HIPAA AND THE STARK LAW: INTERACTION WITH ACCOUNTANTS AND OTHER PROFESSIONALS

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This presentation is intended to provide a general overview of both the privacy standards for electronic healthcare transactions in the Health Insurance Portability and Accountability Act ("HIPAA") and the Federal Physician Self-Referral law, otherwise known as the Stark Law. The presentation will also include a discussion of some of the effects of HIPAA and the Stark Law on accounting professionals.

I. HIPAA: Overview of Final Privacy Standards

A. What is HIPAA?

"HIPAA" is the anacronym for the Health Insurance Portability and Accountability Act of 1996. HIPAA contains certain insurance-related provisions that are intended to improve the availability and portability of health insurance for individuals when changing employers. In HIPAA, Congress also included certain "Administrative Simplification" provisions that required the U.S. Department of Health and Human Services ("DHHS") to adopt national standards related to electronic health care transactions.

B. Who is Covered by (or Must Comply with) the HIPAA Administrative Simplification Standards?

The following individuals and entities (referred to as "Covered Entities" in the regulations) must comply with the HIPAA Administrative Simplification Standards:

- Health Plans;
- Health Care Clearing houses; and
- Health Care Providers who conduct certain financial and administrative transactions electronically.

C. "What" is Covered by the Privacy Standards?

1. The Privacy Standards apply to an individual's Protected Health Information ("PHI"), which includes any information transmitted or maintained in any form or medium, including oral communications. HIPAA provides that health information in any form is protected if it is:

a. Created or received by a Covered Entity;

b. Related to an individual's physical or mental health condition, the provision of health care to an individual or the payment for the provision of health care to an individual; and

c. Identifies the individual or creates a reasonable basis to believe that the information, including demographic information, can be used to identify the individual.

2. According to the U.S. Department of Health and Human Services fact sheet on HIPAA, the HIPAA Privacy Standards cover:

"All medical records and other individually identifiable health information held or disclosed by a covered entity in any form, whether communicated electronically, on paper, or orally."

D. General Rule of the HIPAA Privacy Standards

1. The general rule of the Privacy Standards is: "A *Covered Entity* may not *use or disclose* an individual's Protected Health Information, except as otherwise *permitted* or *required* by this subpart (the Privacy Standards)."

2. The final Privacy Standards require Covered Entities to apply many provisions of the Privacy Standards to entities with which they contract for administrative and other services. These entities are referred to as "Business Associates."

E. What are Permitted Uses or Disclosures of Protected Health Information?

A Covered Entity is permitted to use and disclose PHI as follows:

1. To the individual who is the subject of the PHI;
2. Without consent or authorization of the individual, if such is not required by the Privacy Standards;
3. In compliance with a consent or authorization provided by the individual;
4. Pursuant to an agreement with the individual; or
5. Otherwise permitted by the Privacy Standards.

F. What are Required Uses or Disclosures of Protected Health Information?

A Covered Entity is required to disclose PHI as follows:

1. To an individual at the individual's request; or
2. In response to a compliance review.

G. What are the requirements in the Privacy Standards for releasing PHI?

A Covered Entity must make reasonable efforts to limit the use, disclosure of and request of PHI to the ***minimum necessary*** to accomplish the intended purpose of the use, disclosure or request. This minimum necessary standard does ***not*** apply to: (1) disclosures of PHI made to, or requests for PHI made by, a health care provider for treatment purposes; (2) uses or disclosures made to individuals about their own PHI; or (3) uses or disclosures made to a representative of the DHHS (e.g. pursuant to a compliance review).

H. "Consent" Requirement for Uses or Disclosures to carry out Treatment, Payment, or Health Care Operations

1. The HIPAA Privacy Standards require covered health care providers to obtain an individual's (written) consent prior to using or disclosing PHI to carry out treatment, payment or health care operations. Any other use or disclosure of PHI will require the individual's specific, separate (written) ***authorization***, unless an exception to the authorization requirement applies.

2. Exception to Consent Requirement: A covered health care provider may use or disclose PHI, without an individual's consent, to carry out treatment, payment or health care operations if: (i) the provider has an "***indirect treatment relationship***" with the individual; or (ii) the individual is an inmate.

   A health care provider may also use or disclose PHI, without ***prior*** consent, if the provider later attempts to obtain such consent as soon as is reasonably practicable in the following situations: (i) emergency treatment situations; (ii) if required by law to treat the individual; or (iii) there are barriers for communicating with the individual.

I. "Business Associates"

1. **What is a "Business Associate"**

   a. A Business Associate is a person or entity who provides certain functions, activities, or services for or to a covered entity, involving the use and/or disclosure of PHI.

b. A Business Associate is not a member of the health care provider, health plan, or other covered entity's workforce.

c. A health care provider, health plan, or other covered entity can also be a business associate to another covered entity.

d. The rule includes exceptions. The business associate requirements do not apply to covered entities who disclose PHI to providers for treatment purposes – for example, information exchanges between a hospital and physicians with admitting privileges at the hospital.

e. The HIPAA final privacy regulations issued on December 28, 2000, specifically list accountants as an example of a Business Associate.

2. **General Rules for Business Associates**

The HIPAA Privacy Standards condition disclosure of PHI by Covered Entities to Business Associates on the Covered Entity obtaining satisfactory assurances under the privacy standards (written agreement) that the Business Associate will use the information only for the purposes for which they were engaged by the Covered Entity, will safeguard the information from misuse, and will help the covered entity comply with the covered entity's duties to provide individuals with access to health information about them and a history of certain disclosures (e.g., if the Business Associate maintains the only copy of information, it must promise to cooperate with the covered entity to provide individuals access to information upon request). PHI may be disclosed to a business associate *only* to help the providers and plans carry out their health care functions – not for independent use by the business associate.

3. The following are two general parameters/requirements for accountants who perform any functions on behalf of Covered Entities that utilize or create PHI:

a. The Covered Entity must enter into a written contract with the Business Associate that provides satisfactory assurances that the Business Associate will appropriately safeguard the PHI; and

b. The Covered Entity must address situations where the Business Associate is not complying with its obligations under the agreement with the Covered Entity to safeguard PHI. A Covered Entity may be liable for the Business Associate's actions in regard to PHI if

the Covered Entity knew of a material breach by the Business Associate unless the Covered Entity took reasonable steps to either cure the breach of terminate the contract.

J. Individual Rights in the Final Privacy Standards

The HIPAA Privacy Standards created the following rights for individuals with respect to their Protected Health Information:

A. A Right to Notice of Information Practices of a Covered Entity.

B. A Right to Request the Restriction of the Use and Disclosure of the Individual's PHI.

C. A Right to Access, Inspect, and Copy their own PHI.

D. A Right to Request An Amendment to Their PHI.

E. A Right to Request an Accounting of all Uses and Disclosures.

K. Administrative Requirements for Covered Entities

The Administrative Requirements require Covered Entities to do the following:

A. Designate a Privacy Official to oversee compliance and a contact person to receive complaints and questions.

B. Develop and implement policies and procedures to establish compliance with the final Privacy Standards.

C. Train employees on the organization’s privacy policies and procedures, and re-train employees if material changes are made to such policies.

D. A Covered Entity must have in place appropriate administrative, technical, and physical safeguards to protect the privacy of PHI.

E. Create a process for individuals to make complaints concerning the Covered Entity’s policies and procedures required by HIPAA.

F. A Covered Entity must have and apply appropriate sanctions against members of its workforce who fail to comply with the privacy policies and procedures of the Covered Entity.

G. A Covered Entity must maintain the policies and procedures required by HIPAA in written or electronic form for six years from the date of their creation.

L. Penalties for Non-Compliance

The Privacy Standards authorize the imposition of civil monetary penalties of $100 per violation, up to $25,000 per person, per year for each requirement or prohibition violated. Congress also established criminal penalties for knowingly violating patient privacy. Criminal penalties are up to $50,000 and one year in prison for obtaining or disclosing PHI; up to $100,000 and up to five years in prison for obtaining PHI under false pretenses; and up to $250,000 and up to 10 years in prison for obtaining or disclosing PHI with the intent to sell, transfer or use it for commercial advantage, personal gain or malicious harm.

II. OVERVIEW OF THE STARK LAW, 42 U.S.C. § 1395nn

A. What is the Stark Law?

The Stark Law is a federal law that prohibits physicians from referring Medicare and Medicaid patients to an entity for certain "designated health services," if the physician or an immediate family member of the physician has a (direct or indirect) financial relationship with the entity, unless an exception applies.

The Stark Law also prohibits an entity from presenting a claim to the Medicare program or to any individual or third party payer or other entity for Designated Health Services performed pursuant to a referral prohibited by the Stark law.

B. What are Designated Health Services for purposes of the Stark Law?

The following are "Designated Health Services" for purposes of the Stark Law:

- Clinical Laboratory Services
- Physical and occupational therapy and speech-language pathology services*
- Radiology and certain other imaging services
- Radiation therapy services and supplies
- Durable medical equipment and supplies
- Parenteral and enteral nutrients, equipment, and supplies
- Prosthetics, orthotics, and prosthetic devices and supplies
- Home health services
- Outpatient prescription drugs
- Inpatient hospital services

- Outpatient hospital services

C. What is a Financial Relationship for purposes of the Stark Law?

A "financial relationship" is defined as an ownership or investment interest by a physician or an immediate family member in an entity that furnishes designated health services, or a compensation relationship with such entity.

D. When does a Physician make a Referral for the Stark Law to apply?

A "referral" is defined in the Stark Law as a request by a physician for an item or service for which payment may be made under the Medicare or Medicaid programs, including a request for a consultation (including any tests or procedures ordered or performed by the consulting physician or under the supervision of the consulting physician), and the request or establishment of a plan of care that includes any designated health services.

The definition of "referral" in the Stark Law specifically excludes a request by a pathologist for clinical diagnostic laboratory tests and pathological examination services, by a radiologist for diagnostic radiology services, and by a radiation oncologist for radiation therapy.

E. What are "exceptions" to the Stark Law and potential sanctions for violating the Stark Law?

There are several statutory and regulatory exceptions to the general prohibition of the Stark Law. If all of the criteria in an exception are satisfied, then the referral will not be prohibited by the Stark law.

F. What are the Sanctions and Penalties under the Stark Law?

Potential sanctions and penalties for violations of the Stark Law include:

1. Denial of payment for the designated health services provided in violation of the Stark Law.

2. Refund of any monies received by physicians and facilities for any amounts billed for designated health services provided in violation of the Stark Law.

3. Payment of civil money penalties of up to $15,000 for each service a person "knows or should know" was provided in violation of the Stark Law.

4. Exclusion from the Medicare Program and/or State healthcare programs including Medicaid.

5. Payment of civil money penalties for attempting to circumvent the Stark Law of up to $100,000 for each such arrangement or circumvention scheme.

G. Compensation

The Stark Law provides that a physician in a group practice may ***not*** be compensated directly or indirectly based on the volume or value or his or her referrals of Designated Health Services. However, a physician in a group practice may receive shares of overall profits of the group or a productivity bonus based on services personally performed or incident to such personally performed or incident to such personally performed services, provided the share or bonus is not determined in a manner that is directly related to the volume or value of referrals by such physician.

1. General Rules: Group practice physicians can receive compensation ***directly*** related to the physician's personal productivity and to services incident to the physician's personally performed services(provided the 'incident to' services comply with the Medicare 'incident to' reimbursement requirements), but may not pay these physicians any bonus based directly on their referrals of DHS that are performed by someone else.

2. Revenues generated by Designated Health Services may be distributed to group practice members in accordance with methods that ***indirectly*** take into account Designated Health Service referrals. HCFA provided in Phase I of the Regulations that the key is "if there is not a direct correlation between the total amount of a physician's compensation and the volume or value of the physician's Designated Health Service referrals (regardless of whether the services are personally performed)."

3. Permissible Distribution Methods for Overall Profit shares: In Phase I of the Final Regulations, HCFA listed the following as permissible distribution methods that ***indirectly take into account*** DHS referrals:

    a. A per capita (that is, per physician) division of the overall profits.

    b. A distribution of DHS revenues based on the distribution of the group practice's revenues attributable to services that are not DHS payable by Federal or private payers.

c. Any distribution of DHS revenues if the group practice's DHS revenues are less than 5 percent of the group practice's total revenues and no physician's allocated portion of those revenues is more than 5 percent of the physician's total compensation from the group practice.

4. Permissible Methods for Productivity Bonuses: In Phase I of the Final Regulations, HCFA listed the following as permissible bonus arrangements that ***indirectly take into account*** DHS referrals:

a. A productivity bonus based on the physician's total patient encounters or RVUs.

b. A productivity bonus based on the allocation of the physician's compensation that is attributable to services that are not DHS payable by Federal or private payers.

c. ***Any*** productivity bonus that includes DHS revenues if the group practice's DHS revenues are less than 5 percent of the group practice's total revenues and no physician's allocated portion of those revenues is more than 5 percent of the physician's total compensation from the group.

H. Single Legal Entity Requirement

1. For purposes of the Stark Law, a "group practice" must consist of two or more physicians who are legally organized as a partnership, professional corporation (PC), foundation, not-for-profit corporation, faculty practice plan, or similar association.

CMS requires that a group practice must be a "single legal entity," and such entity can assume any form recognized by the state in which the entity achieves its legal status, including a corporation, partnership, foundation, faculty practice plan, L.L.C.

2. CMS provided in Phase I of the State Final Regulations that the following structures that meet the "Single Legal Entity" Requirement:

- A partnership between two or more physicians.
- A partnership between one physician and another party, provided that the partnership employs at least one other physician.

(Similarly, a partnership between two nonphysician parties can qualify if it employs at least two physicians).

- A corporation or limited liability company with one or more physician shareholders or members, provided that a corporation or limited liability company with only one physician shareholder or member employs at least one other physician.

- A corporation or limited liability company owned by nonphysicians, provided it employs at least two physicians.

- A single legal entity owned by two or more physicians through their individual professional corporations. A solo practitioner who is organized as a legal entity (for example, a professional corporation) and employs at least one other full-time physician.

- A single legal entity (whether a corporation, limited liability company, or other form) owned by one or more other legal entities (that is, a multi-entity arrangement) that involves two or more physicians through employment or indirect ownership, provided that the "investing" or "owner" entities are not themselves functioning group practices.

I. "Unified Business Test"

1. General Rule in the Stark Law is that "the overhead expenses of and the income from the group practice must be distributed in methods *previously determined*.

2. CMS treats a distribution methodology as "previously determined" if it is determined prior to receipt of payment for the services giving rise to the overhead expense or producing the income.

3. CMS imposed a regulatory requirement that a "group practice" must meet a "unified business test," which requires the following three elements:

   (1) Centralized decision making by a body representative of the practice that maintains effective control over the group's assets and liabilities (including budgets, compensation, and salaries);

   (2) Consolidated billing, accounting, and financial reporting; and

(3) Centralized utilization review (for example, utilization review conducted on a group-wide basis).

4. CMS stated in Phase I of the Final Stark Regulations that "many forms of cost center and location-based accounting are permitted, provided that compensation formulate with respect to the distribution of "designated health service" revenues otherwise meet the requirements of the Stark Law.

5. Previous to CMS' comments in Phase I of the Final Stark Regulations, it was widely believed that the "Unified Business Test" prohibit group practices from using profit and cost center or location-based accounting and distribution of expenses and income. Thus, excluding site-specific or speciality-specific accounting (which is now OK).
