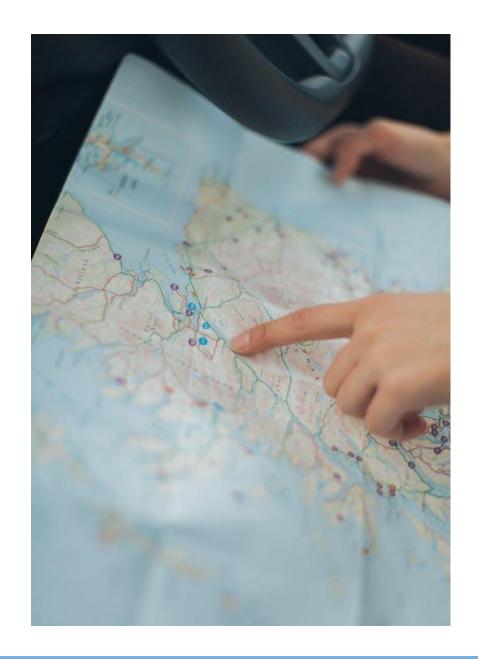
HIPAA + Other Confidentiality Laws

MARCH 4, 2024

KIRSTEN E. LELOUDIS, MPH, JD

UNC SCHOOL OF GOVERNMENT

The information provided in this presentation is for educational purposes only and does not constitute legal advice or establish an attorney-client relationship.



Presentation Roadmap

Overview of Federal Laws

- HIPAA
- 42 CFR Part 2 (substance use disorder information)
- Title X (family planning information)

Overview of State Laws

- G.S. 130A-143 (communicable disease information)
- Minor's consent confidentiality law

"Which Laws Apply?" Exercise

Let's Level Set!

This presentation will...

- Provide you with an overview of five confidentiality laws that frequently apply to NC public health work
- Teach you the basics so that you can identify which law(s) apply to certain information and know where to go for more information about the law

This presentation will not...

- Provide an in-depth look at all five confidentiality laws and how they interact with one another (that could take us weeks!)
- Teach you about every confidentiality law that may apply in the public health field

For each of the confidentiality laws, we will discuss:



- Who must comply with this law?
- What information does this law protect?
- What are permitted uses and disclosures of information under this law?
- Review: key takeaways



What Do We Mean by "Confidentiality?"

Confidentiality laws protect specific types of information by establishing requirements for how the information can be...

- Used or shared
 - Ex: use by the entity that holds the information
 - Ex: sharing the information with the person who the information is about, a family member, law enforcement, another health care provider, a third-party research team, etc.
- Securely stored and transmitted
 - Ex: firewalls, VPNs, encrypted emails, locked file cabinets, etc.
- And more



Why Does Confidentiality Matter?

What do you think?



Why Does Confidentiality Matter?

What do you think?

Possible reasons:

- Protects individuals' privacy
- Helps prevent fraud (misuse of someone else's information)
- Violating confidentiality can result in loss of an individual's and/or the public's trust in your organization
- Violating confidentiality can result in civil, criminal, and other penalties
- And more

Federal Laws: HIPAA



What is HIPAA?

Health Insurance Portability and Accountability Act of 1996

- A federal law that required US DHHS to create regulations governing the security and use of protected health information (PHI)
- The resulting regulations are what people colloquially refer to as "HIPAA"
- Includes the Privacy Rule, Security Rule, Breach Notification Rule, and more

Found at **45 CFR 160, 162, and 164**

Who Must Comply with HIPAA?

Blue Medical Insurance Company

Member Name: Jane Smith

ID#: 12345 6789

Effective Date: 1/1/2023

PCP: John Doe Deductible: \$1000 Co-Pay: \$25/\$50 Coinsurance: 20%



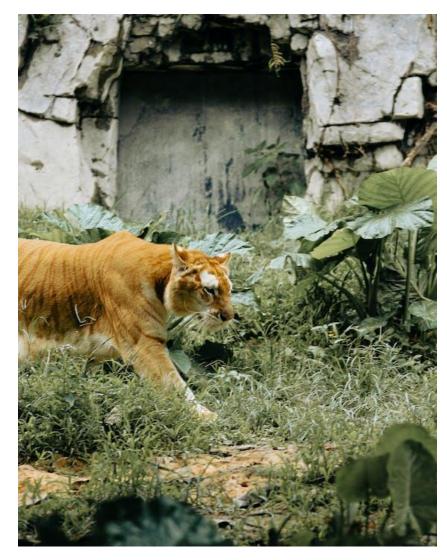


A covered entity (CE) is the name for entities that are regulated- or "covered"- by HIPAA and must comply with HIPAA's requirements. A CE's "business associate" (BA) must also comply with HIPAA.

There are 3 types of CEs:

- Health plan
- Covered health care provider
- Health care clearinghouse

Note: most LHDs are subject to HIPAA because they have/are "covered health care providers"



Like the majestic liger (lion + tiger), a HIPAA hybrid entity is one organization made up of two parts: covered and non-covered components.

HIPAA Hybrid Entities

"Hybrid entity" is defined at 45 CFR 164.103

- A single legal entity
- Whose business activities include HIPAA covered and non-covered functions
- That designates itself as a hybrid entity by identifying its health care components (aka, the components that perform covered functions under HIPAA)
 - This is important! Your organization is not a hybrid entity until you go through the hybrid entity designation process.

In a hybrid entity, only the parts of the organization that are "health care components" must comply with HIPAA



HIPAA Protects...

... protected health information (PHI)

PHI is any individually identifiable information or records in any form (electronic, paper, spoken) created or maintained by a CE that relates to any of the following:

- An individual's physical or mental health status or condition,
- Provision of health care to an individual, or
- Payment for the provision of health care to the individual.

PHI must not be used or disclosed except as permitted by HIPAA

PHI: Exceptions to the Definition

School records covered by FERPA

Individually identifiable health information in school records that are covered by the Family Educational Rights and Privacy Act (FERPA) is not PHI under HIPAA.

Employment records

Individually identifiable health information in employment records that are held by a covered entity *in its* capacity as an employer is not PHI under HIPAA.

Deceased individuals

Individually identifiable health information that pertains to a person who has been deceased for more than 50 years is not PHI under HIPAA.

Permitted Uses and Disclosures

- 1. Disclosures required by HIPAA
 - To the individual (patient or their representative), to US DHHS for compliance investigations or enforcement
- 2. Treatment, payment, or health care operations (TPO)
- 3. Disclosures where individual must have the opportunity to agree/object to the disclosure
 - E.g., hospital directories
- 4. Disclosure with the individual's written authorization (permission)
- 5. "Public interest" disclosures
 - Reporting abuse/neglect, organ donation purposes, judicial proceedings, workers' compensation claims, etc.

Note: Each type of permitted use or disclosure has specific requirements set forth in HIPAA. Reviewing the law before you make a disclosure is recommended- don't just assume it is allowed!



Key Takeaways: HIPAA

A "covered entity" (CE) must comply with HIPAA

- Most LHDs are CEs because they are covered health care providers
- If a LHD has become a hybrid entity, only "covered components" of the LHD must comply with HIPAA

PHI is any individually identifiable information created or maintained by a CE that relates to...

- An individual's physical or mental health status or condition,
- Provision of health care to an individual, or
- Payment for the provision of health care to the individual

Can always disclose PHI with written authorization (permission)

 Many other pathways for sharing PHI- check HIPAA regulations if you are unsure if a disclosure is allowed

Federal Laws: 42 CFR Part 2

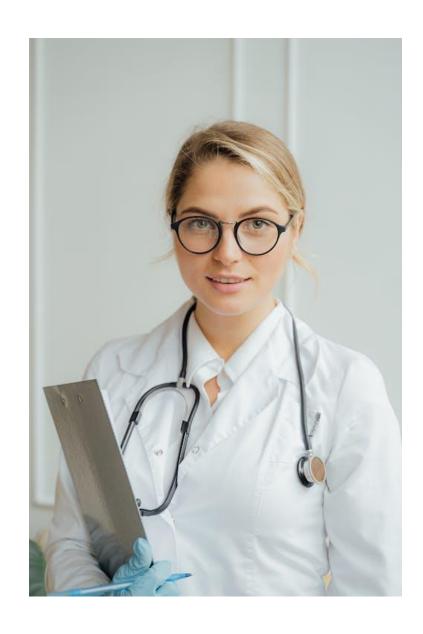


What is 42 CFR Part 2?

A set of federal regulations that protect **substance use disorder** (SUD) treatment information

 Sometimes called the "federal SUD law" or "Part 2 law"

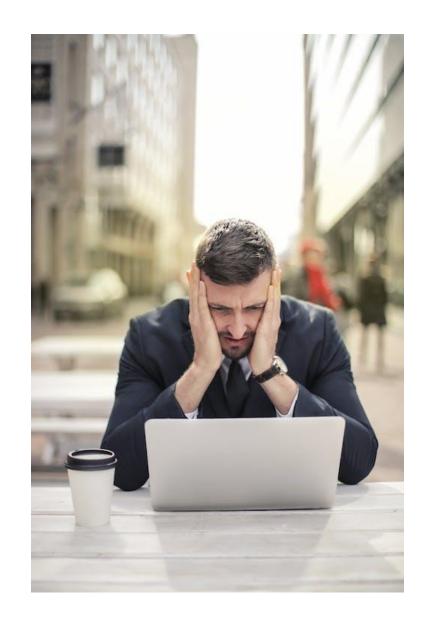
Photo: Kenny Holston, NYTimes, https://www.nytimes.com/2023/05/10/health/addiction-treatmentbuprenorphine-suboxone.html



Who Must Comply with 42 CFR Part 2?

Applies to certain providers of SUD services ("Part 2 programs") <u>and</u> anyone who receives protected SUD information from those providers ("lawful holders")

- More and more LHDs are offering SUD services these days- some are "Part 2 programs"
- LHDs may also be "lawful holders" of protected SUD information



How Do I Know If My LHD Is a Part 2 Program?

Must receive federal funds and be:

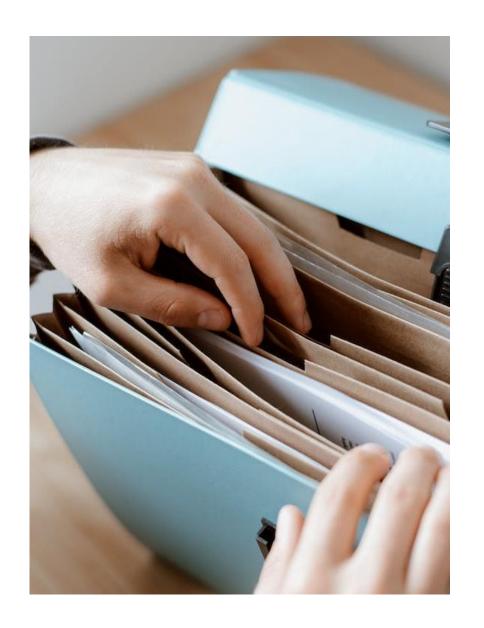
- An individual or entity (other than a general medical facility) who
 holds itself out as providing, and provides, SUD diagnosis,
 treatment, or referral for treatment; or
- An identified unit within a general medical facility that holds itself out as providing, and provides, SUD diagnosis, treatment, or referral for treatment; or
- Medical personnel or other staff in a general medical facility whose primary function is the provision of SUD diagnosis, treatment, or referral for treatment and who are identified as such providers.



How Do I Know If My LHD Is a "Lawful Holder?"

If your LHD receives SUD information that is subject to 42 CFR Part 2, then...

- The party that gave you the protected SUD information must notify you of the information's status and protection under 42 CFR Part 2
- This notice is required by the federal law



What Information is Protected?

Information that is obtained by a SUD program for the purpose of:

- treating or diagnosing a SUD, or
- making a SUD treatment referral

<u>and</u>

The information would identify an individual as having, or having had, a SUD



Permitted Disclosures

Common pathways for disclosing 42 CFR Part 2 information:

- Patient consent
 - Necessary for treatment, payment (e.g., billing), and healthcare operations
- Medical emergency exception
- Reporting child abuse/neglect as required by state law
- Certain court orders mandating disclosure

These permitted disclosures have strict, detailed requirements! Do not assume a pathway for disclosure listed above just applies-check the law and/or consult an attorney for more information about these and other permitted disclosures under 42 CFR Part 2.



Key Takeaways: 42 CFR Part 2

Only applies to "Part 2 programs" and "lawful holders"

Protects information related to an individual's SUD treatment, diagnosis, and/or referral for SUD treatment

Can always share information with patient consentotherwise, limited options for disclosing without permission from the patient or their representative

Federal Laws: Title X



What is Title X?

A federal funding program administered by the US DHHS, Office of Population Affairs

- Title X grants support the delivery of family planning services
- Services may include:
 - Pregnancy assistance and counseling (but typically not prenatal/postnatal care)
 - Contraceptive services
 - STI services
 - Other preventative services (cancer screenings, HPV vaccinations, etc.)
- Most LHDs receive Title X funds through NCDHHS
 - NCDHHS received and further distributed \$7.8 million in Title X funds in 2023



Who Must Comply with Title X Regulations?

Recipients of Title X funds must comply with Title X regulations

• **42 CFR 59.10** governs the confidentiality of information about patients who receive Title X-funded services

→ Reminder: most LHDs in NC receive Title X funds!



What Information is Protected?

The Title X regulations require:

"All information as to personal facts and circumstances obtained by the project staff about individuals receiving services must be held confidential."

 Provision allowing release of information that cannot be used to identify an individual (aggregate statistics, summary information, etc.)- indicates that only individually identifying information is confidential



Permitted Disclosures

Permitted disclosures:

- Documented patient consent
- As necessary to provide services to the patient*
- As required by law* (e.g., NC's mandatory reporting of child abuse)
- In summary/statistical form so an individual cannot be identified
- For billing purposes- but most notify patient of risk that the person who holds the health insurance policy could become aware of the services the patient received (if patient isn't the policy holder)

^{*}Must utilize reasonable safeguards to protect confidentiality as much as possible



Key Takeaways: Title X

Title X is a federally-funded family planning grant program

Grant recipients must comply with Title X re: confidentiality

- Most LHDs receive Title X funds
- Confidentiality only applies to services provided using Title X funds- not other services the LHD may also provide

Title X information can be shared with patient consent

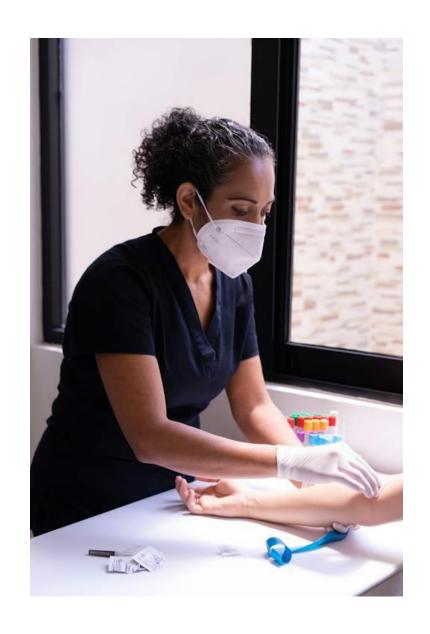
 Otherwise, can only disclose without patient consent if allowed under the federal regulations at 42 CFR 59.10

State Laws: G.S. 130A-143



What is G.S. 130A-143?

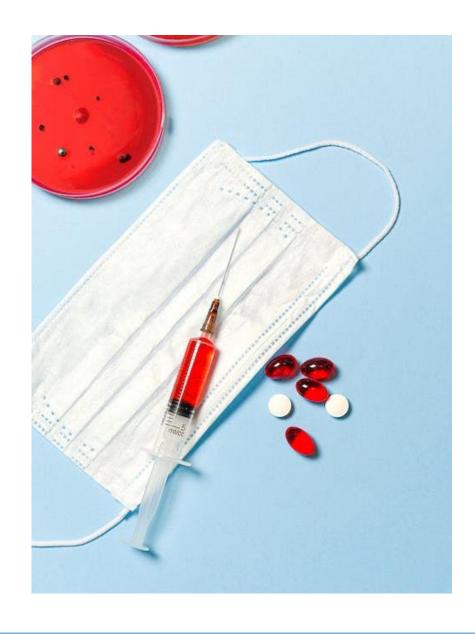
A North Carolina statute governing the confidentiality of information about someone who has (or may have) a reportable communicable disease or condition



Who Must Comply with G.S. 130A-143?

The law applies to "all information and records, whether publicly or privately maintained, that identify a person who has or may have a disease or condition required to be reported" under NC law

- Includes individuals/entities that regularly hold communicable disease information- e.g., health care providers, local health departments, laboratories, school employees, etc.
- ... but also, others who might hold this data: jails/prisons, schools, employers, insurance companies, etc.



What Information is Protected?

The law applies to "all information and records, whether publicly or privately maintained, that identify a person who has or may have a disease or condition required to be reported" under NC law

- Must be individually identifying- the law does not provide a deidentification standard, but NCDHHS has guidance on deidentification and small cell suppression
- Not limited to confirmed cases- includes information about someone who "may have" a disease or condition, such as someone who was exposed but has not yet been diagnosed
- Only applies to reportable diseases and conditions
 - See Rule 10A NCAC 41A .0101 for full list

Permitted Disclosures

- 1. Release only of deidentified medical/epidemiological information for statistical purposes
- 2. Written consent by the person who the information is about (or their personal representative)
- 3. Treatment, payment, and health care operations (TPO) or research, as defined under HIPAA
- 4. As necessary to protect the public health and in accordance with control measure rules
- 5. In accordance with other laws in G.S. 130A-143, Article 6
- 6. Release pursuant to a court order or subpoena by a judicial official
- 7. Release is by NCDHHS or a LHD for enforcement under G.S. 130A-143, Article 6 or Article 22
- 8. Release to law enforcement (specific purposes only)
- 9. Release is by NCDHHS or LHD to another federal, State, tribal, or local public health agency for purpose of preventing or controlling the spread of a communicable disease/condition
- 10. Release is by NCDHHS for "bona fide research purposes" and in accordance with administrative rules
- 11. Release is made in accordance with G.S. 130A-144(b) to State Health Director or local health director
- 12. Release is made pursuant to other laws specifically allowing/requiring release of AIDS information

Reminder: This is only a summary- please see the law for information about specific requirements for disclosure.



Key Takeaways: G.S. 130A-143

Protects individuals' communicable disease information

Compliance required by all holders of this information, whether public or private (and not just health care providers!)

Not limited to confirmed cases- also protects information about someone who "may have" the disease/condition

Only applies to information about **reportable** communicable diseases and conditions- see 10A NCAC 41A .0101 for list

Many pathways for sharing when necessary- review the statute for more information about permitted disclosures

State Laws: Minor's Consent Confidentiality Law



What is the NC Minor's Consent Law?

G.S. 90-21.5(a) allows an unemancipated minor with decisional capacity to give consent:

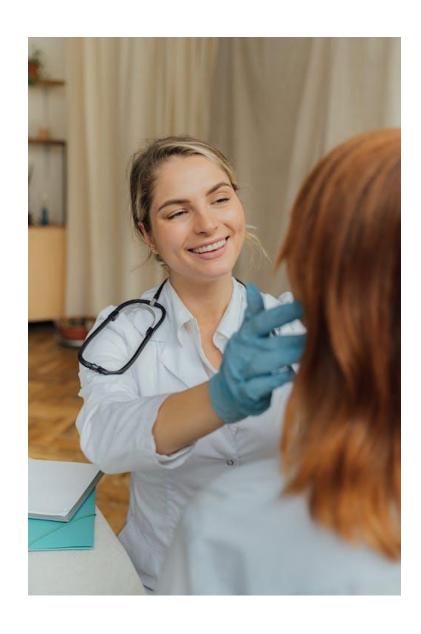
- To a physician
 - Or another health care professional working under a physician's direction/supervision, such as a nurse
- For the **prevention**, **diagnosis**, **or treatment** of:
 - A venereal or reportable disease/condition,
 - Pregnancy,
 - · Emotional disturbance, or
 - Misuse of alcohol or a substance use disorder (SUD)



What is the NC Minor's Consent *Confidentiality* Law?

G.S. 90-21.5(a) has a companion statute, **G.S. 90-21.4(b)**, that makes information about care provided under the minor's consent law confidential

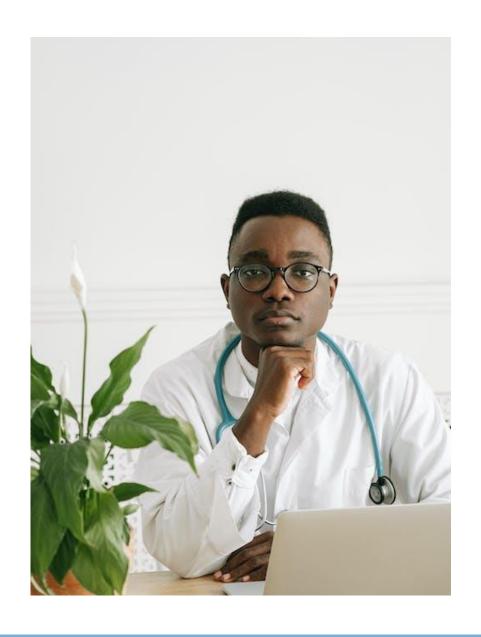
Specifically, G.S. 90-21.4(b) prohibits a provider from sharing information about health services provided to a minor under G.S. 90-21.5(a) with the minor's parent, guardian, custodian, or person standing *in loco parentis* (PILP) without the minor's permission, unless an exception applies



Who Must Comply with the Minor's Consent Confidentiality Law?

G.S. 90-21.4(b) applies to a physician who provides care to a minor patient under the minor's consent law (G.S. 90-21.5(a))

- Also applies to a provider who works under a physician and delivers care to the minor patient under G.S. 90-21.5(a)
- Sometimes, parties that were not involved in providing care to the minor can be required to protect this information, too, because of how HIPAA and the minor's consent law work together
 - When a minor consents to care under G.S. 90-21.5(a), the minor is the "individual" under HIPAA and is the person who can authorize the disclosure of PHI related to the care the minor received under G.S. 90-21.5(a)
 - This means that if minor's consent information is shared with another HIPAA covered entity, that entity needs to treat the minor as the "individual" with regard to the minor's consent information



What Information is Protected?

G.S. 90-21.4(b) about health services provided to a minor under G.S. 90-21.5(a)

 Prohibits sharing the information with minor's parent, guardian, custodian or PILP without the minor's permission, unless an exception applies

Example:

 17 year old comes to the LHD without a parent and asks for hormonal birth control (prevention of pregnancy). Provider determines that minor has decisional capacity and can consent on their own to this health service (care to prevent of pregnancy). Provider writes a prescription for the patient. Information about this visit and the care provided is protected under G.S. 90-21.4(b).



Permitted Disclosures

Can always disclosure with the minor patient's permission

May disclose if an exception applies

2 exceptions to G.S. 90-21.4(b): the provider <u>may</u>* disclose to a parent, guardian, custodian, or PILP if:

- In the provider's opinion, disclosure is essential to protect the life or health of the minor, or
- Parent, guardian, custodian, or PILP "contacts the physician concerning the treatment or medical services being provided to the minor"

^{*}Disclosure is permitted, but not required



Key Takeaways: Minor's Consent Confidentiality Law

G.S. 90-21.4(b) is the companion statute to G.S. 90-21.5(a)

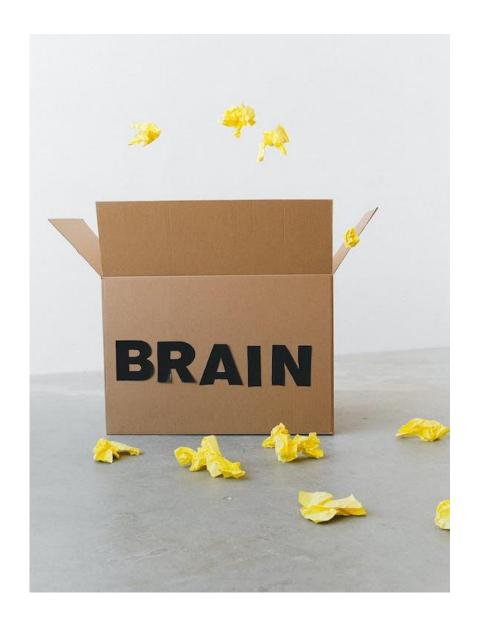
 Protects information about health services provided to minor patients under the minor's consent law

Prohibits disclosure of information to the minor's parent, guardian, custodian, or PILP

Disclosure permitted with minor patient's permission

 Provider may (but does not have to) disclose if one of the two exceptions applies

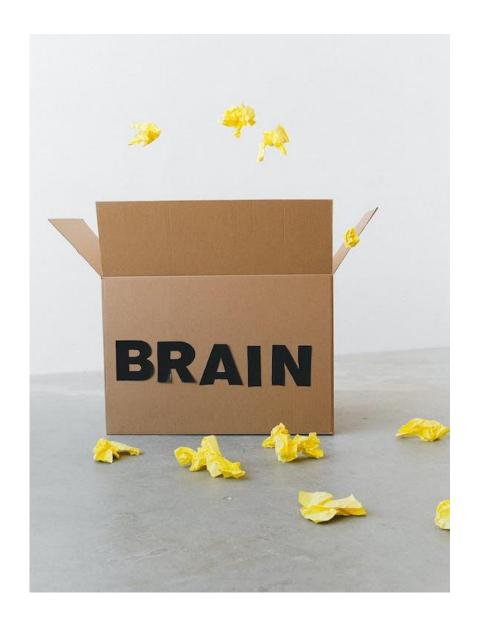
"Which Laws Apply?" Exercise



Next Steps

What do I do if I encounter a question about confidentiality laws?

- 1. Try to determine which law (or laws) apply to the information.
 - There is a good chance one or more of the laws we discussed today will apply!
- Find and read the confidentiality law(s).
 - Citations are included throughout this slide deck and on the "References" slide.
- 3. Consult with your attorney if you have questions about how the information can be used or disclosed (or if you're just not sure which laws apply!).
 - You, your staff, and your attorney are also <u>always</u> welcome to give me a call or send me an email to discuss which laws might apply, what those laws allow, and how multiple laws may fit together.



Next Steps

What do I do if I encounter a question about confidentiality laws?

- 1 Try to determine which law (or laws) apply to the information.
 - There is a good chance one or more of the laws we discussed today will apply!
- Find and read the confidentiality law(s)
 - Citation are included throughout this leck and on the "Reference"
- the information sure what law Let's practice! Let's practice!
 - You are a call or send me those laws allow a now ple ay fit to ay fit to are.

- = HIPAA
- = 42 CFR Part 2 (SUD information)
- = Title X (family planning)
- = G.S. 130A-143 (communicable disease)
- = Minor's consent confidentiality law

Lyle, a 15 year-old patient, comes to Dogwood County Health Department. Lyle tells a nurse that he is sexually active. Lyle's current sexual partner just shared that they'd tested positive for syphilis, and Lyle would like to be tested for syphilis today.

Lyle doesn't want his parents to know he is sexually active or about the syphilis test. The nurse determines that Lyle has decisional capacity necessary to consent to syphilis testing and administers the test. The nurse tells Lyle that his results should come back in 1-2 days.

- = HIPAA
- = 42 CFR Part 2 (SUD information)
- = Title X (family planning)
- = G.S. 130A-143 (communicable disease)
- = Minor's consent confidentiality law

Jane, a 17 year-old patient, comes to Dogwood County Health Department to see a physician assistant (PA) about her anxiety and depression. Jane tells the PA that she was diagnosed with anxiety and depression by a psychiatrist, but that her parents are not supportive of her receiving care- they believe a change in attitude and commitment to just pushing through it will solve things. Jane isn't so sure. Jane asks the PA if she could be prescribed an SSRI.

The PA asks Jane a few more questions and decides she has the decisional capacity to consent to treatment for her depression and anxiety with a common, generic SSRI. The PA writes the script and sends it to the pharmacy.

- = HIPAA
- = 42 CFR Part 2 (SUD information)
- = Title X (family planning)
- = G.S. 130A-143 (communicable disease)
- = Minor's consent confidentiality law

Bex, a 32 year-old patient, comes to the Dogwood County Health Department to receive prenatal care and SUD treatment.

Bex is part of a special program offered by Dogwood County Health Department that is called "RAISE." The program is funded by a SAMHSA grant and is dedicated to providing care to pregnant people who are living with a SUD. During her visit, Bex receives prenatal care (an ultrasound and bloodwork) and SUD care (counseling) from a SUD recovery specialist.

- = HIPAA
- = 42 CFR Part 2 (SUD information)
- = Title X (family planning)
- = G.S. 130A-143 (communicable disease)
- = Minor's consent confidentiality law

Dogwood County Health Department's HR team just received a fax containing medical records. The records pertain to one of the Department's employees, Hugh, who recently had hip surgery and needs to be given a reasonable accommodation (a parking spot closer to the building entrance) while he heals. The records are from Hugh's doctor proving that he did have the hip surgery and that the reasonable accommodation is necessary.

- = HIPAA
- = 42 CFR Part 2 (SUD information)
- = Title X (family planning)
- = G.S. 130A-143 (communicable disease)
- = Minor's consent confidentiality law

Dogwood County Health Department has been tasked with helping investigate an outbreak of food poisoning caused by *E. coli* at a local nursing home. The Department staff collect information about 15 residents and 5 nursing home staff who are part of the outbreak and have been made sick by eating contaminated food served in the dining hall.

The information about the outbreak has all been collected by environmental health section staff and is then turned over to the Department's communicable disease nurse. Several of the nursing home residents and staff are current patients of Dogwood Health Department, so the nurse adds this information about their illness to their existing patient records.

Image References

All images included in this presentation are from Pexels (www.pexels.com) unless otherwise noted and were last accessed on February 8, 2024.

Additional information about the license and use of images available from Pexels can be found here: https://www.pexels.com/license/.

References

Our 5 Confidentiality Laws

Name/description of law	What does it protect?	Legal citation
HIPAA	Protected health information (PHI)	42 CFR 160, 162, 164
42 CFR Part 2	Substance use disorder (SUD) treatment	42 CFR Part 2
	information	
Title X	Information about family planning	42 CFR 59.10
	services provided using Title X funds	
G.S. 130A-143	Information about a person who has or	G.S. 130A-143 (for list of
	may have a reportable communicable	reportable diseases and
	disease or condition	conditions, see 10A NCAC
		41A .0101)
Minor's consent confidentiality	Information about services provided to a	G.S. 90-21.4(b)
law	minor patient under G.S. 90-21.5(a)	

Other Confidentiality Laws

(this is not an exhaustive list)

Name/description of law	What does it protect?	Legal citation
State health director/local	Information provided to the state health	G.S. 130A-15(b)
health director right of access	director or local health director as	
law	required by G.S. 130A-15(a)	
Birth certificate confidentiality	Birth certificate information and records	G.S. 130A, Article 4
FERPA	Education records (including most school	20 U.S.C. 1232g; 34 CFR 99
	health records)	
Personnel information laws	Personnel information about LHD	G.S. 153A-98 (county and
	employees	district LHDs, some CHSAs)
Social security number law	Social security numbers collected by	G.S. 132-1.10
	government entities	
Mental and behavioral health	Information about individuals receiving	G.S. 122C
and IDD law	services for IDD, mental or behavioral	
	health	



Questions?

Thank you for your time.

If you have additional questions at a later date, please send me an email or give me a call.

Email: <u>Kirsten@sog.unc.edu</u> (preferred)

Office: 919-966-4210