Our Agenda

• Overview of privacy laws
  • Federal
    • HIPAA
    • 42 CFR, Part 2
  • State
There are days......

WE HAD A MASSIVE DATA BREACH. HACKERS GOT INTO THE PRIVATE DATA OF ALL OF OUR CUSTOMERS.

NO PROBLEM. WE'LL ISSUE A PRESS RELEASE THAT SAYS WE'RE SORRY AND IT WILL NEVER HAPPEN AGAIN.

THAT'S WHAT WE SAID THE LAST THREE TIMES IT HAPPENED. OUR STRATEGY IS TO WEAR THEM DOWN.
HIPAA

- Title I of HIPAA regulates the availability and breadth of group health plans and certain individual health insurance policies.
- Title II of HIPAA – this is the part with which most of us are familiar
  - Establishes policies and procedures for maintaining the privacy and security of patient health information (PHI)
  - Outlines numerous offenses, and establishes criminal and civil penalties for violations.
- Privacy rule enacted April 2003
  - Updated January 2013
  - HITECH act (Health Information Technology for Economic and Clinical Health Act)
- Also the single-best test to see if the person with whom you are dealing knows anything about HIPAA at all.
Florida Privacy Laws
Florida Law re. Privacy

Non disclosure laws

• 394.4615 – Confidentiality of Records Must Be Maintained in Mental Health Treatment Facilities
• 490.009(1)(u) – Failure to Maintain Confidentiality = Grounds for Professional Discipline
• 490.0147(1) – Confidentiality & Privilege – Disclose Only With Written Consent
• 491.009(1)(u) – Failure to Maintain Confidentiality = Grounds for Professional Discipline
• 491.0147(1) – Confidentiality & Privilege – Disclose Only With Written Consent
• 64B4-5 – 5.001 – Disciplinary Actions for Breach of Confidentiality (Licensees under §491)
• 64B19-17.002 – Disciplinary Actions for Breach of Confidentiality (Licensees under §490)
• 64B19-19.006(1; 4) – Confidentiality – Disclose Voluntarily Only With Written Consent.
Other state laws

• Limitations of Confidentiality
  • Required disclosure
  • Permitted disclosure
  • Exceptions to privileged communications
42 CFR, Part 2 and SAMHSA
SAMHSA

• Substance Abuse and Mental Health Services Administration
• Observations
42 CFR, Part 2

• Congress recognized that the stigma associated with substance use disorders and fear of prosecution deterred people from entering treatment, and enacted the statute authorizing 42 CFR Part 2 to ensure an individual’s right to privacy and confidentiality.

• For decades 42 CFR Part 2 has been in the vanguard of personal privacy protections and the cornerstone of treatment programs across the country.
42 CFR, Part 2, continued

• Implements federal drug and alcohol confidentiality law (42 U.S.C. §290dd-2).
• Protects confidentiality of the identity, diagnosis, prognosis, or treatment of any patient records maintained in connection with the performance of any federally assisted program or activity relating to substance abuse education, prevention, training, treatment, rehabilitation or research.
Privacy and care

• 42 CFR Part 2 and other regulations provide ground rules, but how these rules are applied to ensure privacy and the best care requires careful analysis and monitoring.
  • Who needs what information when?
  • Who determines who needs what information when?
  • What are the consequences and outcomes?
  • And more...
Context and Purpose

• The purpose of 42 CFR Part 2 is to ensure that a patient receiving treatment for a substance use disorder in a Part 2 program is not made more vulnerable than an individual with a substance use disorder who does not seek treatment.
“Before I write my name on the board, I’ll need to know how you’re planning to use that data.”
Why revise?

• Regulations were first promulgated in 1975 and last substantively updated in 1987.

• Significant changes have impacted health care delivery since then:
  • New models of integrated care that rely on information sharing to support coordination of patient care.
  • Electronic infrastructure for information exchange.
  • New focus on performance measurement.

• 1987 to the present
  • Context: I was a sophomore in college in 1987, and had hair.
End Result

- The final rule is intended to modernize the Part 2 rules by facilitating the electronic exchange of substance use disorder information for treatment and other legitimate health care purposes while ensuring appropriate confidentiality protections for records that might identify an individual, directly or indirectly, as having a substance use disorder.
The Process

• SAMHSA held a Public Listening Session in 2014 to solicit feedback on 42 CFR Part 2.
  • Approximately 1,800 individuals participated in the session (in person or by phone).
  • SAMHSA received 112 oral comments and 635 written comments.
• http://www.youtube.com/playlist?list=PLBXgZMI_zqfTRftyiS4ckNi9bYW4Vmj82
The Process, continued

- The NPRM was published in the Federal Register on February 9, 2016 (81 FR 6988).
- The Comment Period was 60 days and closed on April 11, 2016.
- 376 comments were received.
Final Rule

• The final rule was published in the Federal Register on January 18, 2017 (82 FR 6052).
• The effective date was initially scheduled for February 17, 2017.
• Review by the administration resulted in a revised effective date of March 21, 2017.
Changes

• In the final rule, SAMHSA made terminology changes throughout for clarity, consistency, and to modernize the regulations (e.g., from “alcohol and drug abuse” to “substance use disorder”).

• SAMHSA changed the name of the regulations to: Confidentiality of Substance Use Disorder Patient Records.
Confidentiality Restrictions and Safeguards

- The final rule requires that, upon request, patients who have included a general designation in the “To Whom” section of the consent form must be provided a list of entities to whom their information has been disclosed pursuant to a general designation (List of Disclosures).

- However, in the final rule, SAMHSA clarified that the entity that serves as an intermediary, NOT the Part 2 program, is responsible for complying with the List of Disclosures requirement.

- The final rule clarifies that the general designation on the consent form may not be used until entities required to comply with the List of Disclosures provision have the ability to do so.
Confidentiality Restrictions and Safeguards, continued

• Does the consent stay in place if a disclosing program merges with another entity or undergoes a corporate restructuring?
  • Classic lawyer answer – it depends.
  • If it’s a general designation, then the consent is likely unaffected;
  • If it is a specific entity identified, then it depends on what happened in the change or restructuring.
Multiple Party Consent Revocation

Can the patient revoke consent for disclosure to one or more party, but keep the remainder of the consent in place?

- Yes.
- A health information officer should have policies and procedures in place for implementing patient decisions such as this.
- While oral revocations need to be honored under Part 2, SAMHSA recommends obtaining revocation in writing.
On Call Coverage Disclosures

• Qualified Service Organizations may provide services, and thus a Part 2 program may disclose information so the ‘on call’ coverage may be effectively provided.
• Designate recipient as ‘on call coverage provider’ to meet the requirement that the recipient’s name/title be identified.
• Key terms:
  • Diagnosis
  • Treatment
  • Referral for treatment services
Use of single consent form

• Part 2 allows the use of a single consent form authorizing the disclosure of Part 2 patient information to different recipients for different purposes.

• Also requires a consent form to specify the kind and amount of information that can be disclosed to each of the recipients named in the consent. The amount of information to be disclosed “must be limited to that information which is necessary to carry out the purpose of the disclosure”.
  • This should sound familiar --- HIPAA –ish language.
Disclosures without Consent

• **To medical personnel in medical emergency**: a situation that poses an immediate threat to the health of any individual and requires immediate medical intervention – redisclosure may be allowed for treatment purposes.
  
  • Who are ‘medical personnel’? Conveniently not defined in Part 2.
  
  • Health care provider or facility treating the emergency determines the existence of a medical emergency and which personnel are needed to address the medical emergency.
  
  • **Documentation requirement**: The name of the medical personnel to whom the disclosure was made, their affiliation with any health care facility, the name of the individual making the disclosure, the date and time of the disclosure, and the nature of the medical emergency must be documented in the patient’s records by the Part 2 program disclosing them.
Disclosures without Consent, continued

• Medical emergency exception invoked to head off potential medical emergency
  • Drug interactions, for example
    • If a health care provider determines that a medical emergency exists “a condition which poses an immediate threat to the health of any individual [not just the patient], and which requires immediate medical intervention,” then that information and any other information contained in the Part 2 record that the treating health care provider determines he or she needs to treat the medical emergency can be disclosed.
    • If no such determination exists, SAMHSA recommends trying to obtain consent from the patient.
    • If there is a concern re. potential drug interaction in non-emergency situation, and provider has signed a QSOA, access may be gained that way, or with patient consent.
  • General HIPAA-like exception as well.
Disclosures without consent, continued

- Law Enforcement: if an immediate threat to the health or safety of an individual exists due to a crime on program premises or against program personnel. A Part 2 program is permitted to report the crime or attempted crime to a law enforcement agency or to seek its assistance. Part 2 permits a program to disclose information regarding the circumstances of such incident, including the suspect’s name, address, last known whereabouts, and status as a patient in the program.

- Immediate threats to health or safety that do not involve medical emergencies or crimes on programs premises or against program personnel: can make reports to law enforcement about an immediate threat to the health or safety of an individual or the public if patient-identifying information is not disclosed. Immediate threats to health or safety that do not involve a medical emergency or crimes (e.g., a fire) are not addressed in the regulations. Programs should evaluate those circumstances individually.
Disclosures without Consent, continued

• **Court Orders**: Part 2 programs or “any person having a legally recognized interest in the disclosure which is sought” may apply to a court for an order authorizing disclosure of protected patient information. In other words, valid court order = disclose.
Re-disclosure

• Except for what is otherwise permitted under Part 2, re-disclosure, generally, prohibited.

• The final rule clarifies that the prohibition on re-disclosure only applies to information that would identify, directly or indirectly, an individual as having been diagnosed, treated, or referred for treatment for a substance use disorder, such as indicated through standard medical codes, descriptive language, or both, and allows other health-related information shared by the Part 2 program to be re-disclosed, if permissible under other applicable laws.

• SAMHSA made some additional minor clarifying revisions to §2.32 relative to:
  • The use of general authorizations.
  • The restrictions on using information to criminally investigate or prosecute a patient with a substance use disorder.
PRIVACY POLICY

We don’t really know what data about you we have or what we’re doing with it. When we figure all this out, we’ll let you know.
Re-disclosure, continued

- Does the logon or ‘splash’ page notification that contains a Part 2 Notice prohibiting re-disclosure meet the sufficiency requirements?
  - Generally, no.
  - Generally patient consent required for re-disclosures
  - Logon page or ‘splash’ page is a general page
  - Consents must be tied to the specific information being authorized for re-disclosure
Applicability

• Applicability is based on the definition of Program, which did not change except for updating terminology.

• Consistent with SAMHSA’s previous FAQ guidance, a practice comprised of primary care providers could be considered a “general medical facility” and be subject to 42 CFR Part 2 if the practice is both "federally assisted” and meets the definition of a program under §2.11.
What is a program?

• If a provider is not a general medical care facility, then the provider meets Part 2’s definition of a “program” if it is an individual or entity that holds itself out as providing, and provides alcohol or drug abuse diagnosis, treatment or referral for treatment.

• If the provider is an identified unit within a general medical care facility, it is a “program” if it holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment.

• If the provider consists of medical personnel or other staff in a general medical care facility, it is a program if its primary function is the provision of alcohol or drug abuse diagnosis, treatment or referral for treatment and is identified as such specialized medical personnel or other staff within the general medical care facility.
Security of Records

- The final rule:
- Addresses both paper and electronic records.
- Clarifies that both Part 2 programs and other lawful holders of patient identifying information must have in place formal policies and procedures for the security of records, including sanitizing media associated with both paper and electronic records.
  - Must reasonably protect against unauthorized uses and disclosures of patient identifying information and protect against reasonably anticipated threats or hazards to the security of patient identifying information.
Research

• The final 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).
Research, continued

• In the final rule:
  • §2.52(a) clarifies that lawful holders may re-disclose Part 2 data for research purposes, subject to the other conditions imposed in §2.52.
  • §2.52(a)(2) clarifies that disclosure of Part 2 data also is permitted for research that qualifies for exemption under the Common Rule due to the lower risk to subjects in circumstances where exemptions apply.
Research, continued

• The final rule enables researchers holding Part 2 data to link to data sets from federal and non-federal data repositories provided certain conditions are met.
  • Supports more advanced research, including studies of longitudinal effects of patient treatments.
Audit and evaluation

• Includes provisions for both paper and electronic patient records.
• Permits the Part 2 program, not just the Part 2 program director, to determine who is qualified to conduct an audit or evaluation.
• Updates the Medicare and Medicaid audit or evaluation section to include the Children’s Health Insurance Program (CHIP).
• Permits an 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 (including CMS-regulated Qualified Entities).
• Revises the requirements for destroying records by referencing §2.16, Security for Records.
Reports of Violations

• The final rule revises the requirement for reporting violations of Part 2 by opioid treatment programs to the Food and Drug Administration (FDA) because authority over these programs was transferred from the FDA to SAMHSA in 2001.
Notice to Patients

• Clarifies that the written summary of federal law and regulations may be provided to patients in either paper or electronic format.
• Requires the statement regarding the reporting of violations to include contact information for the appropriate authorities.
Disposition of Records – discontinued programs

• Includes provisions for both paper and electronic patient records.
• Adds requirements for sanitizing paper records and electronic media, which is distinctly different from deleting electronic media.
• Requires the process of sanitizing paper media (including printer and FAX ribbons, drums, etc.) or electronic media to be permanent and irreversible, so that there is no risk that the information may be recovered.
Disposition, continued

• Makes a distinction between electronic devices (something that has computing capability, such as a laptop, tablet, etc.) and electronic media (something that can be read on an electronic device, such as a CD/DVD, flash drive, etc.).

• Allows one year to complete the process of sanitizing electronic media that are subject to longer retention periods required by law.

  • This change should allow for select patient records to be removed from both the specific site and any operational sources without disrupting other patient records.
“Don’t worry, that only happens when someone uploads patient information to an unauthorized cloud service.”
Resources

• They’re from the government; they’re here to help you
• https://www.samhsa.gov/
• https://www.samhsa.gov/about-us/who-we-are/laws-regulations/confidentiality-regulations-faqs
Questions?