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LEGAL ISSUES IN PHYSICAL THERAPY

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Disclaimer

The purpose of this presentation is to provide a general overview of legal concepts and is not intended to serve as legal advice. It is important to consult an attorney for individual legal advice.

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Learning Objectives

- Understand the basics of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") as it relates to physical therapy services.
- Recognize lessons learned from prior HIPAA enforcement examples.
- Understand the basics of healthcare fraud and abuse laws to better identify potential compliance and legal issues affecting physical therapists.
- Through the review of recent enforcement examples, be able to return to the workplace and assess current practices for potential issues of concern.

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Why HIPAA?

- The Privacy Rule assures that an individual's health information is properly protected while still permitting the flow of health information needed to provide health care.
- The Security Rule sets a national standard to protect an individual's electronic protected health information ("PHI") that is created, received, used, or maintained by a covered entity (or by a business associate on behalf of the covered entity).

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HIPAA Preemption

- Generally, state laws that are contrary to the Privacy Rule are preempted by federal requirements, meaning that federal HIPAA requirements will apply.
- Exception to this general rule occurs when an individual would have greater privacy protections under state law.

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Who Does the Privacy Rule Cover?

- The HIPAA Privacy Rule applies to:
  - Covered entities
  - Business associates

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Protected Health Information

- Protected health information:
  - Individually identifiable information (including demographic data) that relates to the individual's past, present or future physical or mental health or condition, the provision of health care to the individual, or the past, present or future payment for the provision of health care to the individual, and that identifies the individual or for which there is a reasonable basis to believe can be used to identify the individual.
- Examples

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Disclosures Under HIPAA

- General Rule: A covered entity may not use or disclose protected health information, except:
  - as the HIPAA Privacy Rule or other state or federal law permits or requires;
  - as the individual who is the subject of the PHI (or the individual's personal representative) authorizes in writing; and
  - as required by the Secretary of Health and Human Services for HIPAA compliance purposes.

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Required Disclosures

- A covered entity shall disclose protected health information:
  - to individuals when they request access to, or an accounting of disclosures of, their protected health information;
  - to the Secretary of Health and Human Services when it is undertaking a HIPAA investigation; and
  - when required by federal or state law.

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Permitted Uses and Disclosures

- Treatment
- Payment
- Health care operations
- For public health activities and purposes
- For work-related illness or injury; and
- Workers' compensation

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Authorization

- As a general rule, a covered entity must obtain an individual's written authorization for any use or disclosure of protected health information that is not permitted or required by the Privacy Rule.
- Exception

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Individual's Right to Access PHI

- As a general rule, an individual has a right to access PHI in a designated record set including the right to inspect and obtain a copy of:
  - medical and billing records, or
  - information used in whole or in part by or for the covered entity to make decisions about the individual.
- Exceptions

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The Minimum Necessary Standard

- A covered entity must make reasonable efforts to use, disclose, and request only the minimal amount of PHI needed to accomplish the intended purpose of use, disclosure, or request.
- Exceptions

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Incidental Uses and Disclosures

- An incidental use or disclosure is a secondary use or disclosure that cannot reasonably be prevented, is limited in nature, and that occurs as a result of another use or disclosure that is permitted by the HIPAA Privacy Rule.
- Example

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Notice of Privacy Practices

- Each covered entity must provide a notice of its privacy practices to individuals. Notice describes the covered entity's legal duties as well as the individual's rights.
- The covered entity is required to abide by the terms of the notice.
- The notice must be updated when there is a material change in the covered entity's legal duties or individual's rights.

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HIPAA Requirements

- Training - A covered entity must train all members of its workforce as necessary and appropriate to carry out their function within the covered entity.
- Plan – Must implement policies and procedures.
- Privacy Officer – Covered entity must designate a privacy official.
- Record Retention

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Business Associates

- A business associate is a person or organization that performs functions or activities on behalf of a covered entity that involve the use or disclosure of individually identifiable health information (i.e., PHI).
- Examples include claims processing, utilization review and billing functions.
- Business Associate Agreement.

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PHI Disposal

- HIPAA requires reasonable safeguards to limit incidental disclosures of PHI in connection with disposal
- Work force members involved in disposal of PHI must receive training on disposal
- Enforcement Examples

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The HIPAA Security Rule

- The HIPAA Security Rule is designed to protect the confidentiality and integrity of, and ensure the availability of, electronic protected health information and promote efficiency in the health care industry through the use of standardized electronic transactions (i.e., EDI Rules).

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The Security Standard

- Requires administrative, physical, and technical safeguards to protect PHI.
- Not specific mandates, but rather general guidance.
- Risk analysis and risk management will give guidance on how best to comply with the Security Rule.
- Enforcement Examples

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Risk Analysis

- Security Rule requires an assessment of potential risks and vulnerabilities to the confidentiality, integrity and availability of EPHI held by the organization.
- Nearly 70% of covered entities audited by OCR did not have a complete and accurate security risk analysis.
- Risk analysis is frequent component of OCR corrective action plan requirements.
- Security risk assessment tool available from OCR.

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The Security Standard

- Particular measures utilized depend on factors such as:
  - the size and complexity of the covered entity;
  - the cost of the security measures; and
  - the covered entity's technical infrastructure and hardware.

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Breach Notification Requirements

- Without unreasonable delay and in no case later than sixty days after the discovery of breach of unsecured PHI, the covered entity or its business associate must notify individuals affected by the breach.

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Breach Notification Requirements

- Content of breach notice to individuals:
  - Brief description
  - Steps individuals should take to protect themselves
  - What the covered entity is doing to investigate, mitigate, and protect
  - Contact procedures for individuals to ask questions or learn additional information.

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Omnibus Rule

- Marketing Restrictions
- Sale of PHI
- Fundraising

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Civil Money Penalties

Tier	Nature of Violation	Range of Penalties	Maximum Penalty
A	Violation unknown or by exercising reasonable diligence would not have known	$100 - $50,000 for each violation	$1,500,000 for all violations identical provision in calendar year
B	Violation due to reasonable cause and not willful neglect	$1,000 - $50,000 for each violation	$1,500,000 for all violations identical provision in calendar year
C(i)	Violation due to willful neglect, if corrected within 30 days from knowledge of violation	$10,000 - $50,000 for each violation	$1,500,000 for all violations identical provision in calendar year
C(ii)	Violation due to willful neglect not corrected	$50,000 for each violation	$1,500,000 for all violations identical provision in calendar year

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Complaints

- Office of Civil Rights ("OCR") is responsible for enforcing the HIPAA Privacy Rule.
- Complaints may be submitted to either the designated privacy official of the covered entity or the Office of Civil Rights ("OCR").
- 160,000+ HIPAA Complaints (through 7/31/17).

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OCR Report On Breaches Of Unsecured PHI

- Top 5 causes:
  - Theft
  - Loss of electronic media or paper
  - Unauthorized access
  - Human error
  - Improper disclosure

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Practical Considerations

- Consider policies on laptops, smart phones, flashdrives, etc.
- Consider policies on use of personal email
- Consider policies on terminating access upon termination of employment
- Consider policies for verification of mailing addresses
- Review business associate relationships

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Resources

www.hhs.gov/ocr/privacy
www.cms.gov/HIPAAGenInfo
www.apta.org/HIPAA

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FRAUD AND ABUSE

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Federal Fraud and Abuse Laws

- The Anti-Kickback Statute (42 U.S.C. §1320a-7(b))
- Stark ("Self-Referral" Law) (42 U.S.C. 1395nn)
- False Claims Act (31 U.S.C. §3729 et seq)

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State Fraud and Abuse Laws

- In addition to federal fraud and abuse laws, there are state fraud and abuse laws that should be considered (insurance, anti-kickback, self-referral)

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Anti-Kickback Statute

- Under the Anti-Kickback Statute it is a criminal offense to knowingly and willfully solicit, receive, offer, or pay any remuneration to induce referrals of items or services covered by Medicare or Medicaid or other federally-funded programs.

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Anti-Kickback Statute

- An intent-based statute – the government must prove that one intent of the remuneration paid is to induce referrals, even if there are other lawful or beneficial reasons for the business relationship. (United States vs. Greber)

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Anti-Kickback Safe Harbors

- If all elements of a particular safe harbor are satisfied, the payments and business arrangement are not in violation of the Anti-Kickback statute.
- If an arrangement does not specifically fit within a safe harbor, it is analyzed depending upon the particular facts and circumstances to determine if it violates the Anti-Kickback statute.

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Anti-Kickback Safe Harbors

- Space Rental
  - Historically, many situations involved rental payments in excess of fair market value to induce referrals.
  - For example, a facility rents space to a physical therapy practice at a rate above fair market value with the understanding (the "intent") that the facility will refer patients to the physical therapy office in exchange for the excessive rent.

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To Satisfy Safe Harbor

- If access is for periodic intervals, the intervals and rent must be set in advance rather than variable;
- The lease is for at least one year;
- The charges reflect fair market value;
- The lease is in writing and signed;
- The lease specifies all the premises covered; and
- Space rented does not exceed that necessary for business purpose

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Anti-Kickback Safe Harbors

- Personal Services
  - Medical Directors and other related services.
- OIG Fraud Alert

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To Satisfy Safe Harbor

- Set out in a written agreement signed by the parties;
- Covers all of the services provided;
- If the agreement provides for part-time services, the schedule, length and charge for such intervals is included;
- The agreement is for not less than one year;

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To Satisfy Safe Harbor

- Compensation is set in advance, consistent with fair market value in arms-length transactions and not dependent upon volume or value of referrals or business otherwise generated;
- Services do not promote arrangement that violates state or federal law; and
- Aggregate services under the contract do not exceed that reasonably necessary to accomplish the business purpose.

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Stark Law

- In contrast to the Anti-Kickback statute, no intent is required to violate the Stark Law.
- In addition to the referral prohibition, the Stark Law prohibits the entity and the physician from billing for services provided pursuant to a referral in violation of the Stark Law.

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Stark Exceptions

- There are various exceptions to the Stark Law.
- A relationship must meet all of the terms of an applicable exception to qualify.
- If an exception applies, the arrangement does not violate Stark.

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The False Claims Act

- Basically, the False Claims Act imposes liability on any person who submits a claim to the federal government that he or she knows (or should know) is false. (31 U.S.C. §3729)

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False Claims Act

- Qui Tam Relator – A private party permitted to bring an action on behalf of the government under the False Claims Act.
- Treble Damages
- Enforcement Examples

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Recent Developments

- Department of Justice announcement
- OIG Report on skilled nursing facilities
- Improper billing for splints
- Provision of services not reasonable, necessary or skilled

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Practical Considerations

- Do not bill for services not rendered or provided. Consider auditing practitioners periodically.
- Do not bill for equipment, medical supplies or services that are not reasonable and necessary. Audit supporting documentation.

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Practical Considerations

- Do make sure that documentation is complete, legible and supports the care provided and billed.
- Do implement policies and procedures covering financial arrangements, office and equipment leases, and gifts and gratuities and assure compliance with such policies.

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Practical Considerations

- Do avoid payments in excess of fair market value for services and other items.
- Do avoid impermissible incentives to utilize services.

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Resources

- http://oig.hhs.gov
- www.justice.gov
- www.medicare.gov

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Questions / Comments

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