Health Information Privacy:
Law, Policy, and the Patient

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Agenda

- Legal Framework: Patient Privacy
  - HIPAA
  - The Common Rule
  - Part 2
  - State laws
  - Other Federal Laws: Privacy Act of 1974 and FOIA
- Opportunities and Barriers: Release of Patient Information
- Role of Authorization and Consent

HIPAA Privacy Rule: An Overview

- The Privacy Rule:
  - Governs uses and disclosures of protected health information
  - Establishes individual's rights with respect to their own information
- Applies to:
  - Covered Entities (plans, providers, clearinghouses)
  - Business Associates (significantly expanded definition)
- Protected health information ("PHI")
  - Individually identifiable health information
  - Transmitted or maintained in any format (paper, electronic, oral) by a covered entity or business associate

***45 CFR Part 160 and Subparts A and E of Part 164**

HIPAA: Individual Rights

- Notice: Right to receive a Notice of Privacy Practices describing how a covered entity will use and disclose PHI
- Access: Right to view and obtain a copy of your own PHI
- Accounting: Right to receive an accounting of certain disclosures of PHI made in the last six years
- Amendment: Right to correct errors or add missing information to PHI
- Restrictions: Right to request restrictions on disclosures and to obtain a restriction in certain limited circumstances
- Confidential communications: Right to request confidential communications of PHI
- Complaints: Right to file complaints alleging a violation of HIPAA with the Secretary of the U.S. Department of Health and Human Services

HIPAA: Disclosures

- Required disclosures (no patient authorization required):
  - To the individual upon request*
  - To the Secretary of HHS for investigations or compliance reviews
- Permitted disclosures (no patient authorization required):
  - Treatment, payment, and healthcare operations*
  - Incident to a permitted use or disclosure*
  - As a limited data set*
  - As de-identified data*
  - When giving the individual the opportunity to agree or object*
  - For certain "public" purposes (e.g., when required by law, in emergencies)
- Disclosures with patient authorization*

* These types of disclosures need not be included in an accounting of disclosures

HIPAA: Public Health and Research

- Public Health – no authorization required
  - Disclosures to **legally authorized** public health authorities for the purpose of preventing or controlling disease, injury, or disability
  - Disclosures for specified public health activities (e.g., child abuse reporting, communicable disease reporting)
- Research
  - Disclosures of PHI for research purposes may be made:
    - With a patient's authorization
    - With a waiver or alteration of authorization approved by an IRB or Privacy Board
    - Without authorization or IRB approval for limited types of research
  - Waiver or alteration requirements
  - Final Rule modifications: compound authorizations, future use
- Minimum Necessary

The Common Rule: An Overview

- Rule "shared" by 15 federal departments/agencies
  - The department/agency conducting or supporting research determines whether the institution conducting research has complied with the regulations
- Provides protection for **human subjects** of **research**
  - Subpart A: basic protections for protecting human subjects
  - Subparts B – D: additional regulations governing certain protected populations (pregnant women, human fetuses, neonates; prisoners; children)
- Sets requirements for: the department/agency conducting or supporting research; the institution conducting research; IRBs; and investigators

***45 CFR 46**

Common Rule: Informed Consent

- Researchers must provide subjects with sufficient information so that they can make a voluntary decision whether to participate in the study.
- General requirements: legally effective consent, written consent form approved by the IRB
  - An IRB may waive the signed consent form requirement in limited circumstances
- Specific elements must be included in document, such as:
  - Procedures to be followed
  - Risks to subject
  - A statement regarding the extent to which confidentiality of records will be maintained

42 CFR Part 2 (Part 2): An Overview

- Limits use and disclosure of identifying substance abuse patient information
  - Applies to **federally assisted** substance abuse programs (very broad)
- Patient consent required for most disclosures except certain limited circumstances (e.g., in a medical emergency or for research)
  - Written consent requirement
  - Nine specific elements must be included
- More restrictive than HIPAA
- State law requirements may be more restrictive than Part 2
- Special research protections

State Laws:
HIV/AIDS, Mental Health & Minors

- HIV/AIDS
  - Public health reporting, Ryan White program, OSHA requirements
  - State law varies in terms of required and permissible disclosures:
    - Partner notification, duty to warn statutes
    - To healthcare providers prior to receiving healthcare services
  - Informed Consent
- Mental Health
  - HIPAA requirements
  - State laws vary; additional requirements for disclosures/authorizations
- Minors
  - Application of privacy laws depends on how the state defines minor
  - Federal laws generally have more protective requirements for minors, but defer to state to define scope of minor's privacy rights and capacity to consent; privacy laws each have unique requirements for minors

The Privacy Act of 1974 and FOIA

- Privacy Act of 1974: protects information held or collected by the federal government that can be retrieved by a personal identifier (e.g., name, social security number).
  - May release with written consent of the individual OR pursuant to one of twelve exemptions for disclosure, which include:
    - Statistical research exemption
    - Routine uses (system of records) exemption
    - Disclosures required by FOIA
- Freedom of Information Act (FOIA): any person may obtain access to information contained in the records of federal agencies, unless the information is protected from disclosure
  - Exemption 6: personnel, medical, and similar files may be withheld if disclosure is a "clearly unwarranted" invasion of personal privacy

Privacy Laws: Opportunities or Barriers?

- Multiple exceptions allow data collection, use, and disclosure without patient authorization, particularly for research
  - HIPAA: operations; research; public health
  - Common Rule: IRB waivers
  - Part 2: research
  - Protected populations: variety of state laws
  - Privacy Act/FOIA: exemptions working in concert
- Data Processing: tailor the use of big data by establishing the intended use of the data and meeting necessary federal requirements based on that use.

Common Denominator: Patient Authorization and Consent

- Every federal privacy law permits disclosures with patient authorization or consent
- Common elements:
  - What information is to be disclosed
  - Who can disclose
  - Who can receive disclosed information
  - What is the purpose of the disclosure
  - Signature
- Patient-centered approach

Healthinfolaw.org

- Health system transformation (especially quality improvement, delivery system reform, and research) depends on use and exchange of health information
- Valuable resource covering:
  - All federal and state laws relating to the use and exchange of health information (e.g., HIPAA - http://www.healthinfolaw.org/federal-law/HIPAA)
  - Analyses of emerging issues in state and federal law affecting the transformation of the health care system
  - Content: brief summaries of state and federal laws, fast facts and myth busters, comparative analyses, and longer, in-depth analyses, presented in multiple formats for a variety of audiences

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