

Compliance for Telehealth Providers

Presented by

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- Douglas Grimm, FACHE
- Health Care Practice Group Leader, Washington, DC
- Prior national experience in hospital administration
- Focus on telehealth compliance, reimbursement, and data privacy and security

Agenda

- Overview of the Stark Law
- Framework of the Anti-Kickback Statute (“AKS”)
 - The Law
 - Safe Harbors Potentially Applicable to Telehealth Arrangements
 - OIG Advisory Opinions Applicable to Telehealth Arrangements
- Telehealth Case Studies
- Tips for Entering Into Telehealth Arrangements
- Medicare Reimbursement Rules
- Enforcement

Physician Self-Referral Law (Stark Law)

- Prohibits a physician from referring Medicare or Medicaid patients for designated health services (“DHS”) to an entity with which the physician (or immediate family member) has a financial relationship, unless an exception applies
- Prohibits the entity from submitting claims to Medicare or Medicaid for services resulting from a prohibited referral
- Strict liability statute –
 - Intent does not matter
 - Must meet all elements of an exception

42 U.S.C. § 1395nn

Elements of an Agreement Implicating Stark

- Physician
- Referrals for DHS for Medicare or Medicaid patients
- Made to an entity with which the physician or an immediate family member has a financial relationship
- Existence of a Financial relationship
 - Ownership or Compensation

Stark Law - Exceptions

- Common exceptions for telemedicine:
 - Employment arrangements
 - Personal services arrangements
 - Space and equipment leasing arrangements
 - Electronic prescribing and EHR items and services
- Exceptions generally require:
 - Written and signed agreement
 - Commercially reasonable, FMV compensation
 - Does not reflect the volume/value of referrals

Stark Law – Self Disclosure

Voluntary Self Disclosure Protocol

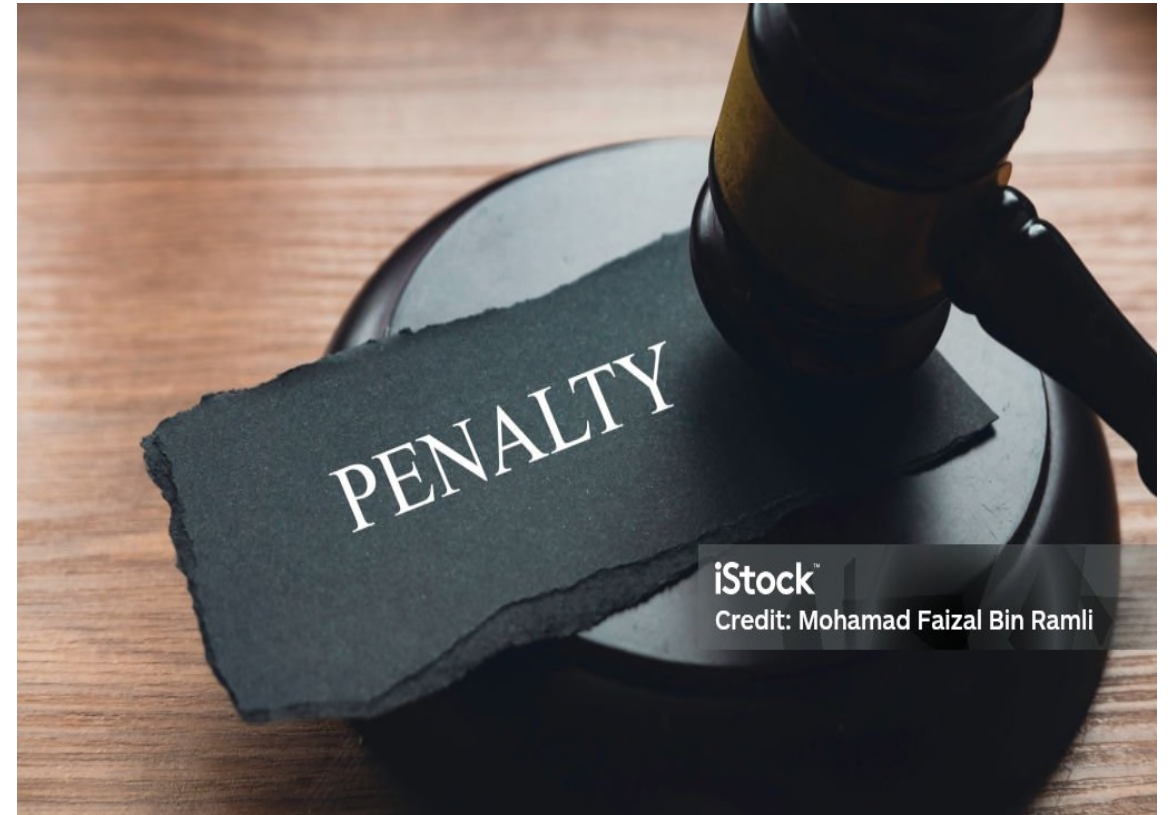
- Providers, suppliers
- Submit information to CMS regarding actual or potential violations.
- Who, What, Why, Damages, Safeguards to Ensure No Further Violation

Stark Law - Example

- Hospital engages physician to provide on-call telestroke services
- Arrangement includes compensation for physician's services and equipment for telestroke assessment
- Any referrals by physician to the hospital for DHS implicate the Stark law (whether or not related to telestroke services)
- Applicable exceptions: Personal Services and Equipment Lease exceptions

Stark Law Penalties

- Civil/Administrative
 - Overpayment refund obligation
 - Civil Monetary Penalties - \$15,000 for each service plus 3x the remuneration
- False Claims Act Liability
 - Stark violation leads to False Claims



Federal Anti-Kickback Statute (“AKS”)

- Criminal statute
- Applies to all individuals
- Prohibits offering or soliciting “**remuneration**” to **induce or reward patient referrals** or the generation of business involving **any item or service** payable by Federal health care programs
- Intent is the focus
- Safe harbors



“Remuneration”

- Remuneration includes anything of value, directly or indirectly, overtly or covertly, and can take many forms
 - Cash
 - Excessive compensation for medical directorships or consultancies or compensation where no legitimate services are provided
 - Free equipment or rent
 - Provision of office assistance
 - Certain reimbursement services
 - Expensive hotel stays, meals, travel, etc.



AKS Safe Harbors – Overview

- No liability if all elements of a safe harbor are met
- BUT ... not an automatic violation if activities do not fit squarely in a safe harbor
- The closer an activity or arrangement comes to satisfying the requirements of a safe harbor, the more likely the activity or arrangement is to be found compliant

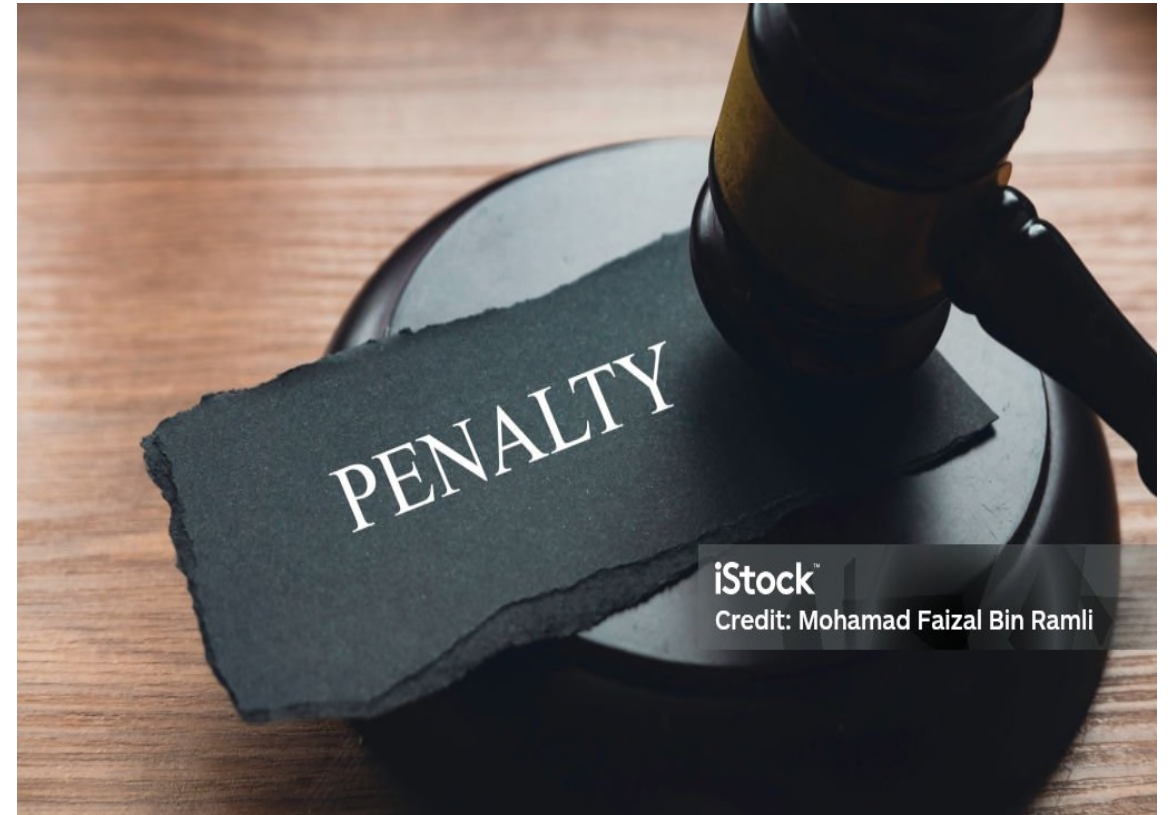
AKS Safe Harbors - Overview

- Examples of common Safe Harbors for telemedicine
 - Employment
 - Personal Services contracts
 - Space or Equipment Leases
 - Electronic prescribing and EHR items and services
- Common requirements
 - Agreement covers all services to be provided
 - Aggregate services are commercially reasonable
 - Aggregate compensation, set in advance, consistent with FMV, not determined in a manner that takes into account the volume or value of referrals or other business generated



AKS Penalties

- Criminal:
 - Up to 5 years in jail, fines of up to \$25,000 per violation, or both
- Civil/Administrative:
 - Civil Monetary Penalties - \$50,000 per violation plus 3x the remuneration
 - Exclusion
- False Claims Act liability - a violation of the AKS can “cause” a False Claim to be submitted



AKS Safe Harbors – Deeper Dive

– Space and Equipment Rental Safe Harbors

- Lease is in writing and signed by the parties
- Term must be at least one year
- Lease covers all of the premises and/or equipment leased and specifies the premises and/or equipment
- If lease is intended to provide lessee with access to the premises/equipment on part-time basis, lease must specify the exact schedule, length, and rent for each period of time
- Aggregate rent is set in advance, FMV, and doesn't vary with volume or value of referrals
- Aggregate space/equipment are commercially reasonable to achieve the business purpose

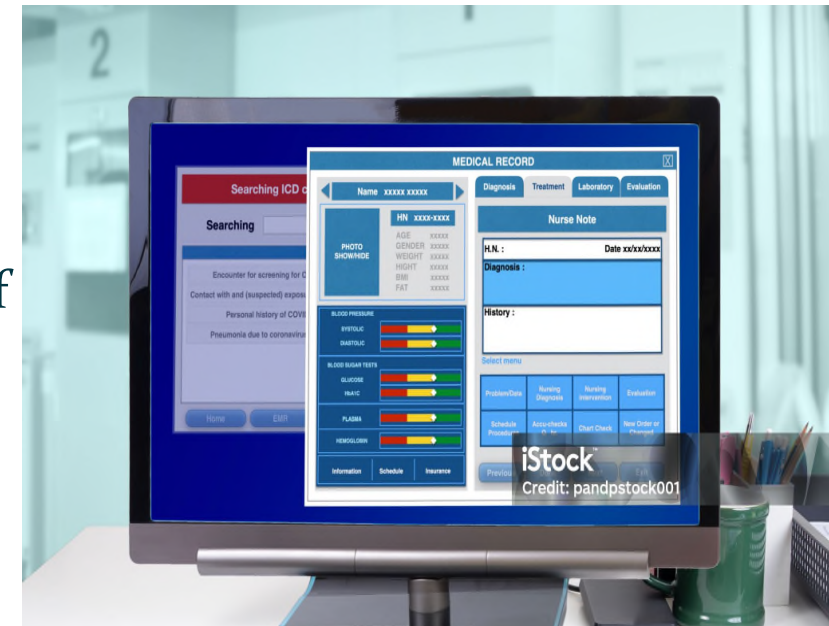
AKS Safe Harbors – A Deeper Dive

– Personal Services and Management Contracts Safe Harbor

- Written and Signed Agreement
- Agreement covers and specifies all services provided
- If the services are intended to be provided on a periodic or part-time basis, must specify the exact schedule, length, and charge for such intervals
- Term of at least one year
- Aggregate compensation is set in advance, FMV, and doesn't vary with volume or value of referrals
- Aggregate services are reasonably necessary to accomplish business purpose
- Services performed do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law
(42 C.F.R. § 1001.952(d))

AKS Safe Harbors – A Deeper Dive

- Electronic Health Records Items and Services
 - Written and signed agreement Items/services provided to a provider by another provider or health plan
 - Software is interoperable
 - Donor does not limit or restrict use or interoperability
 - Recipient does not make receipt of items/services a condition of doing business with donor
 - Does not take into account the volume or value of referrals
 - Transaction based on size of recipient's medical practice or total number of hours the recipient practices medicine



OIG Advisory Opinions



Provide guidance on OIG's interpretation of AKS



Binding only as to requesting parties, but provides guidance to parties with similar factual situations



OIG approved telemedicine-related opinions:

AKS implicated by all arrangements, but no sanctions



Most recent opinion – April 22, 2022

Activities that can implicate the AKS

- Free or discounted medical supplies or equipment - free specimen cups or lab testing supplies, computers, tablets, prescription drugs, DME
- Free marketing services (advertisements, billboards, websites) or joint promotion
- Donations from manufacturers to charities to assist with patient co-payments
- Joint ventures
- Improper patient discounts, including failure to collect copays and routinely waiving patient debts

Example - Advisory Op. 11-12

Facts

- Health system provides emergency tele-stroke consults to community hospitals
- System provides: technology, consults, clinical protocols, training, education, and commitment to accept transfers
- Hospitals provide: communication lines, connectivity, and CT scanners
- Hospitals refer patients to health system

Analysis

- Safeguards: no required referrals; patient freedom of choice; hospital referral history is not a factor
- Medicare is not billed so less risk to federal health care programs
- Benefits include: improved quality of care and faster treatment times

Example - Advisory Op. 22-08

Facts

- FQHC offers telehealth services through smartphone application
- Smartphones are locked – perform limited functions while using the telehealth application
- Smartphones are funded through grants from the FCC and a Local Charity though Requester uses its own funds for a portion of the data/voice services

Analysis

- Risk of inducing patients to receive items and services payable by a Federal health care program
- Low risk of increased costs to Federal health care programs or beneficiaries
- Arrangement does not satisfy an AKS safe harbor but presents only minimal risk under the statute

Who needs to think about compliance with the AKS?

- *Whoever knowingly and willfully...offers or pays...solicits or receives...*
- Hospitals and other types of facility providers (ASCs, SNFs, IDTFs)
- Physicians and physician groups
- Device and pharmaceutical manufacturers
- Sales and marketing teams
- Health care executives
- Others?

How to Ensure Compliance

OIG's Seven Elements of a Compliance Plan

1. Implement written policies, procedures, and standards of conduct
2. Designate a compliance officer and compliance committee
3. Conduct effective training and education
4. Develop effective lines of communication
5. Conduct internal monitoring and auditing
6. Enforce standards through well-publicized disciplinary guidelines
7. Respond promptly to detected offenses and take corrective action

Case Studies

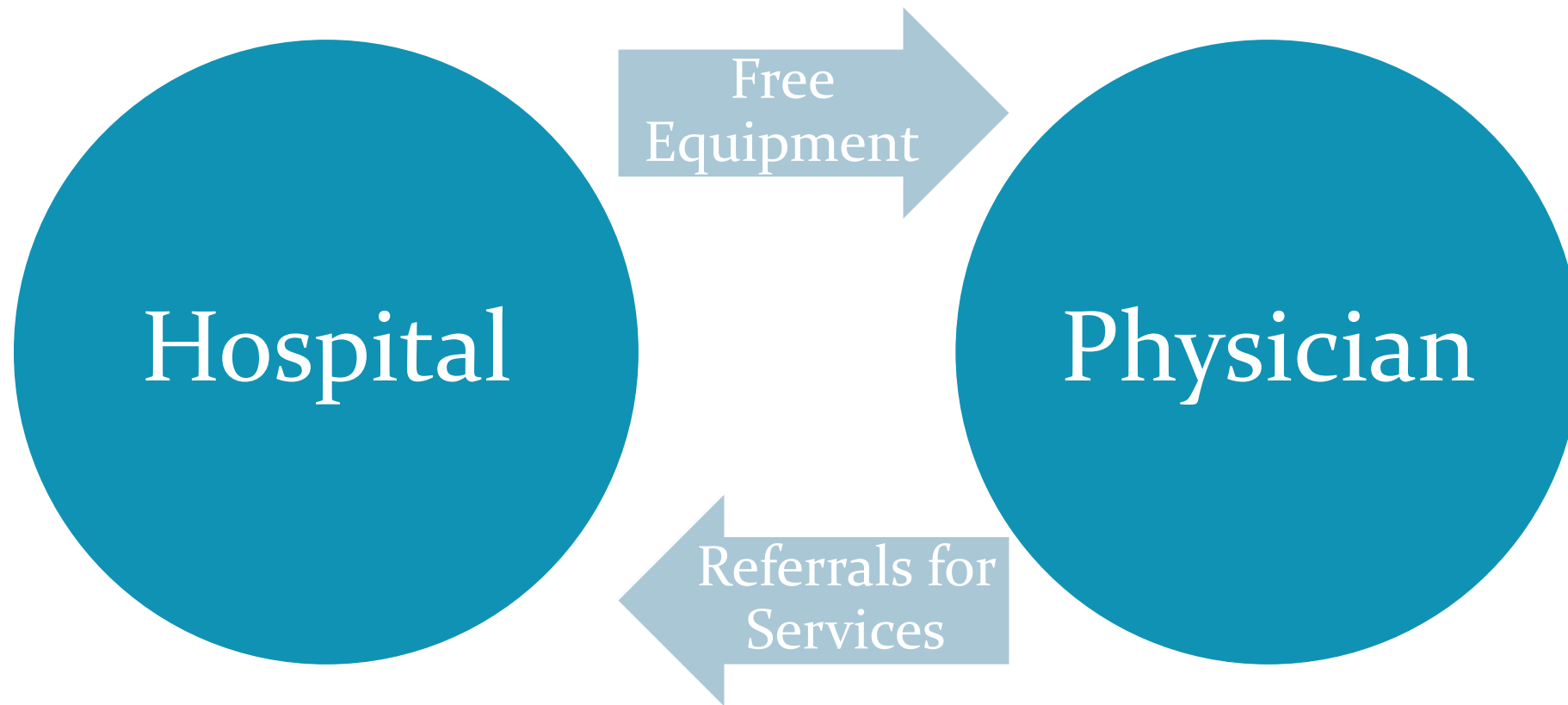
- Examples of Arrangements that May Implicate the AKS

Example 1

Provision of Equipment to Facilitate On-Call Arrangement

- Hospital and physician telemedicine on-call arrangement
 - Physician provides telemedicine consults to hospital’s patients on “on-call” basis
 - Hospital will provide equipment to facilitate telemedicine consultations, including camera, monitor, computer, etc.
- Physician historically has referred patients to the hospital and is expected to continue
 - Safe Harbor: Personal Services

Example 1 – On-Call Arrangement

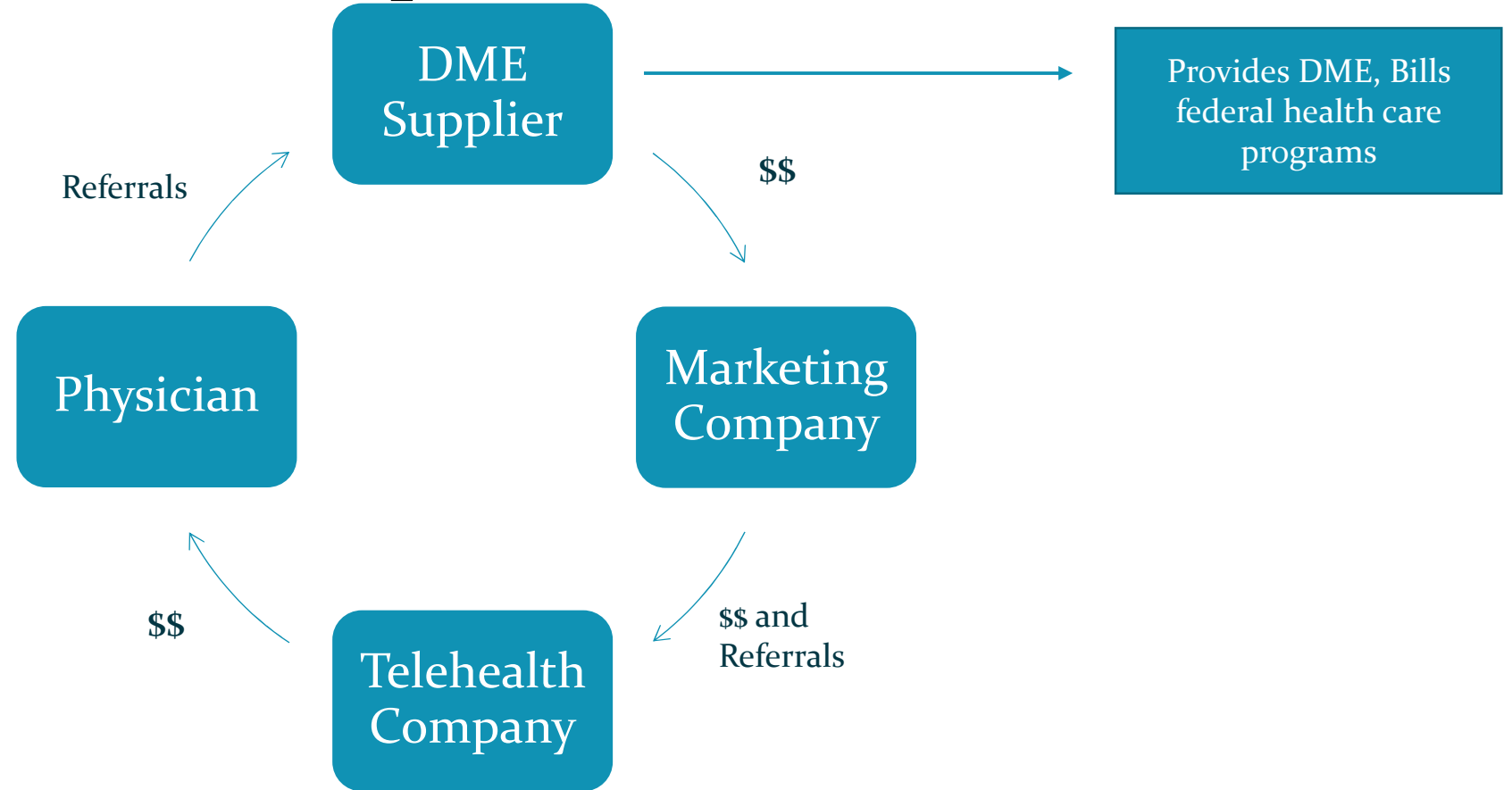


Example 2

Indirect Payments

- DME Supplier purchases leads from a Marketing Company
- Marketing Company sends leads to Telehealth Company
- Telehealth Company contacts patients and sets up appointments for Physicians
- Physicians contracted with the Telehealth Company provide telemedicine services to patients identified by Marketing Company
- Physicians prescribe DME to be filled by DME Supplier
- Marketing Company pays Telehealth Company for patient contacts and appointment scheduling
- Telehealth Company pays Physicians for the telemedicine services
- DME Supplier mails DME to the patients and bills Federal health care programs

Example 2 – Indirect Payments

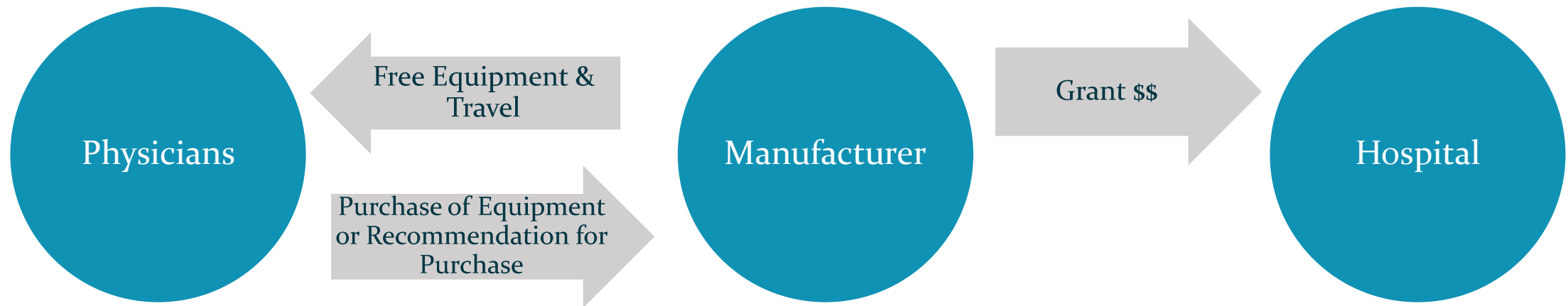


Example 3

Equipment Purchase

- Telemonitoring device manufacturer provides research grants to Hospital that is a potential customer
- Manufacturer also pays for Hospital-Affiliated Physicians to travel to out-of-town conferences where Manufacturer's product is being marketed
- Manufacturer provides free telemonitoring equipment to physicians who play major role in Hospital's purchasing decisions

Example 3 – Inducements to Purchase Equipment



What to Watch For When Entering Into Telehealth Arrangements

Considerations for AKS Compliance

Evaluating AKS Risks in Telehealth Arrangements

Consider:

- Whether parties are potential referral sources for each other – not only telehealth, but also other services
 - Flow of remuneration
 - Safe Harbor
- If no safe harbor, other safeguards from Advisory Opinions:
 - Patient choice of providers
 - Not conditioning participation on referrals
 - No compensation based on volume/value of referrals or other business generated between the parties

Evaluating AKS Risks in Telehealth Arrangements

Consider:

- Overall benefits to patients, including improved access to care
- Whether patients will be informed of the relationship and any financial benefit to the parties
- How the arrangement will be marketed, including how marketing costs will be allocated

Evaluating AKS Risks in Telehealth Arrangements

- Evaluate all prior and current agreements
 - Compensation agreements, Leases
- Review supporting documentation
- Revise or terminate non-compliant arrangements



OIG Telehealth Toolkit

- **OIG Toolkit April 20, 2023: “Analyzing Telehealth Claims to Assess Program Integrity Risks”**
- **Assess program integrity risks, including Medicare Advantage plans, Private health plans, State Medicaid Fraud Control Units, and other Federal health care agencies**
- **Intended to identify providers whose billing presents a risk under Medicare**
- **Steps for Analyzing Telehealth Claims**
 1. Review program policies
 2. Collect claims data
 3. Conduct quality assurance checks
 4. Analyze data to identify program integrity risks
 5. Interpret the results of the analysis

OIG Review of Medicare Payments for Telehealth Services

- May 2023: Payment audit for telehealth psychotherapy services provided during the first year of the PHE
 - Audit period (March 2020 – February 2021)
 - Part B paid \$1b. ~\$348m determined improper
- OIG Recommended CMS:
 - Conduct medical reviews to verify Medicare requirements were met
 - Implement system edits to prevent payment for improperly billed claims
 - Strengthen educational efforts for providers on meeting Medicare requirements

Telehealth Services & Medicare – COVID-19 Considerations

– Permanent Changes

- FQHCs and RHCs can serve as distant site providers for behavioral/mental telehealth services
- Medicare patients can receive telehealth services for behavioral/mental health care in the home
- No geographic restrictions for originating sites for behavioral/mental telehealth services
- Behavioral/mental telehealth services can be delivered via audio-only communication platforms
- Rural Emergency Hospitals are eligible originating sites for telehealth

Telehealth Services & Medicare – COVID-19 Considerations

- Temporary Changes effective through December 31, 2024
 - Medicare patients can receive telehealth services in their home
 - FQHCs and RHCs can serve as a distant site provider for non-behavioral/mental telehealth services
 - No geographic restrictions for originating site for non-behavioral/mental telehealth services
 - Some non-behavioral/mental telehealth services can be delivered using audio-only communication platforms
 - In-person visit within six months of an initial behavioral/mental telehealth service, and then annually, is not required
 - Telehealth services can be provided by all eligible Medicare providers

Enforcement Risk: Potential Telehealth Fraud Schemes

- Up-Coding Time and Complexity
- Misrepresenting the Virtual Service Provided
- Billing for Services Not Rendered or Not Effectively Provided

Questions?

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