

A CHANGING LANDSCAPE:
**ANTI-KICKBACK &
SELF-REFERRAL
DEVELOPMENTS**

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Tony Maida is a partner at McDermott Will & Emery, LLP in the New York office. He counsels clients on government investigations, corporate transactions and compliance programs.

Having served for almost a decade with the Office of Counsel to the Inspector General at the United States Department of Health and Human Services, Tony has extensive experience in health care fraud and abuse and compliance issues, including the federal and state Anti-Kickback and Stark Laws and Medicare and Medicaid coverage and payment rules.

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Registered Nurse since 2008

Worked in hospitals throughout Los Angeles County

Licensed to practice law since 2012

Represent providers in federal and state health care fraud litigation, including False Claims Act and Anti-Kickback cases



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Overview

- I. Anti-Kickback Statute (AKS)
- II. Physician Self-Referral Law (Stark)
- III. OIG and CMS Proposed Rules
- IV. Eliminating Kickbacks in Recovery Act (EKRA) Overview



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DISCLAIMER

- General discussion, not specific legal advice
 - No attorney-client relationship
 - Seek legal counsel as appropriate

PART I ANTI-KICKBACK STATUTE (AKS)

WHAT IS A KICKBACK?

1. **Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b(b):**

- It is illegal to knowingly or willfully offer, pay, solicit or receive “remuneration” (kickback, bribe, rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such a person to either (a) refer an individual to a person for the furnishing or arranging of any items or services or (b) purchase, lease, order...any good, facility service or item for which payment may be made in whole or in part under a Federal health care program.
- “One Purpose Rule” if one purpose to obtain remuneration for referrals or induce further referrals, then violates AKS (Third, Fifth, Seventh, Ninth and Tenth Circuits)
- Government may pursue the person paying/offering/soliciting and the person receiving remuneration
- Requires proof of knowledge that the conduct was unlawful, and can result in criminal fines and prison time or False Claims Act liability
- CMP authority – up to \$50,000 per violation plus treble damages and exclusion by OIG

2. **Eliminating Kickbacks in Recovery Act (EKRA) 18 U.S.C. § 220 – discussed later**



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STATUTORY AND REGULATORY “SAFE HARBORS”



- Carve-outs for certain business relationships that pose minimal risk of fraud and abuse
- Must meet all elements
- Voluntary to participate
- Narrowly drafted



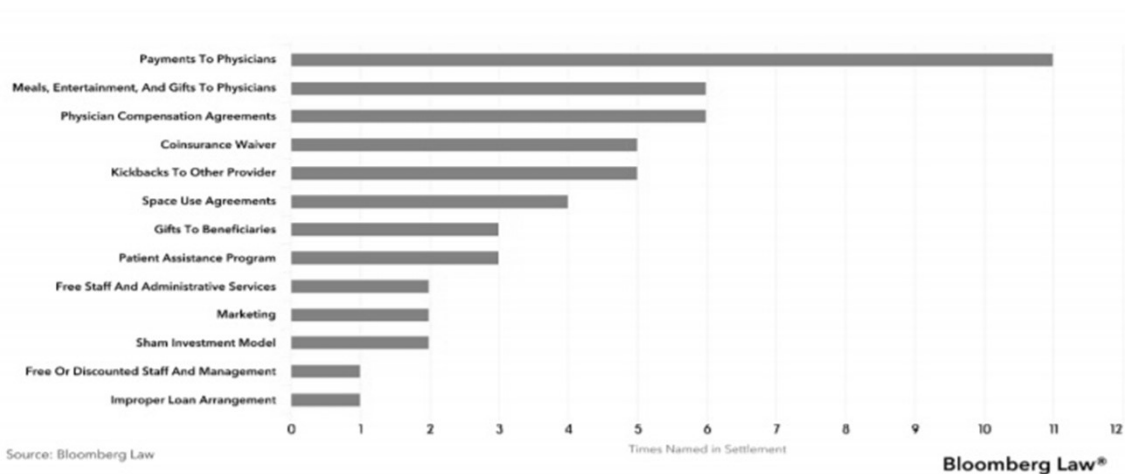
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TRENDS IN KICKBACK ENFORCEMENT

1. Paying money for referrals – made sense in the fee-for-service world, less applicable to hospitals and providers splitting global payments or sharing risk to improve health outcomes, efficiency of health care delivery and access
2. Still, kickbacks are the third most common allegation for Federal False Claims Act liability
3. Substance Use Disorder Providers – patient inducements, travel, discounts, rent, money for specimens, body brokering, etc.
4. Revenue sharing arrangements are being increasingly scrutinized
 - Valuation of the services is key
 - Ideally, any shared profits should be governed by an applicable safe harbor
 - Where no safe harbor applies, parties should scrutinize the financial incentives for potential kickback liability – Would we still enter into this relationship in the absence of patient referrals?

COMMON KICKBACK SCHEMES

Common Types of Kickback Scheme (2017-2018)



PART III PHYSICIAN SELF-REFERRAL LAW (STARK)

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STARK LAW IN A NUTSHELL

A physician may not make a referral for designated health services (“DHS”) to an entity with which the physician (or an immediate family member) has a financial relationship

and

The entity that furnishes DHS may not submit the claim to Medicare

unless

The relationship between the physician (or immediate family member) and the entity meets all of the requirements of an exception.

Stark is a strict liability statute. The arrangement must meet an exception, and the intentions of the parties are not relevant.

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STARK LAW: ANALYTICAL FRAMEWORK

Three Analytical Questions:

1. Is there a *referral* from a *physician* for DHS?
2. Does the physician (or an immediate family member) have a *financial relationship* with the entity providing the DHS?
3. Does the financial relationship fit in an *exception*?

If you answer “Yes” to Questions 1 and 2, the arrangement must meet an exception specifically set forth in statute or regulations



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STARK LAW PENALTIES ARE STARK

- Prohibited claims are not payable (and if paid, are an “overpayment”)
- CMP and FCA Liability
 - Can result in per claim liability up to ~ \$24,000 plus treble damages
 - The knowledge standard is actual knowledge, reckless disregard, or deliberate ignorance
 - FCA is the most common enforcement vehicle for the government to pursue Stark Law violations
- Potential for FHCP exclusion
 - CIA in exchange for a release of exclusion in a settlement



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PART IV

NOTICE OF PROPOSED RULEMAKING

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HHS REGULATORY SPRINT

HHS Priority

- Launched in 2018
- CMS and OIG Requests for Information

Objectives

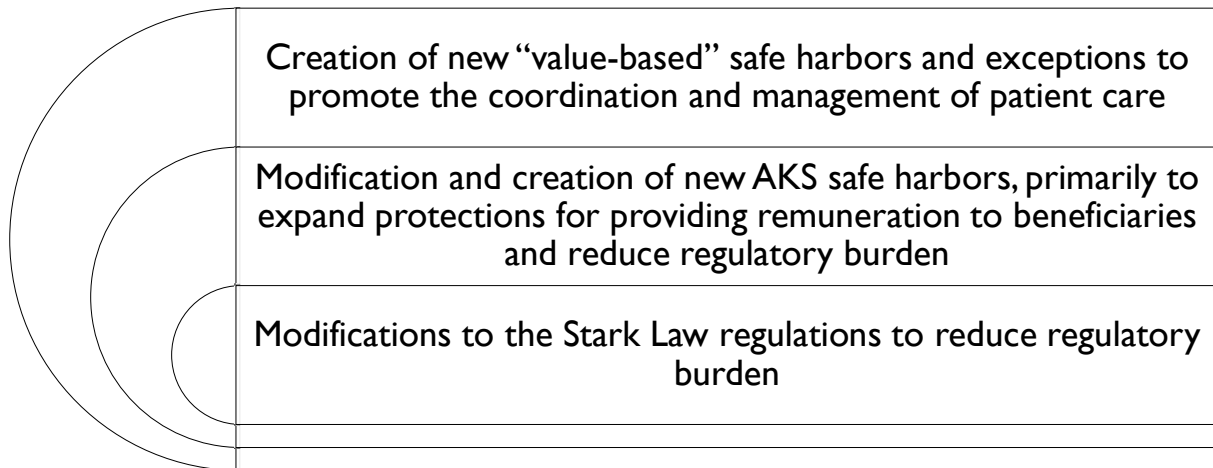
- Accelerate the transition to value-based care
- Facilitate coordinated care

Scope

- OIG: Federal AKS and beneficiary inducement
- CMS: Stark Law
- SAMHSA: Substance abuse records
- OCR: HIPAA

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OVERVIEW OF THE PROPOSED CHANGES



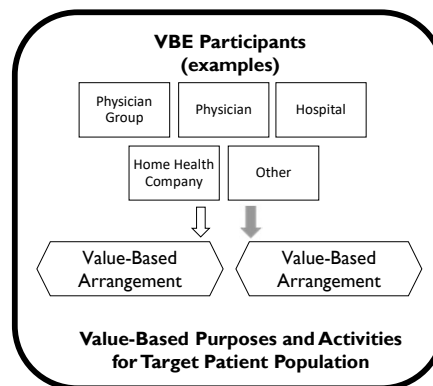
VALUE-BASED AND COORDINATED CARE PROPOSALS

VALUE-BASED FRAMEWORK

Definitions

- Value-based enterprise (VBE)
- VBE participant
- Value-based purpose
- Value-based activities
- Value-based arrangement
- Target patient population

Illustrative Value-based Enterprise



Greater regulatory flexibility for value-based arrangements that involve downside financial risk

FOUR THRESHOLD REQUIREMENTS

Be a "Value-Based Enterprise" (VBE)

Have a "Value-Based Purpose"

Engage in a "Value-Based Activity"

Identify the "target patient population"

PROPOSED SAFE HARBORS FOR VALUE-BASED ARRANGEMENTS

AKS Rule

- New
 - Full financial risk
 - Substantial downside financial risk
 - Repayment obligation of at least 40% of any shared losses
 - Care coordination arrangements to improve quality, health outcomes, and efficiency
 - In-kind only
 - Patient Engagement
 - In-kind only
- Revised
 - Personal services and management contracts for outcomes-based payment arrangements
 - Covers gainsharing and shared loss/gain payments

Stark Rule

- New
 - Full financial risk
 - Meaningful downside financial risk
 - Physician responsible for 25% of remuneration received
 - Other value-based arrangements
- **Monetary or in-kind for any exception**



NPRM PROPOSALS SPECIFIC TO AKS/CMP

SAFE HARBORS SPECIFIC TO AKS/CMP

In addition to the three value-based care initiatives (*care coordination*, section 1001.952(ee), *VBA with substantial downside risk*, section 1001.952(ff)) or *VBA with full downside risk*, section 1001.952(gg)), HHS-OIG proposes the following:

- Patient Engagement and Support Safe Harbor (section 1001.952 (hh)) adds protections for patient inducements to improve quality of care, health outcomes and efficiency of care delivery
- CMS-sponsored models (section 1001.952(ii)) would codify a safe harbor for programs currently receiving waivers
- Personal services and management contracts (section 1001.952(d)) would expand to allow outcome-based pay and unscheduled part-time arrangements
- ACO Beneficiary Incentive Program would codify the exception to the definition of “remuneration” (section 1001.952(kk))



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SAFE HARBORS SPECIFIC TO AKS/CMP (CONT.)

- Warranties (section 1001.952(g)) would protect certain warranties, exclude beneficiaries from reporting requirements applicable to buyers and provide a definition of warranty
- Local transportation subsidies (section 1001.952(bb)) would expand the mileage limits for rural transportation and transportation of discharged patients to home
- EHR Arrangements (section 1001.952(y)) would expand to protect cybersecurity technology, update interoperability, remove sunset
- Donations of cybersecurity and technology (section 1001.952(jj))
- CMP Law would exclude from “remuneration” certain telehealth technologies offered to patients receiving in-home dialysis



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PATIENT ENGAGEMENT AND SUPPORT SAFE HARBOR OVERVIEW

- Protects **in-kind** remuneration furnished by a “VBE participant” to patients in a “target patient population.”
 - The remuneration would need to be:
 - A “preventive item or service” or “tool, support, or service” designed to address social determinants
 - Directly connected to the coordination and management of care of the target patient population
 - Furnished directly to the patient by a VBE participant
 - Directly connected to the coordination and management of care of the target patient population
 - Recommended by the patient’s licensed healthcare provider and going to advance enumerated clinical goals, e.g., adherence to a treatment regimen
 - **Aggregate retail value from a VBE participant cannot exceed \$500 per patient per year (absent financial need determination).**
 - **No** protection for:
 - Gift cards, cash, cash equivalents
 - Marketing/patient recruitment
 - Medically unnecessary or inappropriate items/services
 - Items/services likely to be diverted, sold, or used for unintended purposes



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PROPOSED REVISIONS TO PERSONAL SERVICES AND MANAGEMENT CONTRACTS AND OUTCOMES-BASED PAYMENT ARRANGEMENTS SAFE HARBOR

- Would eliminate requirements that:
 - Aggregate compensation be set forth in advance (not methodology set in advance)
 - Parties specify the schedule of part-time arrangements in advance
- Would establish new protection for “outcomes-based payment” arrangements
 - FMV and commercial reasonableness requirements would apply
 - To receive a payment, the agent must satisfy one or more specific evidence-based, valid outcome measures
 - Cannot be based on internal cost savings alone



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POTENTIAL IMPACT

Benefits

- Recognizes the importance of patient access to technology
- Encourages flexibility in the delivery of patient care and encourages access to care
- Promotes innovation through growth of networks that will reward improved patient outcomes and decreased costs of care
- Attempts to align regulatory changes with ever-involving payment models, including outcomes-based and shared savings programs

Drawbacks

- Excludes certain players including laboratories, pharmaceutical companies, distributors, and device manufacturers
- Risk of decreased competition among providers (sharing patient populations, outcomes, billing)
- Risk of “lemon dropping” – practice of cherry picking the healthiest patients
- Unlikely to benefit individual physicians or small practice groups, as the complex regulatory scheme likely requires hospital or health system involvement to provide the needed infrastructure to comply



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TAKEAWAYS

- Substantial/meaningful risk proposal seems unlikely to be widely adopted
- Full risk proposals provide new flexibility for ACO/CIN/IPA
 - Payor contracting already covered by MCO/risk sharing
 - VBE would be able to provide other remuneration to members, such as staff or equipment for which there was not a clear pathway under the current regulations
 - Unclear whether this proposal will be used widely outside of ACO/CIN/IPA
- No-risk Stark exception and Outcomes-Based AKS safe harbor provide clearer pathway for gainsharing
- Are better outcomes forever achievable?
 - Will need to establish a system to monitor outcomes
- Metrics need to be set in advance
 - May pose practical challenges
- Not many “bright lines”
 - Fair amount of subjective terms that require interpretation



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STARK LAW PROPOSALS CLARIFICATIONS AND BURDEN REDUCTION

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DEFINITIONAL STARK LAW TERMS

VOLUME AND VALUE

- Most important change in the entire Proposed Rule
- Overturns the *Tuomey* and *UPMC* conception of when volume or value of referrals is taken into account
 - *Tuomey* – 4th Circuit (2015) created the “correlation theory” that a surgeon’s compensation varied with or took into account the volume or value of referrals if based on the surgeon’s personal wRVUs
 - *UPMC* – 3rd Circuit (2019) panel opinion created a new flavor – that wRVU compensation “varied with” but did not “take into account” (rehearing opinion removed holding – said they did not need to decide that issue because of sufficient allegations that there was a causal relationship between compensation and volume/value)
- Proposal expressly provides that compensation **to a physician** “takes into account” the volume or value of the physician’s referrals and other business generated by the physician in **only 2 cases**:
 - “Referrals” or “other business generated” is a variable in a physician’s compensation formula and there is a “positive correlation” between the volume or value of the physician’s referrals and the dollar amount of the physician’s compensation
 - Predetermined, direct correlation” between a physician’s prior referrals or business generation and the physician’s prospective fixed-rate compensation (e.g., fixed annual salary or fixed rate of compensation per work RVU)

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DEFINITIONAL STARK LAW TERMS:

FAIR MARKET VALUE

- Aims to be more consistent with the recognized principle of “market” valuation to address perceived inconsistencies with regulations as applied to valuation principles
- Attempt to move away from the “survey says” approach to valuation
 - CMS discusses the “superstar” physician who is very productive and qualified for whom the salary surveys would not be an accurate representation of the fair market value for that physician

DEFINITIONAL STARK LAW TERMS:

COMMERCIAL REASONABLENESS

- No current definition
- Proposed definitions:
 - “the particular arrangement furthers a legitimate purpose of the parties and is on similar terms and conditions as like arrangements [even in the absence of referrals]”
 - “the arrangement makes commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty [even in the absence of referrals]”
- Either approach will include the statement: “An arrangement **may** be commercially reasonable even if it does not result in profit for one or more of the parties”
- This proposal attempts to address the “practice loss theory”

HELPFUL RELIEF FROM THE STARK LAW'S BURDENS

- New relief from the “signed writing” and “set in advance” standards
- Wrong payments by mistake? CMS confirms an opportunity to fix
- Exceptions for leases expanded and liberalized
- Definition of DHS revised to exclude hospital inpatient services if there is no affect on Medicare payment

PART V ELIMINATING KICKBACKS IN RECOVERY ACT OF 2018 (EKRA)

WHAT GAVE RISE TO EKRA?

- Massachusetts attorney general warns of patient brokering in AZ, CA and FL
- UHC alleges lab sales consultants give people \$50 gift cards to urinate in cups at Whataburger bathrooms to bill insurance
- Brokers go to AA, jails and shelters and refer patients to highest bidding centers
- Florida client's insurers charged \$600,000 by 7 treatment centers in 6 months
- Florida treatment owner accused of prostituting women under his care
- Rehab homes accused of giving drugs to clients so they would relapse
- 16 Medi-Cal substance abuse treatment centers under investigation
- Sober homes in FL paid kickbacks and bribes (free or reduced rent and other benefits) to reside at sober homes, attend drug treatment and undergo drug testing if they had insurance
- Sober homes submit urine and saliva samples from employees instead of patients
- Millions paid in False Claims Act settlements



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EKRA LEGISLATIVE HISTORY

- It appears that EKRA originated out of a concern with certain “body broker” activity in connection with substance use disorder treatment centers and a perceived gap in federal law that could address that activity
- “Patient brokering” or “body brokering” is a scheme in which the sober home, treatment center, or other provider pays third parties a “finder’s fee” for each patient that enters treatment
- Oftentimes, these payments accompany providers accused of billing for unnecessary procedures or substandard treatment



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EKRA VS. AKS

SIMILARITIES

- Bona fide employment exception (narrower)
- Personal services and management contracts exception (narrower)
- Discounts or other reductions in price obtained by a provider (broader)
- Discounts in drug prices from manufacturers under the Medicare Medigap program
- Remuneration provided to a federally qualified health center

DIFFERENCES

- Applies to ALL health insurance including commercial, government and employer-sponsored health plans
- Limited to recovery homes, clinical treatment facilities and laboratories
- Alternative payment model exception

EKRA EXCEPTIONS

EKRA EXCEPTIONS: PERSONAL SERVICES AND MANAGEMENT CONTRACTS

- Note that the statute permits payments made by a principal to an agent as compensation for services of the agent under an arrangement that meets the Federal AKS safe harbor (“SH”) for personal services and management contracts (as in effect on the date of enactment);
 - The Federal AKS SH is narrowly drafted to require aggregate payments be set in advance and that, in part-time arrangements, the agreement specify the schedule that services will be performed
 - If the Federal AKS SH were amended in the future, EKRA’s exception would continue to follow the old version

EKRA EXCEPTION: PATIENT COPAY WAIVERS AND DISCOUNTS

- EKRA’s exception appears to be broader than OIG’s guidance on the Federal AKS/Beneficiary Inducement Statute (“BIS”)
- EKRA:
 - Not routinely provided and provided in good faith
 - “Good faith” not defined
 - Advertising not prohibited
- Federal AKS/BIS:
 - Not routinely provided and
 - “good faith” individualized determination of financial need or
 - Failure of reasonable collection efforts
 - No advertising copay waivers

EKRA EXCEPTION: ALTERNATIVE PAYMENT MODELS

- This exception is not contained in the Federal AKS
- EKRA's exception protects remuneration paid pursuant to an alternative payment model or pursuant to a payment arrangement used by a state, health insurance issuer, or group health plan "if the HHS Secretary has determined that such arrangement is necessary for care coordination or value-based care."

EKRA EXCEPTIONS: EMPLOYEES AND CONTRACTORS

- EKRA's exception is more narrow than the Federal AKS
- EKRA:
 - Payments made by an employer to *bona fide* employees and independent contractors if the payment is not determined by or does not vary by:
 - the number of individuals referred;
 - the number of tests or procedures performed; or
 - the amount billed to or received from, in part or in whole, from a health care benefit program from the individuals referred
- Federal AKS:
 - Payments made by an employer to *bona fide* employees for the provision of covered items and services
 - Independent contractors are covered by the personal services and management contracts SH

HOW CAN AFFECTED PROVIDERS PAY EMPLOYEES BONUSES, ESPECIALLY SALES PERSONNEL?

- EKRA employment exception does not protect payments based on:
 1. the number of individuals referred;
 2. the number of tests or procedures performed; or
 3. the amount billed to or received from, in part or in whole, from a health care benefit program from the individuals referred
- What about:
 1. Net profit target
 2. EBITDA targets
 3. Call wait times
 4. Cost containment
 5. Job performance criteria

DOES EKRA APPLY TO MARKETING ARRANGEMENTS IN THE SAME WAY AS THE FEDERAL AKS?

- Meaning of “in exchange for ... using” and “patronage” vs. “arrange for or recommend”
- OIG described marketing as a “technical violation” of AKS that does not normally warrant prosecution and has developed a multifactor analysis for marketing arrangements that examines:
 - The nature and amount of compensation
 - The marketer’s identity and relationship to audience (“white coat”)
 - The nature of the marketing
 - The item/service being marketed
 - The target audience

WHAT IS THE SCOPE OF PERMITTED PATIENT ARRANGEMENTS?

- EKRA’s copay waiver exception requires that the waiver be “non-routine” and “in good faith”
- OIG has the \$15 per instance/\$75 per year nominal remuneration exception under the beneficiary inducement statute – can providers rely on that as a guidepost under EKRA?
- Can providers use the free or discounted transportation safe harbor or the promotes access to care exception as models?

TIPS FOR COMPLIANCE OFFICERS

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Things to consider

- Fair market value determinations – difficult in healthcare service industry, easier when it comes to office space/equipment
- Check for remuneration (cash, gifts, cash equivalents) and inducements of healthcare business
- Check for familial relationships (Stark includes immediate family members)
- Bonuses – discussed in the EKRA context but also compliance risk in the hospital-provider context

Questions to ask

- Would we still enter into this relationship in the absence of a referral relationship?
- Does the referring provider generate business from the relationship, and if so, can the business be reduced to a per-patient fee or inducement?
- How long has it been since the FMV and commercial reasonableness have been considered?



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QUESTIONS?



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