

Public Health Law 101



A CDC Foundational Course for
Public Health Practitioners



Public Health Law Program

<http://www.cdc.gov/phlp>



PUBLIC HEALTH LAW 101

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- Unit 1: Key Concepts of U.S. Law in Public Health Practice
- Unit 2: Ethics and the Law
- Unit 3: Administrative Law
- Unit 4: Role of the Legal Counsel
- Unit 5: Law of Public Health Surveillance, Investigations, and Emergencies
- Unit 6: Privacy and Confidentiality
- Unit 7: Infectious Diseases
- Unit 8: Environmental Public Health, Occupational Health, and Injury
- Unit 9: Chronic Diseases and Birth Defects



**PUBLIC HEALTH LAW 101:
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**Unit 6
Privacy and Confidentiality**



Disclaimer

- These course materials are for instructional use only and are not intended as a substitute for professional legal or other advice. While every effort has been made to verify the accuracy of these materials, legal authorities and requirements may vary from jurisdiction to jurisdiction. Always seek the advice of an attorney or other qualified professional with any questions you may have regarding a legal matter.



Unit 6 Objectives

By the end of this unit, you should:

1. Understand the basic principles of health information privacy, confidentiality, and security.
2. Attain some basic familiarity with the universe of legal protections for the privacy and confidentiality of health data.
3. Gain a basic understanding of the scope, structure, and implementation of the HIPAA Privacy Rule.
4. Be able to discuss the impact of the HIPAA Privacy Rule on public health agencies.
5. Understand the distinctions between public health practice and public health research for the purposes of applying privacy laws and policies.



Objective 6.1

Understand the basic principles of health information privacy, confidentiality, and security.



Health Information Privacy: Key Terms

- **Privacy:** Individual's right to control the acquisition, use, and disclosure of their identifiable health information.
- **Confidentiality:** Privacy interests that arise from specific relationships (e.g., doctor/patient, researcher/subject) and corresponding legal and ethical duties.
- **Security:** Technological or administrative safeguards or tools to protect identifiable health information from unwarranted access, use, or disclosure.



Health Information Privacy: Key Terms

“If the **security** safeguards in an automated system fail or are compromised, a breach of **confidentiality** can occur and the **privacy** of data subjects invaded.”

Source: Willis Ware, "Lessons for the future: Privacy dimensions of medical record keeping," *Proceedings, Conference on Health Records: Social Needs and Personal Privacy* (1993).



Health Information Privacy: Key Concepts

- Protecting health information privacy requires legal protections addressing 4 types of data exchanges:
 - **Acquisitions:** acquiring or accessing identifiable health data by an entity
 - **Uses:** sharing, employment, examination, or analyzing identifiable health data within an entity
 - **Disclosures:** release, transfer, provision, access to, or disclosing identifiable health data outside the entity that holds it
 - **Storage:** keeping identifiable health data in any medium within an entity that is not actively using the data



Health Information Privacy

- **Risks**
 - **Disclosure:** Accessibility and intimate nature of identifiable health data may cause social, psychological, and economic harms to those whose privacy is violated through unwarranted disclosures.
 - **Emerging computer technologies** and the development of national electronic health information infrastructure may threaten individual privacy.
- **Synergies:** Protecting health information privacy is essential to health care and public health systems.



Imperatives for Protecting Health Information Privacy

- Improvements in health care and community health require the responsible sharing of some health data.
- In the absence of privacy protections, patients and others may avoid some clinical, public health, and research interventions.
- Individual privacy protections must be balanced with legitimate communal uses of health data (i.e., health research and public health).



Objective 6.2

Attain some basic familiarity with the universe of legal protections for the privacy and confidentiality of health data.

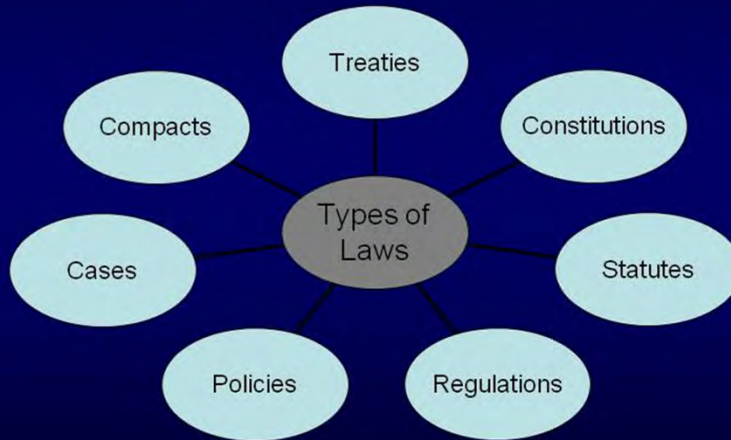


The Universe of Health Information Privacy Laws and Policies

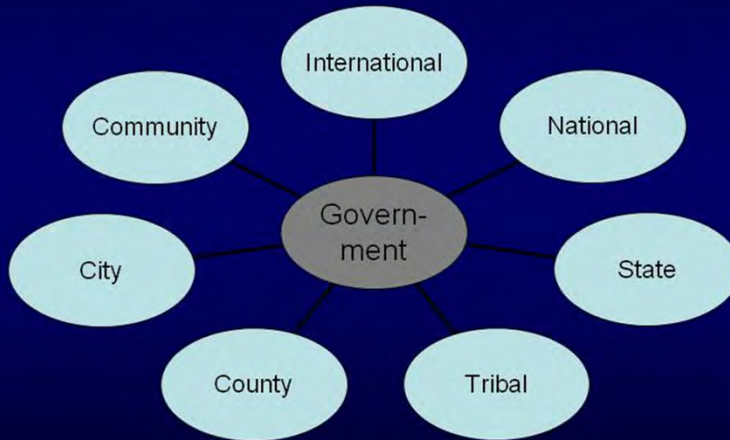
- The universe of health information privacy laws encompasses:
 - All types of laws
 - Every level of government
 - Multiple categories of entities
 - A broad spectrum of health data



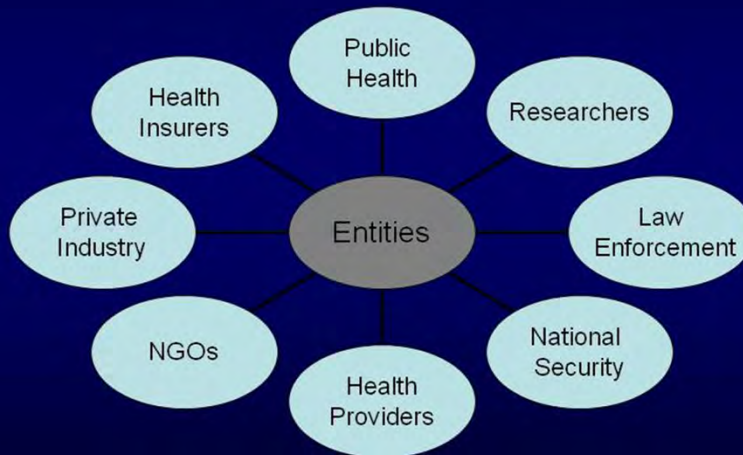
Health Information Privacy Laws and Policies: Types of Laws and Policies



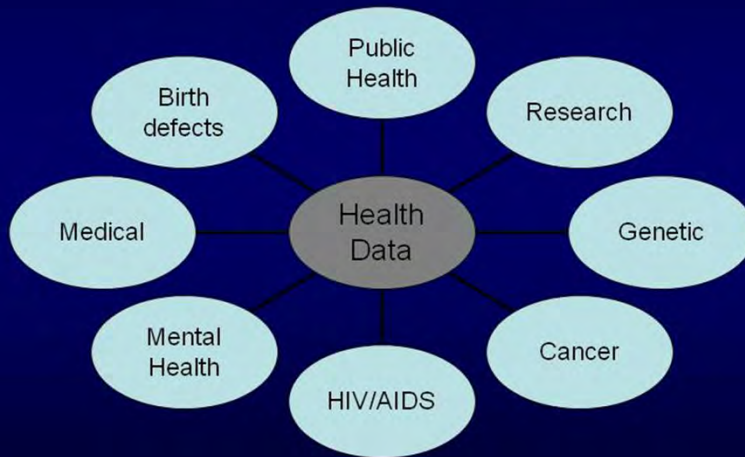
Health Information Privacy Laws and Policies: Levels of Government



Health Information Privacy Laws and Policies: Regulated Entities



Health Information Privacy Laws and Policies: Types of Health Data



Health Information Privacy Protections Vary by State

- States generally do not have comprehensive privacy and confidentiality statutes, but regulate by:
 - Source of information
 - Type of information
 - Holder of information
- Public health departments also have statutes and regulations applicable to their activities and information handling.
- 42 states have Health Information Exchange (HIE) networks that provide for electronic data-sharing; law must be in place to address this data sharing.



Health Information Privacy Laws and Policies: Common Characteristics

- Underlying all these laws are common characteristics:
 - Focus is primarily on individual (as contrasted with group) privacy protections
 - Only identifiable health data are covered (non-identifiable data do not require individual health privacy protections)
 - Consistent need to balance individual and communal interests in identifiable health data



Objective 6.3

Gain a basic understanding of the scope, structure, and implementation of the HIPAA Privacy Rule.



Key Questions for the Public Health Practitioner

- What is HIPAA?
- What is the HIPAA Privacy Rule?
- Who does the Rule cover?
- How is PHI regulated?
- How are uses / disclosures of PHI regulated?
- What is the relation of the Privacy Rule to other laws?
- How are violations addressed?
- Is a public health agency a Covered Entity?



Health Information Privacy: Federal Protections

The Health Insurance Portability
and Accountability Act of 1996
(HIPAA)



HIPAA and the Basis for Health Information Privacy Protections

- HIPAA seeks to increase individual access to health insurance by:
 - Reducing individual health insurance costs
 - Lowering administrative claims costs
 - Efficiently transmitting electronic data under enhanced health information privacy protections that encourage people to seek health care
- HIPAA represents the first national standards for protecting health information privacy
- The HIPAA Privacy Rule is one of the regulations that implements HIPAA
 - The Privacy Rule regulates the use and disclosure of protected health information by entities subject to the rule



HIPAA Privacy Rule: What Is Covered

“Protected Health Information (PHI)”

Individually-identifiable health information used or disclosed by a covered entity in any form, whether electronically, on paper, or orally

45 C.F.R. 160.103



HIPAA Privacy Rule What Is Covered

- PHI does not include:
 - Education records covered by FERPA
 - Employment records held by a covered entity in its role as employer
 - Non-identifiable health information

45 C.F.R. 160.103



HIPAA Privacy Rule Who Is Covered

- Covered Entities (CEs):
 - Health plans
 - Health care clearinghouses
 - Health providers that conduct certain electronic transactions

45 C.F.R. 160.103



HIPAA Privacy Rule

Who Is Covered

Business associates of covered entities are bound by contract or agreement with the covered entity to follow the same or greater level of protection in the Rule and include:

- Claims or data processors
- Billing companies
- Quality assurance providers
- Utilization reviewers
- Lawyers
- Accountants
- Financial service providers



45 C.F.R. 160.103



HIPAA Privacy Rule: Who Is *Not* Covered

- Life insurance companies
- Auto insurance companies
- Workers' compensation carriers
- Employers
- Others who acquire, use, and disclose vast quantities of health data



HIPAA Privacy Rule: How PHI is Covered

- Boundaries - setting limits on uses and disclosures
- Fair Information Practices - allowing individuals some level of access to their health data
- Accountability - making covered entities accountable for handling and abuses



HIPAA Privacy Rule: How Uses/Disclosures Are Regulated

- CEs may use or disclose PHI without individual's informed consent
 - For treatment, payment, or health care operations
 - Through limited data sets (which include minimal identifiable data and use requirements)
 - For exceptions specified in rule
- Otherwise, uses or disclosures of PHI require either individual opportunities to object or written authorizations



HIPAA Privacy Rule: How Uses / Disclosures Are Regulated

- Written authorization or opportunity to object not required for specified disclosures, including disclosures concerning:
 - Law enforcement
 - Judicial and administrative proceedings
 - Decedents
 - Health emergencies
 - Minors
 - Health research
 - Public health



HIPAA Privacy Rule: How Uses / Disclosures Are Regulated

- Minimum Necessary Rule:
 - When using or disclosing PHI, a covered entity must make reasonable efforts to limit such information to the *minimum necessary* to accomplish the intended purpose of the use, disclosure, or request.
 - Exceptions include disclosures required by law and disclosures to the individual.



HIPAA Privacy Rule: Relation to Other Laws

- Does the Privacy Rule supplant other laws (state constitutions, statutes, administrative laws, judicial law)?
- No, the Privacy Rule generally creates a floor of federal protections.
 - Existing state laws that provide greater health information privacy protections or do not otherwise conflict with the Rule remain in effect.



HIPAA Privacy Rule: Addressing Violations

- **Violations or breaches of the Privacy Rule may result in:**
 - Complaints filed with the Secretary of HHS
 - Ensuing investigation by the Secretary
 - Compliance reviews by the Secretary
 - Informal resolution by the Secretary whenever possible
 - Imposition of civil penalties
 - Criminal sanctions against individuals
- **Civil and criminal penalties rarely have been assessed**
 - HHS has focused almost exclusively on voluntary enforcement, compliance reviews, and investigations
 - HHS provides technical assistance to facilitate compliance



Objective 6.4

Be able to discuss the impact of the HIPAA Privacy Rule on public health agencies.



Impact of the Privacy Rule on Public Health

Externally – Impact on the flow of identifiable health data into or out of public health agencies

Internally – Impact on the practice of public health or public health research by public health agencies or its partners



External Impact of the Privacy Rule on Public Health

The public health exception within the HIPAA Privacy Rule allows a covered entity to disclose PHI without individual authorization to a “*public health authority* that is authorized by law to collect and receive such information for the purpose of preventing or controlling disease, injury, or disability, including . . . reporting of disease . . . and the conduct of public health surveillance . . . investigations, and . . . interventions.”



External Impact of the Privacy Rule on Public Health

- Examples of specific public health-based exceptions include disclosures:
 - To maintain the quality, safety, or effectiveness of FDA products
 - To notify persons exposed to communicable diseases
 - Reports of child abuse or neglect
 - To prevent serious threats to persons or the public



What Is a Public Health Authority?

- A **public health authority** is an:
agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency . . . that is responsible for public health matters as part of its official mandate.
45 CFR 164.501
- **Includes:**
 - Some federal agencies (e.g., CDC, FDA, NIH)
 - State or Tribal health departments
 - Contractors / others acting under authority of these agencies



State Public Health Reporting Laws and the Privacy Rule

- All states require health care providers to report communicable diseases and other conditions
 - The specific diseases or conditions vary from state to state
 - May be found in statutory or regulatory laws
- The Privacy Rule does not pre-empt (or override) state law that “provides for the reporting of disease or injury . . . or for the conduct of public health surveillance [or] investigation”

45 CFR 160.203(c)



Internal Impact of the Privacy Rule on Public Health

- Public Health Authorities that perform covered functions (e.g., certain health care providers, health plans) also are covered entities under the Rule
- Covered Public Health Authorities may still conduct their public health functions
- Electing hybrid status allows the authority to separate non-covered functions from requirements of the Rule



Objective 6.5

Understand the distinctions between public health practice and public health research for the purposes of applying privacy laws and policies.



Distinguishing between Public Health Practice and Public Health Research

- The Privacy Rule provides different rules for the disclosure of PHI for public health practice and research purposes
- In general, disclosures for research purposes are more restricted than disclosures for public health purposes
- The Privacy Rule uses the same definition of research as the Common Rule
 - *Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.*



Distinguishing between Public Health Practice and Public Health Research

- Distinguishing practice from research is often difficult because many public health activities are based on scientific methods similar to those used in research
 - Covered entities may misinterpret public health practice activities as research activities, and deny public health authorities access to PHI
- The *purpose of the activity* is key
 - Research: to contribute to generalizable knowledge
 - Practice: to prevent or control disease or injury and improve health, or to improve a public health program or service

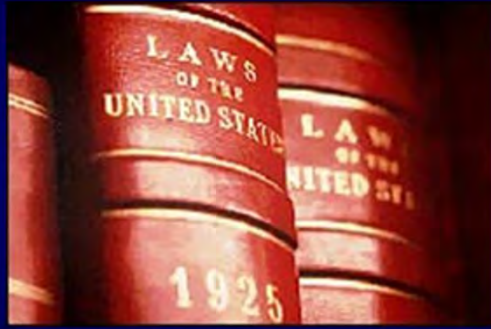


Distinguishing between Public Health Practice and Public Health Research

- Institutional Review Boards review activities and determine whether they are public health practice or research
- CDC's Office of Scientific Integrity (OSI) and the Office for Human Research Protections (OHRP) at HHS provide clarification, guidance, and advice on the distinctions between public health practice activities and research activities



**Conclusion:
Unit 6**



Summary

- A multitude of health information privacy laws and policies attempt to balance individual and communal interests in acquisition, use, and disclosure of identifiable health data
- Health information privacy protections vary extensively by state, although themes are similar across jurisdictions



Summary (continued)

- The HIPAA Privacy Rule presents national health information privacy standards
 - It creates a floor (but not a ceiling) for privacy protections
 - It affects public health authorities in internal and external ways related to their practice and research activities
- Distinguishing practice from research activities is an important objective when applying health information privacy laws



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