:

1. A patient signs a Part 2-compliant consent form authorizing the Part 2 program to disclose the information to the HIO, or
2. A Qualified Service Organization Agreement (QSOA) is in place between the Part 2 program and the HIO.

25

42 CFR Part 2

SAMHSA Guidance:

- <http://www.samhsa.gov/health/Privacy/docs/EHR-FAQs.pdf>
- 2010, “Frequently Asked Questions: Applying the Substance Abuse Confidentiality Regulations to Health Information Exchange (HIE)”
- 2011, “Applying the Substance Abuse Confidentiality Regulations 42 CFR Part 2 (Revised)”
- 2016, Notice of Proposed Rulemaking, “Federal Rules Governing the Confidentiality of Substance Use Disorder Records”, Federal Registry

26

THANK YOU

Charles H. Smith, PhD

Regional Administrator - Region VIII

(Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming)

Substance Abuse and Mental Health Services Administration

U.S. Department of Health and Human Services

999 18th Street, South Tower, Room 4-342

Denver, CO 80202

303-844-7873

charles.smith@samhsa.hhs.gov

27

United States Department of
Health & Human Services



Office for Civil Rights

Access Guidance and Enforcement Update

Office for Civil Rights (OCR)

U.S. Department of Health and Human Services

Hyla Schreurs, J.D.

Supervisory Equal Opportunity Specialist



HIPAA Right of Access Guidance

- <http://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html>
 - Comprehensive Fact Sheet
 - Series of FAQs
 - Scope
 - Form and Format and Manner of Access
 - Timeliness
 - Fees
 - Directing Copy to a Third Party, and Certain Other Topics

29



Access – Scope

- Designated record set broadly includes medical, payment, and other records used to make decisions about the individual
 - Doesn't matter how old the PHI is, where it is kept, or where it originated
 - Includes clinical laboratory test reports and underlying information (including genomic information)

30



Access – Scope (cont.)

- Very limited exclusions and grounds for denial
 - E.g., psychotherapy notes, information compiled for litigation, records not used to make decisions about individuals (e.g., certain business records) BUT underlying information remains accessible
 - Covered entity may not require individual to provide rationale for request or deny based on rationale offered
 - No denial for failure to pay for health care services
 - Concerns that individual may not understand or be upset by the PHI not sufficient to deny access

31



Access – Requests for Access

- Covered entity may require written request
- Can be electronic
- Reasonable steps to verify identity
- BUT cannot create barrier to or unreasonably delay access
 - E.g., cannot require individual to make separate trip to office to request access

32



Office for Civil Rights

Access – Form and Format and Manner of Access

- Individual has right to copy in form and format requested if “readily producible”
 - If PHI maintained electronically, at least one type of electronic format must be accessible by individual
 - Depends on capabilities, not willingness
 - Includes requested mode of transmission/transfer of copy
 - Right to copy by e-mail (or mail), including unsecure e-mail if requested by individual (plus light warning about security risks)
 - Other modes if within capabilities of entity and mode would not present unacceptable security risks to PHI on entity’s systems

33



Office for Civil Rights

Access – Timeliness

Access must be provided within 30 days (one 30-day extension permitted) BUT expectation that entities can respond much sooner

34



Office for Civil Rights

Calculating Costs for Access Fees: 3 Acceptable Methods

1. Actual costs
 - Actual labor for copying (at reasonable rates, including only the time to create and send a copy in the form, format, and manner requested), **postage**, and **supplies** (paper, USB drive, toner, CD)
2. Average costs
 - Cost schedule based on average labor costs for standard requests is okay
 - Per page fee acceptable only for paper records (copied or scanned)
 - Applicable supply and postage costs may be added to average labor costs
3. Flat fee for electronic copies of electronic PHI only (\$6.50 cap).
 - An alternative to calculating actual or average costs for certain requests

35



Office for Civil Rights

Access – Right to Direct PHI to 3rd Party

- Individual has right to have entity transmit PHI to 3rd party of individual's choice (e.g., for research)
- Same requirements for providing access directly to the individual apply (e.g., fee limitations, form and format and timeliness requirements)

36



BREACH HIGHLIGHTS AND RECENT ENFORCEMENT ACTIVITY

37



Breach Notification Requirements

- Covered entity must notify affected individuals, HHS, and in some cases, the media, of breach
- Business associate must notify covered entity of breach
- Notification to be provided without unreasonable delay (but no later than 60 calendar days) after discovery of breach
 - Annual reporting to HHS of smaller breaches (affecting less than 500 individuals) permitted
- OCR posts breaches affecting 500+ individuals on OCR website

38



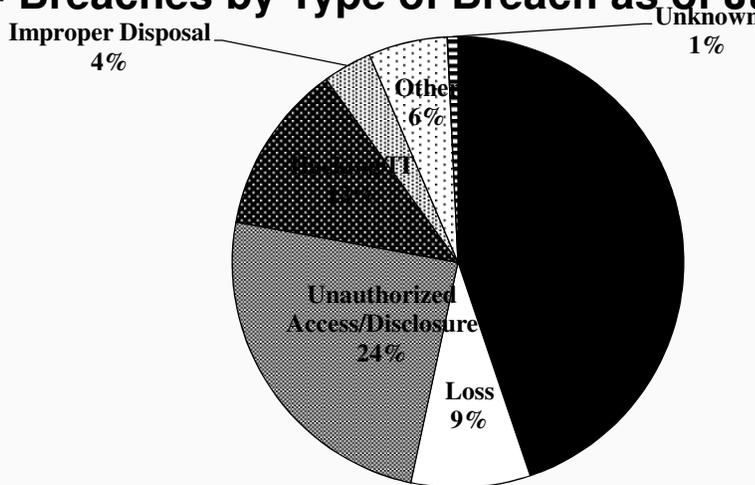
September 2009 through July 31, 2016

- Approximately 1,630 reports involving a breach of PHI affecting 500 or more individuals
 - Theft and Loss are 45% of large breaches
 - Hacking/IT now account for 12% of incidents
 - Laptops and other portable storage devices account for 29% of large breaches
 - Paper records are 23% of large breaches
 - Individuals affected are approximately 159,445,990

39



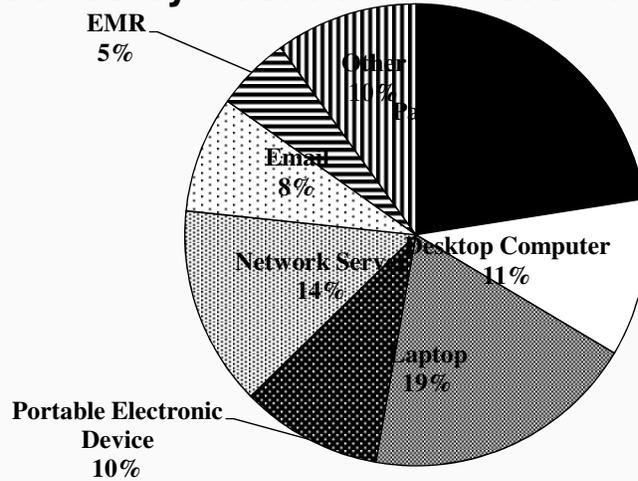
500+ Breaches by Type of Breach as of July 31, 2016



40



500+ Breaches by Location of Breach as of July 31, 2016



41



- OCR posts breaches affecting 500+ individuals on OCR website (after verification of report)
 - Public can search and sort posted breaches
- OCR opens investigations into breaches affecting 500+ individuals, and into a number of smaller breaches

42



Office for Civil Rights

- Over 137,770 complaints received to date
- Approximately 885 compliance reviews initiated
- Over 24,331 cases resolved with corrective action and/or technical assistance
- Expect to receive 17,000 complaints this year

As of 3/31/2016

43



Office for Civil Rights

- In most cases, entities able to demonstrate satisfactory compliance through voluntary cooperation and corrective action
- In some cases though, nature or scope of indicated noncompliance warrants additional enforcement action
- Resolution Agreements/Corrective Action Plans
 - 35 settlement agreements that include detailed corrective action plans and monetary settlement amounts
- 2 civil money penalties

As of July 31, 2016

44



Recurring Compliance Issues

- Business Associate Agreements
- Risk Analysis
- Failure to Manage Identified Risk, e.g. Encrypt
- Lack of Transmission Security
- Lack of Appropriate Auditing
- No Patching of Software
- Insider Threat
- Improper Disposal
- Insufficient Data Backup and Contingency Planning



Corrective Actions May Include:

- Updating risk analysis and risk management plans
- Updating policies and procedures
- Training of workforce
- Implementing specific technical or other safeguards
- Mitigation
- CAPs may include monitoring



Office for Civil Rights

Some Good Practices:

- Review all vendor and contractor relationships to ensure BAAs are in place as appropriate and address breach/security incident obligations
- Risk analysis and risk management should be integrated into business processes; conducted regularly and when new technologies and business operations are planned
- Dispose of PHI on media and paper that has been identified for disposal in a timely manner
- Incorporate lessons learned from incidents into the overall security management process
- Provide training specific to organization and job responsibilities and on regular basis; reinforce workforce members' critical role in protecting privacy and security

47



Office for Civil Rights

<http://www.hhs.gov/hipaa>

Join us on Twitter @hhsocr

303-844-7508

Hyla.Schreurs@hhs.gov

48