My Top 10 Legal Issues Affecting Healthcare Practices

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HIPAA Privacy and Security

- **HIPAA’s Privacy Rule** provides federal protections for individually identifiable health information held by covered entities and their business associates and gives patients certain rights with respect to that information.

- **HIPAA’s Security Rule** specifies a series of administrative, physical, and technical safeguards for covered entities and their business associates to use to assure the confidentiality, integrity, and availability of electronic protected health information ("ePHI").

HIPAA Privacy and Security Practical Tips

- Maintaining breach notification log and investigating HIPAA breaches.
- Reporting breaches to OCR on an annual basis, or more frequently depending on the size of the breach.
- Working with affiliated providers that have access to your EHR.
- Disciplinary processes for employees.
- Notifications of breaches to patients and handling their responses.
- Conducting privacy and security audits.
- Identifying the roles of individuals involved in privacy and security audits.
- Handling OCR investigations.
Business Associates

- **Business Associate (“BA”)** – A BA is a person or entity that provides services to a covered entity other than in the capacity of an employee. These services can include:
  - claims processing or administration;
  - data analysis, processing or administration;
  - utilization review;
  - quality assurance;
  - patient safety activities listed at 42 C.F.R. § 3.20;
  - billing;
  - benefit management; and
  - practice management.

- Under new regulations, covered entities are now directly liable for the breaches of BAs.
- It is therefore important to enter into Business Associate Agreements (“BAA”s) with BAs who have access to PHI so that they understand their obligations under HIPAA.

**SOURCE:**
- 45 C.F.R. § 160.103.
- 45 C.F.R. § 164.504.
Business Associates Practical Tips

• Identifying BAs and maintaining an inventory of BAs.
• Ensuring that monthly exclusion check includes BAs and vendors.
• Accurately identifying who the BA is and who the covered entity is.
• Educating providers and vendors on their responsibilities and liabilities.
• Insurance.
Issue 3
ANTI-KICKBACK STATUTE AND STARK LAW
Recent Headlines

- Department of Justice signals increased enforcement aimed at physicians (Sept. 2011, The Christ Hospital Examiner, A Physician’s Publication)
- New York Heart Center to pay $1.34 million to settle FCA, Stark Law allegations (Aug. 19, 2014, Becker’s Hospital Review)
- Medical directorship arrangements: Increased government enforcement and best practices for compliance (Compliance Today, April, 2014).
- Justice Department Recovers $3.8 Billion from False Claims Act Cases in Fiscal Year 2013: Second Largest Annual Recovery in History, Whistleblower Lawsuits Soar to 752 (Dec. 20, 2013, DOJ Press Release)
- Memorial Health Facing Lawsuit, Accused of Medicare Fraud (Sept. 19, 2014 (WSAV, NBC Savannah)
Anti-Kickback Statute ("AKS")

- Prohibits the knowing and willful payment of "remuneration" to induce or reward patient referrals or to generate business paid for by the Federal healthcare programs, e.g., routinely waiving patient copays.
- It’s a “one purpose” test, which means that if one purpose of the payment was to induce future referrals, the AKS has been violated.

**Source:** 42 U.S.C.§ 1320a–7b (2011).
Anti-Kickback Statute ("AKS") (cont’d)

• Kickbacks can lead to:
  • overutilization;
  • increased program costs;
  • corruption of decision making;
  • patient steering; and
  • unfair competition.
• Safe harbors exist such as rental agreements, personal services and management contracts, ambulatory surgical centers, etc.

Examples of Anti-Kickback Statute Risk Areas

- Compensation arrangements with hospitals, labs, pharmaceutical/device companies, ASCs
  - Service Agreements
  - Medical Directorships
  - Leases
  - Call Coverage
- Cross-Referral relationships
- Discounts/rebates
- Marketing arrangements
- Royalties
- Speaking/consulting fees
- Sunshine Act
Recent AKS Enforcement Action

• Georgia based hospital and physician recently settled claims that they violated both Stark and AKS by entering arrangement that compensated physician for his professional/medical director services above FMV.
  – Physician agreed to pay $200,000; hospital to pay $329,000 and enter Corporate Integrity Agreement
• An Alabama-based hospital system paid a medical group a % of Medicare payments it received for tests and procedures referred by the group’s physicians.
  – The hospital and physician group agreed to collectively pay $24.5 million to settle kickback allegations.
  – Original lawsuit filed by former employee of the group under the “whistleblower” provisions of the False Claims Act.
Physician Self-Referral Law ("Stark Law")

- Prohibits physicians from referring patients to receive “designated health services” ("DHS") payable by Medicare or Medicaid to entities with which the physician or an immediate family member has a financial relationship.

- DHS services include:
  - Clinical laboratory services;
  - Outpatient prescription drugs;
  - PT;
  - OT;
  - Radiology, including MRI
  - Radiation therapy services
  - Parenteral and enteral nutrients;
  - DME and supplies;
  - Prosthetics, orthotics and prosthetic devices;
  - Home health
  - Outpatient prescription drugs; and
  - Inpatient and outpatient hospital services.

- There are significant financial penalties attached to violations of the Stark Law.

Stark Law Penalties

• No bad intent required to violate the law.
• Prohibited referrals can result in 100% overpayment and obligation to refund overpayment.
• May also be the basis for “false claims” – treble damages and significant penalties (up to $11,000 per claim).
• Civil penalties may include exclusion from Medicare.
Stark Law: Recent Self-Disclosure

• A Louisiana physician group practice self-disclosed to CMS that its arrangements with two physicians failed to satisfy the requirements of the in-office ancillary services exception.

• All disclosed Stark Law violations were settled for $13,572.
Group Practices Under Stark

- For the first time, the US Department of Justice recently brought allegations against a group practice in New York related to the group’s **internal physician compensation methodology**.
- Settlement resulted in group paying approx. $1.3 million.
• Identifying arrangements with providers and third-parties.
• Educating providers.
• Implementing conflict of interest policies.
• Identifying ownership interests.
• Vendor soliciting providers directly.
• Sunshine Act.
• Providing free services and waivers to patients.
Issue 4

CONTRACT MANAGEMENT
Contract Management

• Medicare COPs for hospitals require that the Board has a list of all contracts within the organization.
• Practically every organization needs to have a contract management system to identify:
  – how contracts are managed;
  – who has sign-off power;
  – who has access;
  – contract deadlines and renewals;
  – contract breaches;
  – certificates of insurance;
  – compliance with applicable laws and warranties of no exclusions; and
  – Indemnification
• Consequences- $$$$$
Meaningful Use

• The Medicare and Medicaid electronic health record ("EHR") Incentive Programs provide financial incentives for the "meaningful use" of certified EHR technology.

• To receive an EHR incentive payment, providers have to show that they are “meaningfully using” their certified EHR technology by meeting certain measurement thresholds that range from recording patient information as structured data to exchanging summary care records.
Meaningful Use (cont’d)

• To receive an incentive payment, providers must attest to demonstrating meaningful use every year.

• The government can audit providers to determine whether they are meeting the requirements under meaningful use regulations.
  – If the audit reveals that requirements are not being met, then the provider may have to refund the incentive payment and can also be fined for fraud.

Meaningful Use Practical Applications

• Understanding CMS audit process.
• Maintaining documentation of compliance.
• Understanding clinical workflow and how EHR is used.
• Understanding reconciliation and continuity of care.
• Understanding the penalties.
Issue 6
OIG Guidance to Boards of Directors
OIG Guidance to Boards of Directors

The OIG Guidance for Boards:
• Lists questions for Boards to ask about compliance initiatives and roles.
• Defines the roles of legal, compliance, risk management, quality, and other functions.
• Discusses privileged versus non-privileged communications.
  – e.g., legal vs. compliance
• Provides examples for exceptions and recommended controls.

SOURCES:
Social Media

• When drafting Social Media Policies, healthcare organizations must consider
  – Human Resources or employment issues;
    and
  – HIPAA concerns
Social Media Practical Tips

• Have a disciplinary plan in place.
• Anticipate HIPAA and HR violations by employees.
• Anticipate patient violations of employee and institutional rights.
Issue 8

WELLNESS PROGRAMS
Wellness Programs

- In addition to not knowing how the EEOC will define a “voluntary” wellness program, healthcare organizations also face the task of keeping the wellness records of employees private under HIPAA regulations.
- It is therefore recommended that employers have employees sign HIPAA-compliant authorizations before gathering employee biometric data or other personal health information.
Wellness Programs
Practical Tips

• Employers should be aware of all the laws that apply to employer wellness programs.
• The relationship between wellness programs and employer-sponsored health insurance.
• Consent and authorization forms.
• Outcomes-based vs. Participation-based programs.
Issue 9

Documentation and Coding and ICD-10
Documentation and Coding

- Payers trust providers to provide necessary, cost-effective, and quality care.
- The Government’s payment of claims is generally based solely on providers’ representations in the claims documents.
- Accurate coding is especially important with the ensuing transition to ICD-10.
Documentation and Coding – Comparison of ICD-9 and ICD-10

ICD 9: 15,000 codes

ICD-10: 68,000 codes
Documentation and Coding go Hand in Glove
Documentation and Coding (cont’d)

• Inaccurate or fraudulent billing can result in having to repay the payer and possibly significant financial penalties under the False Claims Act.
• ICD-10 Transition.
• Risk based and shared savings contracts.

Burnout

• With the changes in healthcare system, providers, employees, and patients are suffering from burnout.
• The legal and social issues surrounding burnout are:
  – addiction;
  – depression;
  – malpractice;
  – distraction;
  – non-productivity and disillusionment
  – employee absenteeism;
  – patient no-show and non-conformance with needed medical care

See e.g., Neil Chesanow, Why Internists are number one in physician burnout. Medscape. June 23, 2015
Questions and Contact Information

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