Remote Practice, Tangible Risk:
Identifying and Avoiding Fraud & Abuse and Other Legal Pitfalls in the Practice of Telemedicine

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Objectives:
What you need to know to prevent telemedicine pitfalls

• Know conditions for federal reimbursement
• Determine obligations for credentialing and privileging
• Be aware of potential risks under the federal Anti-Kickback Statute
• Be vigilant of physician relationships implicated by the federal Stark Law
• Navigate information privacy and security risks presented by telemedicine
• Avoid corporate practice of medicine hurdles when structuring operations to practice interstate medicine
What is Telemedicine?

- Delivery of health care services
- Using communications technology
- When patient and treating practitioner are not in the same physical location

What Telemedicine Isn’t

- Not a separate medical specialty or area of practice
- Instead, an innovative method of delivery that permits patient care to reach beyond the boundaries of the medical office building
Criteria for Medicare Reimbursement

1. **Qualifying distant site practitioner**
2. **Qualifying originating site**
3. **Location of originating site**
4. **Technology**
5. **Approved CPT codes**

**Distant Site Practitioner**

- Qualifying practitioner
  - Physician, PA, Nurse Practitioner, Clinical Social Worker, etc. appropriately licensed
  - Medical examination of the patient must be under control of distant site practitioner
- Billing
  - Paid an equal amount that the practitioner would have received if the service were furnished without telemedicine technology
Approved Medicare Telehealth Services

- Physicians and other practitioners
  - Office or outpatient visits
  - Professional consultations
  - Pharmacologic management
  - Other Medicare physician fee schedule services
- Additional requirements for consultations furnished to patients in hospital or SNF settings

Originating Site

- Qualifying site
  - Physician office, hospital, SNF, rural health clinic, renal dialysis center, etc.
- Bills facility fee
  - Medicare Part B
  - Lesser of 80% of actual charge or 80% of originating site facility fee
Location of Originating Site

- Classification of a “rural” HPSA:
  - Effective January 1, 2014, includes any area located within a rural census tract
  - Even if the area falls outside of an MSA
  - Revised definition of “rural” effectively expands access to care
- 2014 rule also added CPT codes to the list of Medicare Telehealth Services

Medicare Reimbursement - Technology

**CMS requires:**
- Multimedia communications equipment with two-way, live interactive capabilities
- “Store and forward” system under a federal demonstration program

**Medicare will NOT pay for:**
- Telephones
- Fax machines
- Email systems
Credentialing and Privileging

<table>
<thead>
<tr>
<th>Original CMS Policy</th>
<th>CMS Final Rule July, 2011</th>
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<tbody>
<tr>
<td>• Originating site must fully credential and privilege practitioners providing telehealth services from a distant site</td>
<td>• Revises Medicare hospital conditions of participation</td>
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<td>• Permits originating site hospitals to rely on credentialing and privileging information provided by the distant site hospital for telehealth practitioners</td>
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<td>• Written agreement required between originating site and distant site – must meet certain requirements</td>
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**Conditions for Relying on Credentialing and Privileging Information**

- Distant site hospital is a Medicare-participating hospital or entity that can ensure Medicare compliance;
- Distant site practitioner is privileged at the distant site hospital or entity, and a current list of those privileges are provided;
- Practitioner holds a license issued or recognized by the state in which the distant site hospital or entity is located; and
- Written agreement must ensure accountability
The Federal Anti Kickback Statute

“The anti-kickback statute prohibits in the health care industry some practices that are common in other business sectors, such as offering gifts to reward past or potential new referrals.”

See OIG Supplemental Compliance Guidance for Hospitals, 70 FR at 4861 (Jan. 31, 2005)

The Federal Anti-Kickback Statute

42 USC 1320a-7b

Prohibits anyone from:

- Knowingly and willfully
- Soliciting or receiving
- Any remuneration
- Directly or indirectly, covertly or overtly
- In cash or in kind
- In return for referring an individual for the furnishing or arranging for the furnishing OR
- In return for purchasing, leasing, ordering or arranging for or recommending purchasing, leasing, or ordering
- Any good, facility, or service or item
- For which payment may be made, in whole or in part, under a federal health care program
Intent Standard: the One Purpose Test

• As interpreted by OIG and some federal courts, the “one purpose” test means that if just one of your many purposes in paying the remuneration is to influence referrals, you have violated the law.
• Due to the “one purpose” test, enforcers have unlimited discretion to prosecute an arrangement that implicates the AKS but does not fully meet an exception/safe harbor.

Examples of Remuneration

• Free or below-market goods or services provided to the referral source
• Absorbing a cost that the referral source otherwise must absorb
• Contractual Joint Ventures
• Swapping
Penalties

- Criminal and civil penalties
- $25,000 per offense
- Imprisonment up to 5 years
- Civil monetary penalties (exclusion and $50,000)
- Possible False Claims Act liability

Safe Harbors

- The OIG has established regulatory “safe harbors” that will protect an arrangement from enforcement if all of the requirements of the safe harbor are met.
- Failure to comply with a safe harbor is not a per se violation of the Anti-kickback Statute, but may increase the risk that the arrangement may be scrutinized by the OIG.
- Safe harbors intended to evolve with the practice of medicine
### Facts

- Hospital has nationally ranked neuroscience program ("hub")
- Community hospitals frequently transfer stroke patients to facilities with specialized capabilities to treat these patients
- Treatment most effective when begun in ER
- Hub hospital seeks to create a network of affiliated community hospitals ("spokes") to provide immediate consultations

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**Proposed telemedicine network for acute stroke care**

**Facts**

- Hub hospital offers to spoke hospitals, at no charge:
  - Neuro emergency telemedicine technology
  - Clinical consultations via telemedicine
  - Clinical protocols
- Hub hospital accepts acute stroke transfers from spoke hospitals
- Hub hospital bills 3rd party payors for consults when permissible
- Spokes agree to period of exclusivity
Hypothetical:
Proposed telemedicine network for acute stroke care

OIG’s Concerns

- Gifts to potential referral sources with independent value
  - Inducement to refer patients
- “Swapping”
- Increased costs to federal health care programs

Does the Arrangement Meet a Safe Harbor?

1. Space rental
2. Equipment rental
3. Personal services and management contracts
4. Bona fide employees
5. Electronic prescribing
6. Donation of EHR technology
Proceeding Outside a Safe Harbor

- Failure to bring an arrangement within a safe harbor will not violate the Anti-Kickback Statute per se.
- The situation will be analyzed on a facts/circumstances basis.
- Government may infer bad intent from certain facts/circumstances.

OIG’s Analysis

- Unlikely to generate appreciable referrals
  - Intended to reduce transfers to stroke center
  - No additional compensation to emergency physicians
  - Participating hospitals not required to refer patients to the stroke center
- Volume or value of referrals is not a condition to participation in network
  - Initially, program offered only to hospitals with preexisting affiliation
  - Expanded only based on demonstrated need
OIG’s Analysis, cont’d.

- Primary beneficiaries are stroke patients who can be treated in spoke hospital’s ER
  - Participating hospitals pay their own way for staffing, operational and maintenance costs
  - Distinguished “educational offerings” from CME courses provided for free
- Each party responsible for marketing
- Low likelihood of increased costs to Medicare program

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Anti-Kickback Statute Takeaways

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<tr>
<th>Risks</th>
<th>Favorable Factors</th>
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<tr>
<td>Scrutiny of donations/gifts that have independent value</td>
<td>Increased access to care, benefitting rural communities in particular</td>
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<tr>
<td>Risk of “swapping” arrangements</td>
<td>Limited reimbursement for telemedicine consults under federal health care programs</td>
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<tr>
<td>Be wary – limits to protection for services not reimbursable under federal health care programs</td>
<td>Lack of appreciable referrals; reduction of transfers and readmissions</td>
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<tr>
<td>Expanding business of originating site</td>
<td>No requirement or encouragement to refer</td>
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<td>“Per click” arrangements</td>
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### The Stark Law
42 USC 1395nn

- Prohibits a **physician**
- From making a **referral**
- For a **designated health service**
- Reimbursable by **Medicare and/or Medicaid**
- To any entity with which the physician (or physician's family member) has any **financial relationship**
- Unless an **exception** applies:
  - To the referral or service, or
  - To the financial relationship

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### The Stark Law: Consequences

- If a physician makes a referral for DHS in violation of the Stark Law, the entity receiving the referral cannot bill Medicare or Medicaid for services provided pursuant to that referral.
- If the entity knows that a referral violated the Stark Law and received payment for that service, the entity must refund the payment.
- If the entity knowingly fails to refund the payment for 60 days, the entity may be liable under the False Claims Act for treble and statutory damages on each claim submitted.
The Stark Law:
What is a referral?

- A request for, or the ordering of, or the certifying or recertifying of the need for, a designated health service by a physician
- Establishment of a plan of care
- A request for a consultation with another physician and any test or procedure ordered by the physician-consultant
- **Exception** for services personally performed by the referring physician
- **Exception** for services requested by a pathologist, radiologist or radiation oncologist pursuant to a consultation

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Does the Arrangement Meet a Financial Relationship Exception?

1. Community-wide health information systems
2. Electronic prescribing technology or training
3. EHR items and services
4. Personal services arrangements
5. In-Office Ancillary Services
6. Ownership of a rural provider
Avoiding Stark Law Risks In Telemedicine Arrangements

- Understand how Stark applies
  - Strict liability
  - More limited in scope than the AKS
    - Physicians
    - DHS
- Referral from originating site to distant site (or vice versa)
- Identify financial relationships
  - Ownership interest
  - Compensation arrangement
- Structure to meet an exception

HIPAA

- HIPAA refers to the Health Insurance Portability and Accountability Act of 1996
- Impacts covered entities and business associates of covered entities
- HITECH Act enacted February 17, 2009
  - Strengthened privacy and security protections and enhanced penalty provisions
- HIPAA Final Omnibus Rule issued January 25, 2013
Civil Penalties

- Did not know (even with diligence)- minimum of $100 per violation
- Reasonable Cause- minimum of $1,000 per violation
- Willful Neglect; violation cured- minimum of $10,000 per violation (if corrected; if not, $50,000)
- For all types: Up to $1,500,000 per year for multiple violations of the same part of HIPAA

Criminal Enforcement

- Criminal penalties can be imposed not only on covered entities and business associates but also on individual employees who obtain or disclose PHI without authorization
- Range of penalties
  - from $50,000 plus one year imprisonment for knowingly violating HIPAA; to
  - $250,000 plus ten years’ imprisonment for doing so with intent to profit by or do harm with the information
Elements of HIPAA

Privacy Rule
• PHI may not be used or disclosed except:
  ➢ as permitted or required (without an authorization)
  OR
  ➢ as authorized by the individual
• Minimum necessary
• Safeguards
• Individual Rights provisions
• Business Associates
  ➢ Direct liability
  ➢ Satisfactory assurances (BAAs)

Elements of HIPAA

Security Rule
• Safeguards to ensure the confidentiality, integrity, and availability of all ePHI
  ➢ Administrative Safeguards
  ➢ Physical Safeguards
  ➢ Technical Safeguards
• Protect against reasonably anticipated threats
• Protect against reasonably anticipated uses or disclosures of ePHI that are not in compliance with the Privacy Rule
• Ensure compliance by workforce
### Elements of HIPAA

#### Security Rule

- Security Rule is flexible and scalable
  - Size, complexity and capabilities
  - Technical infrastructure
  - Costs of security measures
  - Probability and criticality of risks to EPHI
- Implications:
  - Implementation of telemedicine may require re-evaluation of security measures in place

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“[Risk Analysis] and its component implementation specifications form the foundation upon which an entity’s necessary security activities are built.”

Department of Health and Human Services
February 20, 2003
Elements of HIPAA

**Breach Notification Rule**
- Federal reporting obligation introduced by HITECH Act
  - Covered entities must notify individuals (media, OCR)
  - Business associates must notify covered entity
- Triggered by Breach of Unsecured PHI
  - PHI that is not secured through encryption or destruction
- Presumption of a breach *unless* covered entity or business associate demonstrates that there is a low probability that the PHI has been compromised
  - “Significant harm” standard is gone

HIPAA – Implications for Telemedicine

**Real World Example**
- Specialist physician at a metropolitan multispecialty hospital receives a request for consultation with patients at a rural provider
- Originating site has Skype capabilities and requests that physician visits be conducted via Skype
- The hospital’s compliance officer is asked what steps need to be in place to permit this practice
- Consider obligations under the Privacy, Security and Breach Notification Rules
Does HIPAA Permit Practicing Medicine through Skype?

**Privacy Rule**

- **Authorization**
  - Treatment exception
  - Obtain authorization when required
  - OCR guidance on “duty to warn”
- **Safeguards**
  - Conduct sessions in a private place
  - Allow provider to end session if there are concerns about privacy
  - Close session when complete

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**Privacy Rule, cont’d.**

- **Individual Rights provisions**
  - Notice of Privacy Practices
  - Access to PHI
  - Accounting of disclosures
- **Business associate relationships**
  - Review of server, software and cloud vendors
  - “Mere conduit” exception
Does HIPAA Permit Practicing Medicine through Skype?

**Security Rule**

“If the covered entity... is planning to incorporate new technology to make operations more efficient, the potential risk should be analyzed to ensure the ePHI is reasonably and appropriately protected. If it is determined that existing security measures are not sufficient to protect against the risks associated with the... introduction of new technology, then the entity must determine if additional security measures are needed.”

Office for Civil Rights  
July 14, 2010

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Security Rule, cont’d.

- Administrative safeguards  
  - Information system activity review  
  - Security Awareness and training  
  - Incident investigation and reporting
- Physical safeguards  
  - Are appropriate device and workstation controls in place?
- Technical safeguards  
  - Is encryption reasonable and appropriate?
Does HIPAA Permit Practicing Medicine through Skype?

Breach Notification Rule
- Increased risk of exposure
  - If not secure connection, notification required
- Implications of breach reporting
  - Have you documented a risk analysis?
  - Have you implemented reasonable and appropriate safeguards?
  - Are you exercising oversight of your vendors?

Post-HITECH: A Changed World of HIPAA Enforcement

- State attorneys general to enforce HIPAA violations on behalf of the state’s residents
- Mandatory formal investigation of complaint if the violation was due to possible “willful neglect”
- Increased civil penalties
- Stricter enforcement, harsher penalties
  - No provider is too small
  - No breach is too insignificant
HIPAA Audits

• HITECH Act required HHS to perform periodic audits of covered entities’ and business associates’ HIPAA compliance
• Initial round of audits completed in late 2012 (115 covered entities)
• Second round of audits to begin in Fall 2014
  – 350 covered entities and business associates
  – Start time is delayed; no update

HIPAA Audits: Implications for Telemedicine

• Findings from first round of audits suggest providers struggle most with Security Rule compliance
  – Security Rule accounted for majority of cited deficiencies
  – 80% of all providers and 57% of all health plans did NOT have a complete or accurate risk analysis
• Second round of audits
  – OCR focused on risk analysis, encryption, security controls
  – Documentation of policies/procedures is not enough; OCR will look for evidence that policies/procedures are being carried out
The Corporate Practice of Medicine Doctrine

- Prohibits a lay corporation from owning an interest in a medical practice or employing physicians
  - Intended to prevent non-clinicians from interfering with professional medical judgment
- Established by statute and/or developed at common law
  - States vary greatly with respect to the degree of enforcement, scope of exceptions, etc.

Issues

- Restriction on ability to employ physicians can create challenges to the interstate practice of medicine
- May require physicians to be affiliated with or employed by a professional corporation in each of the states where they “practice medicine”
  - Logistical, contracting issues may arise
  - CPOM more likely to be enforced through contract disputes, though government enforcement is possible
Compliance with CPOM in Telemedicine

- Know the lay of the land

- When practicing medicine across state lines, may need to restructure operations
  - Friendly PC maintains control over clinical decisions
  - Management Services Organization maintains control over financial and management affairs

- State licensure and PC requirements
  - Consider how state licensure requirements may impact the friendly PC structure

Questions?

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