Fraud and Abuse Laws in Telemedicine

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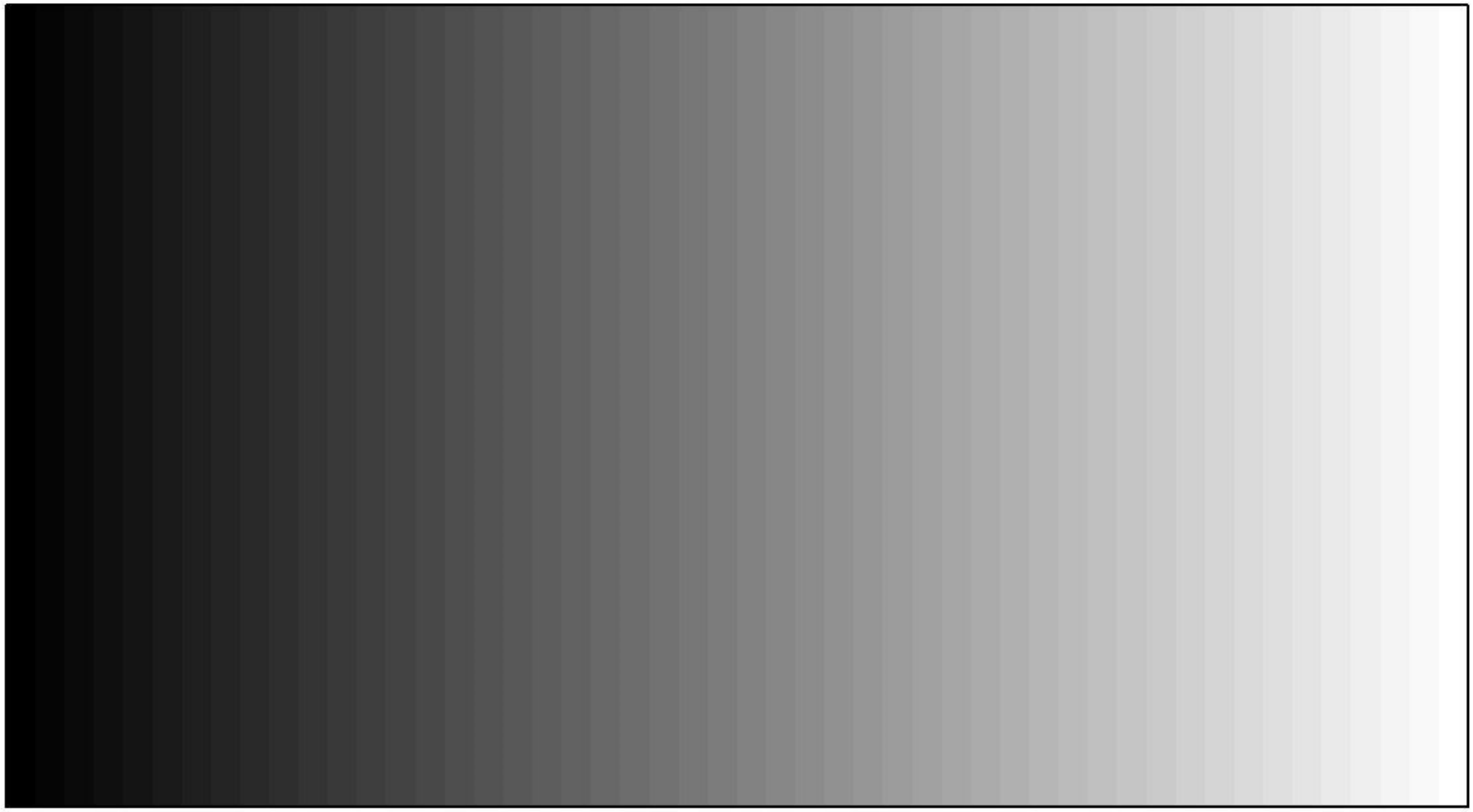
DEFINING SUCCESS TOGETHER

The Wild West

50 Shades of Gray....



Agenda

1. Telehealth Overview
    a. Key Definitions
    b. Models and Legal Issues
    c. Reimbursement
2. Federal Fraud & Abuse
    a. Anti-Kickback Issues
    b. Stark Law Issues
    c. Civil Money Penalty Law Issues
3. State Fraud & Abuse Issues
4. Case Studies

Telehealth Overview

Telehealth Overview

- **Definitions of Telehealth**
  - **American Telemedicine Association:** "The use of medical information exchanged from one site to another via electronic communications to improve a patient's clinical health status. Telemedicine includes a growing variety of applications and services using two-way video, email, smart phones, wireless tools and other forms of telecommunications technology."
  - **The Federation of State Medical Boards**: "Generally, telemedicine is not an audio-only, telephone conversation, e-mail/instant messaging conversation or fax. It typically involves the application of secure videoconferencing or store and forward technology to provide or support health care delivery by replicating the interaction of a traditional encounter in person between a provider and a patient."
  - **Institute of Medicine**: "Although evolving, telemedicine is sometimes associated with direct patient clinical services and telehealth is sometimes associated with a broader definition of remote health care services."

Definitions of Key Terms

- "**Asynchronous**" versus "**Synchronous / Live Video**"
  - Videoconferencing
  - Remote patient monitoring
  - Store and forward
- "**Distant site**" is the location of the provider
- "**Originating Site**" is the location of the patient
- "**Mobile Health**" or "**mHealth**" is the use of telehealth using mobile devices

Common Telehealth Models

- Physician-to-Physician
- Institution-to-Institution
- Specialist-to-Institution
- Intra-Organization
- Direct-to-Consumer
- Remote Patient Monitoring (RPM)

Common Legal Issues

Medicare Coverage

- Patient must present from:
  - A recognized clinical "originating site"
  - A rural "geographic" site
- Medicare covers a specific list of CPT/HCPCS codes
  - Professional consultations and mental health services
- Other conditions of payment
  - Approved types of practitioner
  - Audio & video required
  - Physician present at originating site, only if medically necessary
- Medicare pays MPFS + originating site fee

Medicaid Coverage

- Coverage and payment varies among states*
  - Synchronous / live video service: 46 states
  - Asynchronous store-and-forward services (not including tele-radiology): 9 states
  - Remote patient monitoring services: 14 states
  - Coverage for all three: 3 states
  - No published policies for any of the three: 4 states

*National Telehealth Policy Resource Center, Center for Connected Health Policy

Commercial Payors

- More commercial payors are choosing to cover telehealth
- Telehealth "parity" laws
  - 29 states has adopted
  - "Partial parity" versus "Full Parity"
    - Parity in "coverage"
    - Parity in "payment"
  - Scope of application
    - Which payors must comply?

Innovative Payment Models

- **Medicare Shared Savings Program (MSSP)**
  - ACOs have flexibility to use telehealth
  - All conditions of payment must be met for Medicare payment
  - ACOs can take advantage of MSSP fraud & abuse waivers
- **Next Generation ACOs**
  - Waiver of "originating" and "geographic" site requirements for beneficiaries attributed to Next Generation ACO
- **Bundled Payment for Care Initiative (BPCI)**
  - Waiver of "originating" and "geographic" site requirements for patients during Model 2 episode
- **Comprehensive Care for Joint Replacement (CCJR)**
  - Waiver of "originating" and "geographic" site requirements
  - New G-Codes to be developed for "at-home" services

Federal Fraud & Abuse Issues

Telemedicine is merely the ***practice of medicine*** via electronic means

Federal Anti-Kickback Statute

- **Definition**: It is a criminal offense to ***knowingly and willfully*** offer, pay, solicit, or receive, directly or indirectly, ***any remuneration in return for referring, furnishing, arranging or recommending*** items or services ***reimbursable*** by any federal health care program.
- **Common Safe Harbors in Telehealth**
  - Space rental safe harbor
  - Equipment rental safe harbor
  - Personal services and management contracts safe harbor
  - Bona fide employment safe harbor
  - Electronic health records items and services safe harbor
  - Managed care organization safe harbor

OIG Advisory Opinion 98-18:
Ophthalmologist & Optometrist Equipment Lease

- **Facts**
  - Ophthalmologist subleased imaging equipment to optometrist
  - Optometrist transmitted ocular images to the ophthalmologist for interpretation
  - Ophthalmologist provides free tele-consultations
- **OIG Analysis**
  - Sublease satisfied all elements of the equipment rental safe harbor
  - However, free telemedicine consultations were remuneration (could enable optometrist to expand business)
  - Optometrist would not advertise or bill for consultations
  - Patients free to choose any ophthalmologist
- **Conclusion: AKS implicated, but no sanctions**

Advisory Opinion 99-14: Expiration of Grants for Telemedicine Network

- **Facts**
  - Telemedicine hub and spoke model between health system and rural facilities for specialist services under federal grant. Upon expiration of the grant, parties sought to continue the telemedicine network
  - Health system would provide telecommunications lines and equipment
  - Rural facilities would provide staff, space and promotion
  - Clinicians could bill for the consultations
- **OIG Analysis**
  - Remuneration: (i) the rural facilities receive free equipment and subsidized line charges, and (ii) the health facilities receive additional opportunities to earn fees
  - Health system may be subsidizing practice of its practitioners (with equipment) and the rural system practitioners (by making specialists available), both of whom are referral sources for health system
  - Low overutilization risk as consults do not result in claims to payors (including Medicare/Medicaid)
  - Congressional intent in grant program was to support and expand access to specialists
- **Conclusion: AKS implicated, but no sanctions**

OIG Advisory Opinion 04-07: Health System & School-Based Clinics

- **Facts**
  - Health system develops telemedicine program for low-income children in 18 rural counties for specialist consultations
  - School nurses see children on-site, consult with specialist via telemedicine when necessary
  - Consultations not reimbursable under Medicaid or CHIP
- **Analysis**
  - Remuneration: (i) the school-based clinics obtain free telecommunications equipment and subsidized line charges; (ii) the consulting practitioners might receive additional opportunities to earn professional fees; and (iii) the patients receive free specialist consultations
  - Low risk of overutilization because services not billable
  - Safeguard created as students needing follow-up are referred to existing or community PCPs
  - Public benefit by promoting access to low-income children
- **Conclusion: AKS implicated, but no sanctions**

Advisory Opinion 11-12: Tele-Stroke Program

- **Facts**
  - Health system provides emergency tele-stroke consultations to community hospitals without access to stroke care.
  - Health systems provide technology, neurologist consultations, clinical protocols, training, education, and a commitment to accept transfers
  - Hospitals agree to pay for and install communication lines, connectivity, and CT scanner necessary to allow neurologists to view images remotely
- **OIG Analysis**
  - AKS triggered as community hospitals are a referral source for the Health System
  - Safeguards: referrals by community hospitals to Health System not required; patient freedom of choice maintained; Medicare not billed; and participating hospitals not chosen based on history of referrals
  - Benefits: quality of care; patients who may have been transferred to health system anyway benefit from receiving treatment sooner
- **Conclusion: AKS implicated, but no sanctions**

Considerations for Evaluating a Telehealth Arrangement

(1) Whether the arrangement can be structured to satisfy an applicable safe harbor.

(2) Whether the parties are potential referral sources to one another;

(3) Whether remuneration is passing from one party to another;

(4) Whether the telemedicine services themselves are reimbursable by a FHCP or whether other reimbursable items/services are referred;

(5) Whether any safeguards were put into place such as not conditioning participation on referrals, providing patients with a choice of provider, and/or ensuring that referring physicians are not compensated for making referrals to a particular party;

(6) Whether the parties intend to market the telehealth arrangement and how the marketing costs will be allocated; and

(7) Whether the patients will be informed of the relationship as well as any financial benefit to the parties.

Stark Law

- **Definition**: The Stark Law prohibits a physician (or an immediate family member of a physician) who has a financial relationship with an entity from referring patients to that entity for certain designated health services payable by Medicare, unless an exception applies.
- **Common Exceptions in Telehealth**
  - Rental of Office Space
  - Rental of Equipment
  - Bona Fide Employment Relationships
  - Personal Service Arrangements
  - Fair Market Value Compensation
  - In-Office Ancillary Services
  - Prepaid Plans
  - Indirect Compensation Arrangements
  - Electronic Health Records Items and Services

Examples

- A hospital provides its employed and contracted physicians with free access to the hospital's telehealth equipment. Access to the equipment is not limited to services for hospital patients.
- A laboratory provides free telehealth imaging equipment to local primary care practices for the provision of telepathology.
- A hospital permits its contracted infectious disease specialist to locate his telemedicine equipment on the hospital's premises so that the infectious disease specialist can perform tele-consults for other institutions while performing his on-call coverage requirements for the hospital. The hospital does not charge the infectious disease specialist for the use of the hospital's space.

Analyzing a Telehealth Arrangement Under the Stark Law

- Consider whether the arrangement involves a financial relationship, either direct or indirect, between a DHS entity and a physician (or an immediate family member of a physician) in a position to refer patients to the entity for DHS payable by Medicare and if so, whether an exception applies to each such financial relationship.
- Consider all DHS referred by the physician to the entity.
- Address all remuneration (e.g. – many arrangements involve both equipment and services)

Civil Monetary Penalties Law

- **Definition:** The Civil Monetary Penalties Law (CMPL) authorizes the imposition of civil money penalties against an entity that (in pertinent part to telemedicine) offers or gives remuneration to any beneficiary of a federal health care program likely to influence the receipt of reimbursable items or services or choice of provider.
- **Relevant Exceptions**
  - Preventive Care
  - Financial Need Exception
  - Promoting Access to Care

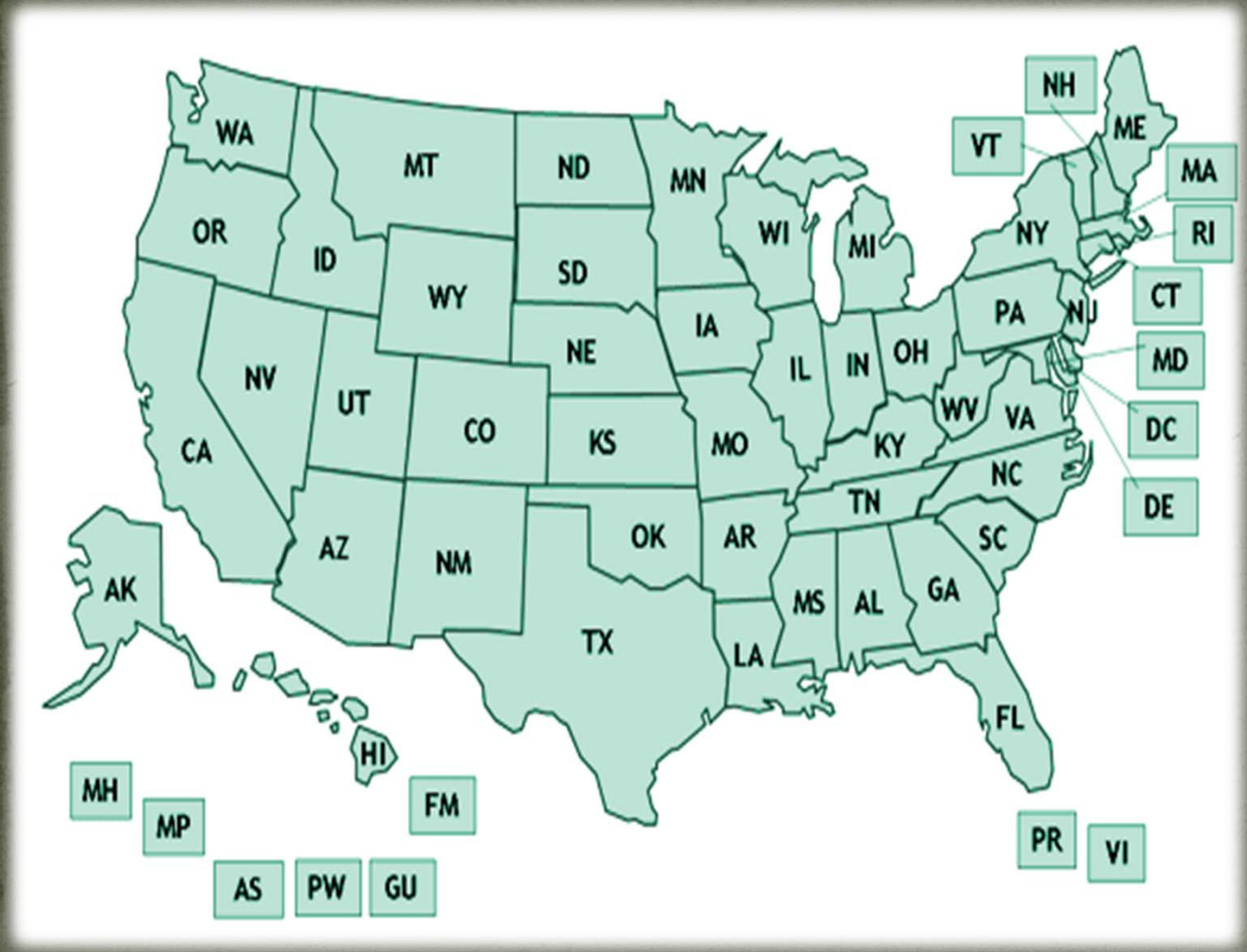
OIG Special Advisory Bulletin: Gifts and Other Inducements to Beneficiaries

- The OIG is concerned that beneficiary incentives that influence beneficiary choice raise both quality and cost concerns.
  - "[P]roviders may have an economic incentive to offset the additional costs attributable to the giveaway by providing unnecessary services or by substituting cheaper or lower quality services."
  - "[T]he use of giveaways to attract business favors large providers with greater financial resources for such activities, disadvantaging smaller providers and businesses."
- "Congress broadly prohibited offering remuneration to Medicare and Medicaid beneficiaries, subject to limited, well-defined exceptions."
- "[U]nless a provider's practices fit within an exception (as implemented by regulations) or are the subject of a favorable advisory opinion covering a provider's own activity, any gifts or free services to beneficiaries should not exceed the $10 per item and $50 annual limits."

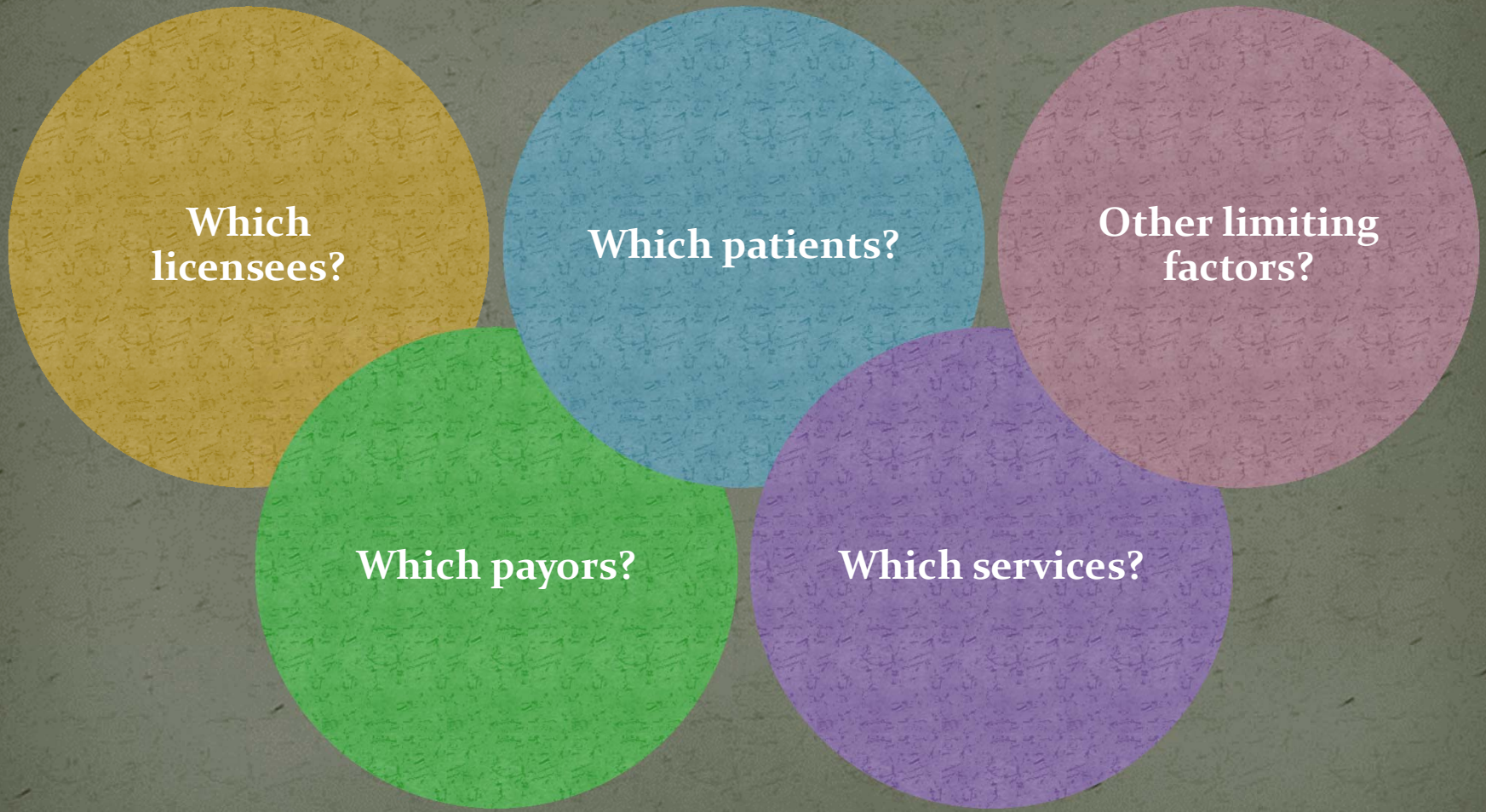
Beneficiary Inducement – Promoting Access to Care

- Any remuneration which ***promotes access to care <u>and</u>*** poses a ***low risk of harm*** to patients and federal health care programs does not constitute "remuneration" under the beneficiary inducement provision of the CMPL.
- **OIG has identified the following safeguards:**
  - Financial need determination
  - Merited by patient's condition
  - Not advertised or marketed
  - Patient informed only after accepted for treatment
  - Other programs not promoted in connection
  - Eligibility not conditioned on receipt of lucrative service
  - Entity does not claim costs or shift cost to FHCP

State Fraud & Abuse Issues



Analyzing State Fraud & Abuse Laws



State Anti-Kickback Statute

- **Florida**
  - "It is unlawful for any person, including any health care provider or health care facility, to: … (a) Offer or pay any commission, bonus, rebate, kickback, or bribe, directly or indirectly, in cash or in kind, or engage in any split-fee arrangement, in any form whatsoever, to induce the referral of patients or patronage to or from a health care provider or health care facility" (Fla. Stat. § 817.505)
- **Potential application to telehealth**
  - Free or discounted software, equipment, space, personnel to patients or a referral source
  - Percentage-based marketing arrangements

State Physician Referral Laws

- **New York**
  - "A practitioner authorized to order clinical laboratory services, pharmacy services, radiation therapy services, physical therapy services or x-ray or imaging services may not make a referral for such services to a health care provider authorized to provide such services where such practitioner or immediate family member of such practitioner has a financial relationship with such health care provider." (N.Y. Pub. Health Law § 238.)
- **Potential applications to telehealth**
  - In-office referrals for telehealth ancillary services
  - Compensation arrangements with facilities to provide professional telehealth services

State Fee-Splitting Laws

- **Illinois Medical Practice Act**
  - "A licensee under this Act may not directly or indirectly divide, share or split any professional fee or other form of compensation for professional services with anyone in exchange for a referral or otherwise, other than as provided in this Section 22.2." (225 Ill. Comp. Stat. 60/22.2)
- **Potential applications to telehealth**
  - Management arrangements with percentage-based compensation
  - Marketing arrangements that are not FMV

State Patient Brokering Statutes

- **California**
  - "No person, firm, partnership, association or corporation, or agent or employee thereof, shall for profit refer or recommend a person to a physician, hospital, health-related facility, or dispensary for any form of medical care or treatment of any ailment or physical condition. The imposition of a fee or charge for any such referral or recommendation creates a presumption that the referral or recommendation is for profit." (Cal. Health & Safety Code § 445)
- **Potential applications to telehealth**
  - Subscription to network of telehealth provider
  - Middle-man arrangements

State False Claim Acts

- **Texas**
  - "(a) A person commits an offense if, with intent to defraud or deceive an insurer, the person, in support of a claim for payment under an insurance policy: (1) prepares or causes to be prepared a statement that: (A) the person knows contains false or misleading material information; and (B) is presented to an insurer." (7 Texas Pe. Code § 35.02)
- **Common applications to telehealth**
  - CPT coding
  - Billing for costs not incurred

State Disclosure Laws

- **Washington**:
  - "Ownership of a financial interest in any firm, corporation or association which furnishes any kind of clinical laboratory or other services prescribed for medical, surgical, or dental diagnosis shall not be prohibited under this section where:
    - "(a) the referring practitioner affirmatively discloses to the patient in writing, the fact that such practitioner has a financial interest in such firm, corporation, or association; and
    - "(b) the referring practitioner provides the patient with a list of effective alternative facilities...."

(Rev. Code of Wash. § 19.68.010)

State Medical Boards & State AGs

- Possible Consumer Fraud?
  - Internet Questionnaires
    - Colorado law prohibits dispensing prescription drugs based on an internet-based questionnaire. (3 Colo. Code of Regs. 719-1)
  - Physician Patient Examination vs. Telephone Examination
    - Colorado Medical Board permits drugs prescribed pursuant to an electronic "appropriate medical evaluation and review of relevant clinical history, commensurate with the presentation of the patient to establish diagnoses and identify the underlying conditions and/or contra-indications to the treatment recommended/provided." (Policy 40-27)

FTC & State AGs: Consumer Protection

- **Federal Trade Commission:** Settlement with Payments MD (Dec. 2014)
  - Consumers on website could authorize health plans to disclose their medical records, and for three other purposes, by clicking one box.
  - Complaint said PaymentsMD had "inadequately informed consumers that [they] would be seeking such information" and had been "deceiving consumers about the way they collect and use information."
  - Order states that PaymentsMD must "obtain consumers' affirmative express consent" before sharing their health information.
- Consider implications how telehealth providers obtain informed consent, deliver a Notice of Privacy Practices, etc.

Case Studies

Case Study #1: Remote Patient Monitoring

- Hospital A implements a RPM program for its CHF patients as follows:
  - Hospital provides patient with a telescale, a wireless blood pressure monitor, and an iPad.
  - Patient takes vitals which are transmitted to an app on the iPad and sent to a HHA monitoring center.
  - HHA monitors patient remotely and conducts in-person visits as necessary.
  - Patient can attend follow up appointments with physician via telemedicine using an app on the iPad.
  - Hospital, physician and the HHA all advertise this RPM service.

Case Study #1: Analysis

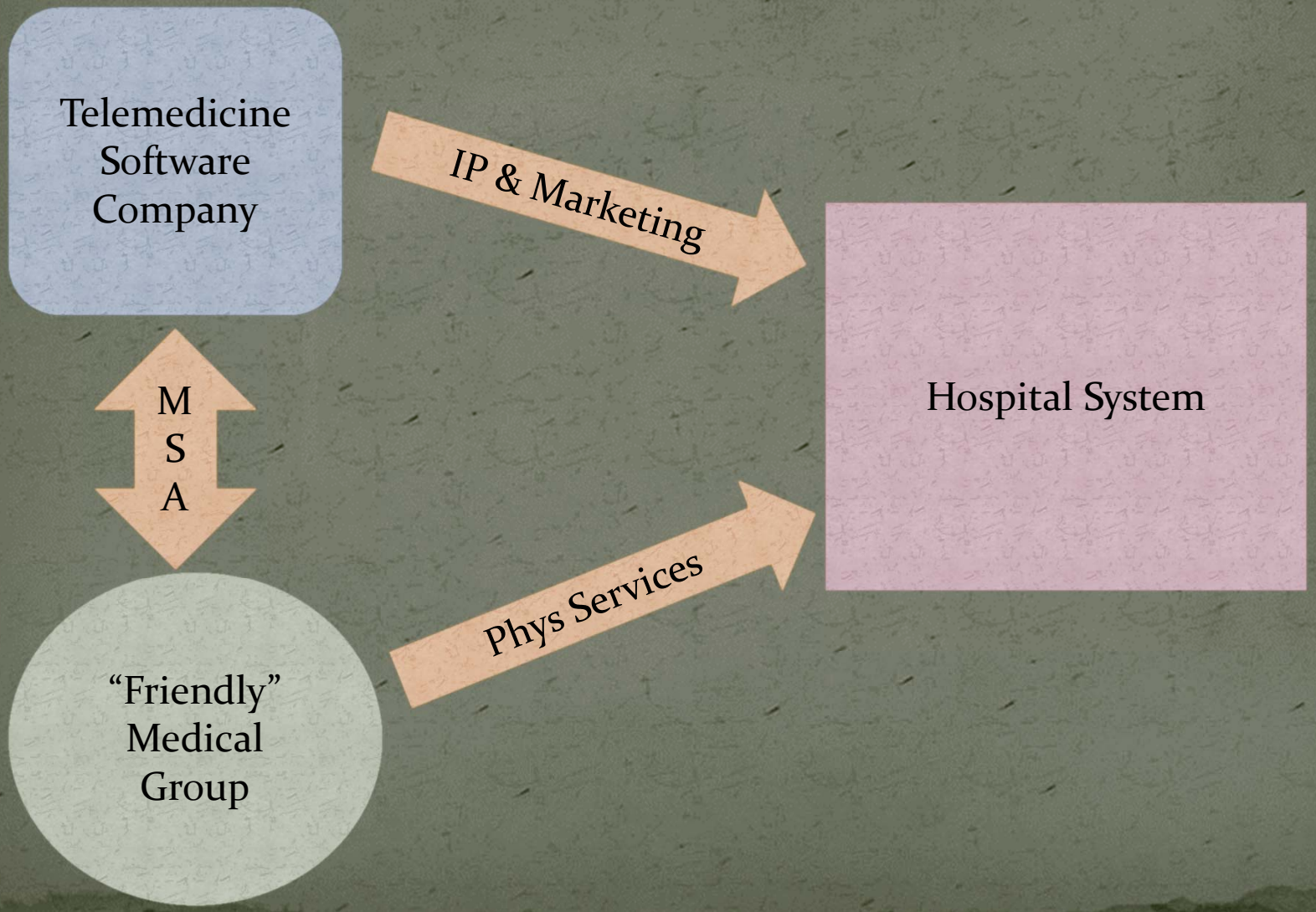
- CMPL Beneficiary Inducement:
  - Likely to influence where patient gets the surgery?
  - FHCP patients?
  - Exceptions?
- AKS:
  - Remuneration?
  - FHCP patients?
  - No Safe Harbor.
- Stark:
  - Financial relationship?
  - DHS?
  - Exception?

- State Fraud and Abuse Issues?

Case Study #2: Direct-to-Consumer

- Hospital System launches telehealth clinic for direct-to-consumer offering (no government or commercial payors)
  - License software from telemedicine company
  - Virtual clinic is staffed with telemedicine company's practitioners
- Telemedicine company markets virtual clinic to public
- Referrals
  - Medical group may order ancillaries, refer to specialists, admit, etc. at Hospital System
  - Patients not eligible for virtual clinic may be routed to Hospital System

Direct to Consumer Diagram



Case Study #2: Analysis

- Marketing the virtual clinic
  - Federal anti-kickback issues?
  - State anti-kickback issues?
- MSO and "Friendly" Medical Group
  - Federal anti-kickback
  - State fee-splitting?
- Medical Group Referrals
  - Stark?
  - State physician-referral statute?

Case Study #3: Physician - Physician

- A primary care practice utilizes an independent radiologist to interpret radiology studies performed at the PCP site. The PCP site uses store-and-forward technology to transmit the images to the radiologist. The PCP bills globally for the radiology services and compensates the independent radiologist for each interpretation at the PC rate established by Medicare for that study.

Case Study #3: Analysis

- **Stark:**
  - **IOAS Exception**: Allows physicians in a group practice to order and provide DHS in the office.
    - **Group Practice Definition**: IC physicians can be "Physicians in the Group" for purposes of GP definition.
    - **Performed or Supervised by a Physician in the Group**
    - **Same Building / Centralized Building**: DHS is "furnished" in the location where the service is actually performed, or dispensed, for the patient.
    - Billed by the performing/supervising physician or by the Group Practice under the Group's billing number.
  - **PCP can't bill for the interpretation unless it was performed at the PCP site.**
- **State Fraud and Abuse Issues?**

Case Study #4: Telehealth in ACOs

- Accountable Care Organizations
  - ACO launches aggressive telehealth program
  - Medical group selected to care for the sickest 1.0% of the ACO's patients
    - Gainsharing: Physicians paid incentives for reducing costs
    - P4P: Physicians paid incentives for achieving quality targets
  - Group gives beneficiaries health monitoring equipment
    - Blood pressure monitoring
    - Blue tooth scale
    - iPad for secure video chats with case manager and physician

Case Study #4: Analysis

- Medicare Shared Savings Program waivers?
  - Status of waivers for Next Gen ACOs?
    - Subject to different risk sharing requirements
    - MSSP Fraud & Abuse Waivers not available
    - Next Gen Waivers?
- Beneficiary Inducement
  - Telehealth not covered for most MSSP beneficiaries
  - Telehealth could be covered for most Next Gen ACO patients
- How does analysis change under
  - BPCI?
  - CCRJ?

Thank you!

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