Anti-Kickback Statute (Safe Harbor Law)/Stark Law

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SOCIETY FOR AMBULATORY ANESTHESIA
Outpatient • Office Based • Non-Operating Room

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Disclosures

- Am an attorney in private practice
- I have the following financial relationships to disclose:
  - Owner of Judith Jurin Semo, PLLC
    - Private law practice
  - Diversified portfolio that includes investment in health care companies (no active role)
  - Will not be discussing off-label uses of drugs/devices

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Objectives

- Review health care regulatory environment
- Review key concepts of Anti-Kickback Statute and Stark Law & how they apply to ASC practice & Medical Director responsibilities
- Suggest strategies to promote compliance

** A note: Not legal advice

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Health Care is Highly Regulated

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Legal Aspects of Health Care

- Legal rules govern much of medical practice
  - Who can practice
  - What services they can provide
  - Facilities in which services can be performed
  - Relationships w/patients
  - Relationships w/colleagues-competitors

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Overview

Health Care is Highly Regulated!

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Regulatory Issues

- "Fraud & Abuse"
  - Self-referral: Stark
  - Anti-Kickback Statute ("AKS")
  - Civil Monetary Penalties Statute
    - Payments to reduce/limit medically necessary services to Medicare/Medicaid patients
  - False Claims Act ("FCA")
- Antitrust
- Medicare Conditions of Participation (Hospitals) ("CoPs")
- HIPAA compliance
- Billing compliance
- National Practitioner Data Bank
- Tax exemption issues

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Acronyms

- AKS – Anti-Kickback Statute
- CMP – Civil monetary penalty
- CR – Commercial reasonableness
- DHS – Designated health care services
- FCA – False Claims Act
- FMV – Fair market value
- GMV – General market value

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Comparing the Anti-Kickback Statute & the Stark Law

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Anti-Kickback vs. Stark

	Anti-Kickback	Stark
Intent	Intent req'd for violation	Strict liability No intent req'd
Safe harbor/ exception	Safe harbors optional	Must fit w/in exception
Sanctions	Criminal sancs. Civil penalties	Nonpayment Civil penalties – knowing viols.

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Stark vs. Anti-Kickback

	Kickback	Stark
Conduct prohibited	Offering or soliciting something of value in exchange for referrals*	Referrals by physicians for certain services (DHS) to certain entities**

* Referrals of items or services payable under federal health care programs

** Entities with which they have a financial relationship

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Common Elements of AKS & Stark

- Both laws are intended to prevent corruption in decisions regarding selection and provision of medical services to patients in federal health care programs

Anti-Kickback	Stark
• No *quid pro quo* • Not offer/receive "remuneration" in exchange for referrals	• Preclude referrals for certain services (DHS) to entities w/which the physician has a financial interest • By ownership or compensation

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Commercial Reasonableness

- Important for AKS safe harbor (personal services) & Stark exception (FMV)
- Does the arrangement make business sense in the absence of referrals?
- Medical Director arrangement should easily satisfy commercial reasonableness test

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Anti-Kickback Statute

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Federal Anti-Kickback Statute

- Prohibits *knowingly and willfully:*
  - Offering,
  - Paying,
  - Soliciting, or
  - Receiving
- Any *remuneration*
- To induce referrals of
  - Services reimbursable by federal health care programs

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Anti-Kickback Statute

"In some industries, it is acceptable to reward those who refer business to you. However, in the Federal health care programs, paying for referrals is a crime." (HHS OIG)

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Federal Anti-Kickback Statute

- Courts: Anti-Kickback Statute is violated
  - If even *one purpose* of remuneration was
    - To obtain money for the referral of services or
    - To induce further referrals
  - Even if other justifiable bases for making some level of payment

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High Stakes: Increases in Penalties

- Bipartisan Budget Act of 2018
  - Significantly increased civil & criminal penalties for federal health care program violations
    - Doubled statutory civil fines (for AKS, from $50K to $100K)
    - Quadrupled some criminal fines (including violations of Anti-Kickback Statute – from $25K to $100K)
    - Increases maximum jail time – doubled from 5 years to 10 years

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"Safe Harbors"

- Payment/business practice not subject to enforcement action
  - Purpose: provide *specificity* given broad scope of kickback prohibitions
- Optional: not illegal if do not fit into a safe harbor:
  - Legal if *no intent* to induce referrals
  - But no assurance of protection

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"Safe Harbors"

- 35 safe harbors – must meet all req'ts to be protected
- Multiple
- Of greatest interest to anesthesiologists
  - Personal services & management contracts
  - Employees
  - Investments in group practices
  - Investment in ASCs

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Personal Services Safe Harbor

- In writing & signed
- Covers/specifies all services to be furnished
- Term at least 1 year
- Methodology to set compensation is set in advance, consistent w/FMV, & does not reflect volume/value of referrals
- Services do not violate State/Fed law
- Aggregate services are reasonably necessary for commercially reasonable business purpose

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ASC Safe Harbor

- Regulatory concern: Is return on ASC investment *a disguised payment for referrals*?
  - *E.g.*, joint investment by physicians in specialties that typically cross-refer
  - So each is positioned to earn a profit from such referrals
- ASC safe harbor covers four types of ASCs
  - Surgeon-owned
  - Single-specialty
  - Multi-specialty
  - Hospital-physician

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ASC Safe Harbor

- Several common requirements – *e.g.*
  - Medicare-certified
  - No loans (by ASC or investors) to invest
  - Investment interests offered on terms *unrelated to volume/value of referrals*
  - Ancillary services "directly & integrally" related to primary procedures
  - No discrimination v. federal program patients
  - Disclosure of ownership to patients

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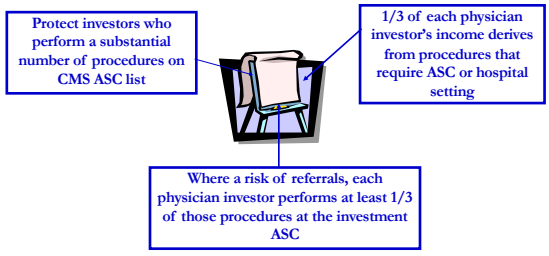
Common Elements



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ASC Safe Harbor Rationale

- Ensure that physician's investment represents an *extension of the physician's office*
  - 1/3-1/3 test: assure no significant incentive beyond professional fees to refer to the ASC or its investors
  - Issue for anesthesiologists: anesthesia services are not "procedures" for purposes of the safe harbor

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Anesthesiologists' Investments in ASCs

- OIG: Anesthesiologists' investments *not* protected if they can:
  - *Provide services to*,
  - Refer patients to, or
  - Generate business for
  - ASC or any of its investors
- Providing anesthesia for patients in ASC or serving as medical director is a "service"
  - So fall ***out*** of ASC safe harbor
  - But investment in an ASC is not illegal
    - Because no intent to induce referrals

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Anesthesiologists' Investments in ASCs

- Satisfy the spirit of ASC safe harbor
  - Anesthesiologists typically do not refer (if not providing pain management services)
    - Not using ASC investment to profit from referrals to other physicians who use the ASC
  - ASC represents an extension of their standard practice

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Significant Changes to AKS/Stark Rules

- Effective Jan. 19, 2021: Amended AKS and Stark rules to reduce regulatory barriers to care coordination and to promote payment for value and delivery of coordinated care
- Without getting into the weeds . . .
  - On the AKS:
    - OIG modified conditions an arrangement must meet to satisfy the "personal services and management contracts" safe harbor
      - One of the most relevant safe harbors for considering anesthesia arrangements – both legitimate and suspect

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Significant Changes to AKS Safe Harbors

- Increased protection and flexibility for the "personal services and management contracts" safe harbor:
  - Removed req't for part-time arrangements to specify the schedule, length, and exact charge for intervals of time worked
    - Greater flexibility for periodic services arrangements where parties unable to predict exact frequency of their need for services
  - On aggregate compensation, substituted requirement that the methodology for determining comp be set in advance
    - Rather than requiring that aggregate comp be set in advance
      - Allows productivity and unit-based methodologies, so long as
        - Consistent with fair market value and
        - Set in advance

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Significant Changes to AKS Rules

- Other changes to "personal services & management contracts" safe harbor:
  - Permitted outcomes-based payments – *e.g.*, payments for
    - Improving patient health, or
    - Reducing payor costs (while improving quality of care)
- Many other changes relating to innovative arrangements and value-based care
  - New safe harbors to protect value-based arrangements

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Changes to Key Definitions

- New rule includes revised definitions of key definitions
  - Fair market value ("FMV") and commercial reasonableness ("CR")
  - FMV: "[t]he value in an arms-length transaction, consistent with the general market value ("GMV") of the transaction"
    - GMV means "with respect to compensation for services, the compensation that would be paid at the time the parties enter into the service arrangement as the result of bona fide bargaining between well-informed parties that are not otherwise in a position to generate business for each other."
  - CR means "that the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties."

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Key Themes in Revised Definitions

- "Volume or value standard" is a separate and distinct concept from FMV and CR
- Using wRVUs (in physician comp plans) not suspect for considering volume or value
- Arrangements may be commercially reasonable, even if they are not profitable
  - Especially important in anesthesiology contracts and arrangements
- Salary surveys alone do not constitute FMV
- Comp set at or below 75th percentile is not always FMV
- Value of a physician's services should be the same regardless of identity of the purchaser (*e.g.*, a private physician group or a hospital)
- Even when arrangements have a legitimate business purpose, they may not be CR
  - *E.g.*, second medical director for the same service line

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Anti-Kickback Law Penalties

- Both parties culpable
  - Party soliciting the kickback &
  - Party providing the kickback
- Felony
  - Maximum fine of $100,000 (quadrupled in 2018)
  - Imprisonment up to 10 years, or both (doubled in 2018)
  - Conviction ➔ automatic exclusion from federal health care programs
  - CMPs: $100,000*/violation + damages up to 3 x total remuneration (doubled in 2018)

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Anti-Kickback Law Intent

- Health care reform law (ACA):
  - Clarifies intent standard for conviction
    - Need not have actual knowledge that the alleged activity violates the Anti-Kickback Statute
    - Need not have specific intent to violate the Anti-Kickback Statute
- Easier to be convicted

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The Game Changer

- Affordable Care Act (2010):
  - Claims arising out of violations of the Anti-Kickback Statute are **false claims** for purposes of the False Claims Act (FCA)
- FCA penalties:
  - $12,537 (minimum) - $25,076 (maximum)/claim **+**
  - Three times the claim amount **+**
  - Legal fees

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The Game Changer: FCA Liability

- *E.g.*, single claim for $400 can result in penalties of
  - $13,737 (min)/$26,276 (max)
    - Penalties (per claim)+ 3x claim amount
- FCA penalties are in addition to penalties for AKS violations
- Practical pointers:
  - Liability for violations is staggering
  - Will force a settlement

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Stark Law

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Stark

- Contracts between physicians & hospitals involving any payment for the physicians' services will likely implicate the Stark Law
  - Somewhat different considerations with ASCs (due to definitions of DHS)
- Strict liability under Stark
  - Civil statute
  - Not intent-based

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Stark

- Hospitals & health systems are very concerned about Stark law compliance
- Examples of enforcement/whistleblower suits
  - Huge exposure
    - Tuomey Healthcare - $237M judgment
      - 10.16.15: Resolved w/DOJ for $72.4M
      - 9.27.16: Former Tuomey CEO settled w/DOJ - $1M
    - Halifax Hospital
      - 3.11.14: $85M settlement w/DOJ

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Stark

- Stark Law: A physician may not make referrals for certain "designated health services" ("DHS") payable by Medicare or Medicaid where physician (or immediate family member) has a financial relationship w/entity to which patient is referred
  - Unless all elements of an exception are met
- If physician is paid by the hospital or ASC for Medical Director role, creates a financial relationship under Stark

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Designated Health Services

- Clinical lab services
- Physical therapy, occupational therapy, & outpatient speech-language pathology services
- Radiology & certain other imaging services
- Radiation therapy services & supplies
- DME & supplies
- Parenteral & enteral nutrients, equipment, & supplies
- Prosthetics, orthotics, & prosthetic devices & supplies
- Home health services
- Outpatient prescription drugs
- Inpatient & outpatient hospital services

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Designated Health Services

- DHS do not include
  - Physicians' professional services
  - Anesthesiology services
  - ASC services
- No "referral" if physician personally performs a service
  - Many inpatient & outpatient services for which anesthesiologists refer are not personally performed by the anesthesiologist
- In ASC, less potential for referrals for DHS, but health systems are skittish about Stark compliance – will carry over to ASC setting

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Stark "Exceptions"

- Exceptions that may be available in context of Medical Director services
  - Ones that relate to compensation arrangements
    - Rather than financial interest via ownership
  - **Personal service arrangement exception**
  - **Fair market value exception**

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Common Elements: Personal Service & FMV Exceptions

- Agreement in writing & specifies services covered
- Covers all services to be furnished
- Aggregate services are reasonable & nec'y for legitimate business purposes of the arrangement
- Compensation is "set in advance" &
  - Does not exceed fair market value
  - Does not take volume/value of referrals or other business generated into account (except for physician incentive plan)
- Services do not involve counseling/promotion of an arrangement that violates Federal or State law

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Time: Personal Service & FMV Exceptions

Personal Service Arrangements

- Must be at least a year
- If an arrangement is terminated (w/ or w/o cause), parties may not enter into the same or substantially the same arrangement during the first year of the original arrangement

FMV Compensation

- May be for any period of time & contain a termination clause
- Parties may not enter into more than one arrangement for the same items or services during the course of a year

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Stark Personal Service & FMV Exceptions

- Key elements for Medical Director arrangement:
  - Compensation must be
    - Set in advance
      - Can be a formula
    - Not exceed fair market value
    - Not take into account volume or value of physician's referrals

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Structuring Compensation for Medical Director

- Base compensation
  - Independent appraisal of FMV of
    - Administrative services
      - Paid hourly or fixed fee
  - Documentation of time spent
- Incentive compensation
  - Objective quality indicators
  - Not based on subjective indicators
  - Not primarily based on cost reduction/revenue increases
  - Independent appraisal of proposed bonus/incentive

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Stark Rule Changes

- Also effective Jan. 19, 2021: Stark Rule changes, which include:
  - New exception for limited monetary comp (capped at $5K/year; adjusted for inflation) without a signed writing or comp set in advance
  - Changes to group practice definition – especially relating to physician profit-sharing (effective date of 1.1.22 for these changes, to allow group practices time to revise comp plans)
    - Key definition for many Stark exceptions
    - New rule addresses distribution of profits related to participation in a value-based enterprise ("VBE")
  - CMS noted intent to interpret Stark Law "prohibitions narrowly and the exceptions broadly"
    - Permits more flexibility for comp arrangements between a physician referrer and a provider of designated health services

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Examples of Anti-Kickback & FCA Enforcement

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Active Enforcement of AKS/FCA

- Enforcement continues!
- **There's money in enforcement!**
  - DOJ makes money from enforcement: "Justice Department's False Claims Act Settlements and Judgments Exceed $5.6 Billion in Fiscal Year 2021"
    - "Second Largest Amount Recorded, Largest Since 2014"
    - Of the > $5.6B, >$5B relates to health care
      - Additional recoveries for state Medicaid programs
    - https://www.justice.gov/opa/pr/justice-department-s-false-claims-act-settlements-and-judgments-exceed-56-billion-fiscal-year
  - Whistleblowers make money from enforcement!
    - Between 15-30% of the recovery
    - Whistleblowers filed 598 *qui tam* suits in 2021 alone

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$28M Settlement of AKS/FCA Claims

- More than $28M settlement: Three anesthesia practices, several Georgia ASCs, as well as their physician-owners & an administrator (Nov. 2021)
  - Allegations that the anesthesia groups made payments for drugs, supplies, equipment and labor, and provided free staffing to a number of Georgia ASCs to induce the ASCs to select the anesthesia groups to be their exclusive anesthesia providers
  - https://www.justice.gov/usao-ndga/pr/anesthesia-providers-and-outpatient-surgery-centers-pay-more-28-million-resolve
  - Whistleblower case brought by an anesthesiologist in a competing group, the competing group, & the group's administrator
    - That group had lost ASC work to the settling groups
    - The whistleblowers received > $4.7M from the recovery

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$72.3M Settlement of AKS/FCA Claims

- $72.3 million settlement: OK Center for Orthopaedic and Multi-Specialty Surgery ("OCOM"), affiliates, Southwest Orthopaedic Specialists ("SOS") & two SOS physicians (July 2020)
  - Multiple allegations of improper remuneration, free or below-market office space, employees, and supplies
  - Also alleged: preferential investment opportunities in connection with provision of anesthesia services at OCOM
  - Company-model-type structure: SOS and its surgeon owners created an anesthesia group to profit from provision of anesthesia at the ASC
    - https://www.justice.gov/opa/pr/oklahoma-city-hospital-management-company-and-physician-group-pay-723-million-settle-federal
  - Whistleblower case brought by SOS administrator/business mgr (while still employed) – served in that role for 15 years

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Settlement of AKS Claim - Anesthesia

- Dec. 2018: Interventional pain management physician, Jonathan Daitch, MD, agreed to civil settlement of $1.718M to resolve claims he violated FCA by receiving illegal kickbacks associated with provision of anesthesia services and submission of medically unnecessary urine tests
  - Dr. Daitch and his partner, Dr. Frey, owned Anesthesia Partners of SWFL, LLC
  - Provided anesthesia services exclusively for procedures performed by the two pain physicians
  - Anesthesia Partners contracted w/CRNAs to provide anesthesia – billed for them
    - Paid CRNAs a contracted rate
    - DOJ contention: Daitch's ownership interest in Anes. Partners & remuneration he received via his ownership interest induced him to refer his patients to Anes. Partners
  - https://www.justice.gov/usao-mdfl/pr/fort-myers-doctor-agrees-pay-more-17-million-resolve-allegations-fraud (settlement w/Daitch)
  - June 2018: Settlement w/Frey: https://www.justice.gov/usao-mdfl/pr/fort-myers-pain-management-physician-pleads-guilty-healthcare-offenses-and-agrees-28

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$3.2M Settlement of AKS/FCA Claims

- Mar. 2018: DOJ settlement with orthopaedic and anesthesia providers - $3.2M – allegations:
  - Southern Crescent Anesthesiology ("SCA"), Sentry Anesthesia Management ("Sentry"), & individual provided a free medical director to an ASC to induce it to perform more procedures in the ASC than in the office
  - Other allegations related to false claims for prescription drugs purchased outside US and not approved by FDA
  - Whistleblower action by former practice administrator
  - https://www.justice.gov/usao-ndga/pr/orthopaedic-and-anesthesia-providers-pay-32-million-settle-false-claim-act-allegations

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$1M+ Settlement of AKS Claims

- Aug. 2016: DOJ settlement with Sweet Dreams Nurse Anesthesia ("Sweet Dreams") ($1,034,415 to US and $12,078.79 to State of GA)
  - Multiple alleged violations, including:
    - Sweet Dreams provided free anesthesia drugs to ASCs in exchange for ASCs granting Sweet Dreams an exclusive contract to provide anesthesia services at those ASCs
    - Sweet Dreams affiliate funded construction of an ASC in exchange for selection of Sweet Dreams as the exclusive anesthesia provides at that ASC and other affiliated podiatry-based ASCs
    - Whistleblower suit by CRNA who worked for Sweet Dreams
  - https://www.justice.gov/usao-mdga/pr/sweet-dreams-nurse-anesthesia-group-pays-more-1-million-resolve-kickback-allegations

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Other Settlements

- April 2021: $4.1M settlement with Anesthesia Services Associates, PLLC d/b/a Comprehensive Pain Specialists – operated > 40 pain clinics in 12 states
  - Multiple allegations, including alleged false claims for medically unnecessary and/or non-reimbursable testing and acupuncture
  - Other alleged FCA violations relating to
    - Urine drug testing
    - Services not provided and testing not ordered
  - https://www.justice.gov/usao-mdtn/pr/comprehensive-pain-specialists-and-former-owners-agree-pay-41-million-settle-fraud

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Stark and Holdover Agreements

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Holdover Agreements

- Effective Jan. 1, 2016: Stark Law exception allows **indefinite** holdover of expired agreement
  - Parties must continue under the same terms
  - Previously, holdover arrangements were limited to six months
- Useful to know if you are involved in negotiating facility agreements

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Conclusion

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Conclusion

- The AKS & Stark Laws are similar, but entirely different
- Both are intended to prevent corruption in medical decision-making in federal health care programs
- Lots of details as to the safe harbors (for AKS) & exceptions (Stark)
  - And the rules change from time to time
- Important to get the basics – leave the details to counsel
- Medical Director roles can easily comply with both laws

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