



# Recent Developments: Stark Law, Anti-Kickback Statute & Other Fraud and Abuse Laws

Wendy Wright

Associate

McGuireWoods LLP

May 18, 2020

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[www.mcguirewoods.com](http://www.mcguirewoods.com)

## Speaker & Disclaimer

Wendy Wright is an associate at McGuireWoods, LLP. She is a member of the healthcare team and practices in Washington, D.C.

Wendy's practice focuses on counseling clients on structuring arrangements in compliance with federal and state fraud and abuse laws, including the Stark Law, Anti-Kickback Statute, and Civil Monetary Penalty Laws; assisting with structure, regulatory due diligence, and licensing in connection with various transactions, including acquisitions, mergers, member substitutions, and joint ventures. Her clients include private equity funds, physician groups, hospital systems, academic medical centers, and other healthcare providers.

*Everything shared today is opinion. I am not dispensing legal advice and listening does not establish an attorney-client relationship.*

# Roadmap

- I. Enforcement in 2019 and Predictions for 2020
- II. Stark Law
- III. Anti-Kickback Statute
- IV. Beneficiary Inducement Civil Monetary Penalty Law
- V. AKS and CMP Protections
- VI. COVID-19 Waivers

# Healthcare Fraud Enforcement 2019

- Over \$3 billion total
- \$2.6 billion healthcare-related
- Qui tam relators
- Largest recoveries pharmaceutical and medical device companies



# Enforcement Predictions 2020

- DOJ will continue to use statutory authority to dismiss declined Qui Tam cases (*Granston Memo*)
- Parties will seek to get cooperation credit from the government (*Justice Manual Section 4-4.112*)
- Direct providers of healthcare services will remain targets of False Claims Act (“FCA”) enforcement.
- Expansion of targets subject to FCA scrutiny
  - Medicare Advantage plans
  - EHR vendors
- Qui tam FCA actions will remain one of the greatest risks to the healthcare industry

# STARK LAW

# Stark Law Prohibitions

- Physician Prohibition
  - Prohibits physician from referring Medicare\* patients
  - To an entity for the furnishing of designated health services
  - If the referring physician (or physician's immediate family member) has a financial relationship with the entity
- Entity Prohibition
  - Prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer)
  - For such referred designated health services
- UNLESS an exception applies

\*Courts interpreted the Stark Law to also apply to Medicaid claims.

# Designated Health Services

Clinical laboratory services\*

Physical therapy services\*

Radiology and certain other imaging services\*

Radiation therapy services and supplies\*

Durable medical equipment and supplies

Parenteral and enteral nutrients, equipment, and supplies

Home health services

Occupational therapy services

Outpatient prescription services

Inpatient and outpatient hospital services

Outpatient speech-language pathology services

Prosthetics, orthotics, and prosthetic devices and supplies

\*See the List of CPT/HCPCS Codes List published annually by CMS.



# Financial Relationships

- Direct or Indirect Ownership or Investment Interest
  - Equity/stock
  - LLC membership interests
  - Partnership interests
  - Secured debt, loans
- Direct or Indirect Compensation
  - Leases between healthcare facilities and physicians or physician groups
  - Medical director and other service agreements
  - Independent contractor relationships with physicians
  - Employment arrangements
  - Incidental medical staff benefits
- Does the arrangement create any sort of benefit for a physician (or the physician's immediate family member)?

# Application

- Determining when the Stark Law Applies
  1. Does the arrangement involve a referral of a Medicare or Medicaid patient by a physician (or physician's immediate family member)?
  2. Is the referral for a “designated health service”?
  3. Is there a financial relationship of any kind between the referring physician (or physician's immediate family member) and the entity to which the referral is being made?

# Application contd.

- Must satisfy all of the requirements of an exception
  - Common compensation requirements
    - Signed, written agreement
    - Specifies the services or property to be provided
    - Arrangement is Commercially Reasonable and compensation is consistent with Fair Market Value
    - Compensation must be set in advance and not take into account the volume or value of referrals generated between the parties
- Strict Liability Statute
  - No particular “intent” required
  - Technical violations count (e.g. late signatures, expired arrangements)

# Penalties for Stark Law Violation

- Non-payment of improper DHS claims
- Duty to refund payments received while not in compliance
  - Overpayments must be reported and returned within 60 days of identification and timely investigation
- Civil money penalty (up to \$25,372) for each known violation
- Civil money penalty (up to \$102,522) for schemes to evade Stark
- Possible exclusion from federal healthcare programs
- False Claims Act liability

# 2019 Stark Law Proposed Rule

- New Value-Based Exceptions
- New Limited Remuneration Exception
- Clarification of Key Terms
  - Commercially reasonable
  - Volume or value
  - Other business generated
  - Fair market value
  - General market value
- Additional Clarifications

# Value-Based Safe Harbor

- Exceptions for value based arrangements
  - Care coordination arrangements to improve quality, health outcomes, and efficiency
  - Arrangements with substantial downside financial risk
  - Arrangements with full financial risk
- Designed to protect certain arrangements entered into with or by a value-based enterprise (“VBE”)
- Not all entities are eligible to be a VBE participant

# Limited Remuneration to a Physician Exception

- Allows physicians to be paid up to \$3,500 per calendar year
- Conditions include:
  - Does not take into account the volume or value of referrals or other business generated
  - Does not exceed fair market value
  - Commercially reasonable
- Conditions do not include:
  - Signed writing
  - Compensation to be set in advance
- Cannot apply to arrangements protected under a different exception

# Commercially Reasonable

- “Furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements”
- “Makes commercial sense and is entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty”



# “Volume or Value” or “Other Business Generated”

- **Compensation from an entity to a physician:** physician receives additional compensation as number or value of his or her referrals or business generated increases
- **Compensation from a physician to an entity:** predetermined, direct correlation between the physician’s prior referrals or business generated
- **Fixed rate compensation:** pre-determined, direct correlation between the physician’s prior referrals or business generated

# “Fair Market Value” and “General Market Value”

- Fair Market Value
  - Definition for equipment rentals, office space rentals, and all other arrangements generally
  - Each definition states that “fair market value” means the value in arm’s length transaction, with like parties and under like circumstances of like assets
- General Market Value
  - More in line with the valuation industry
  - The value of an asset or service to the actual parties to a transaction that is set to occur within a specified timeframe.

# Additional Clarifications

- Writing and Signature Requirements
  - Electronic signature approval
  - 90-day grace period for unsigned writings
  
- Fair Market Value Exception
  - Short-term equipment and office space leases
  
- Physician Recruitment Exception
  - Physician practice signature not required if pass-through to recruited physician
  
- Period of Disallowance Rule

# ANTI-KICKBACK STATUTE

# Anti-Kickback Statute Prohibition

- Prohibits any PERSON or ENTITY from
  - knowingly and willfully
  - soliciting, receiving, offering, or paying (directly or indirectly)
  - anything of value
  - to induce or in return for
  - referrals of patients for or
  - for purchasing or ordering or arranging for the purchase or order of
  - any items or services payable by a Federal healthcare program (including, Medicare and Medicaid).
- “One Purpose” Test: covers any arrangement where one purpose of the offer or payment is to induce referring, ordering, recommending, or arranging for items or services that may be covered under a federal or state healthcare program.

# AKS Exceptions and Safe Harbors

- Protection from liability if an arrangement meets a statutory exception or regulatory safe harbor.
- Any arrangement not meeting an exception or safe harbor may be reviewed to determine if it results in the types of abuses that statute is designed to combat.
- Due to the “one purpose” test, there is unlimited discretion to prosecute an arrangement that implicates the AKS but does not fully meet an exception or safe harbor.

# AKS Red Flags

- Payments for services that are unnecessary or not commercially reasonable
- Payments for services not provided
- Payments not consistent with fair market value
- Payments that vary with volume / value of business generated by referral source
- Free or discounted items and services, including “professional courtesy” and joint marketing programs
- Ownership arrangements, particularly joint venture arrangements where investment returns are tied to business generated
- Waivers of copayments and deductibles

# Penalties for AKS Violations

- **Criminal Penalties**
  - Felony
  - Up to 10 years of imprisonment for each offense\*
  - Criminal fine of up to \$100,000 (for each illegal payment)\*
- **Civil Penalties**
  - Civil Monetary Penalties of up to \$102,522 per offense
  - Exclusion from Medicare and Medicaid programs
  - False Claims Act liability



# Differences between AKS and Stark Law

## Anti-Kickback Statute

- Applies to anyone doing business with a federal healthcare program
- Bad intent required
- But does not require knowledge of AKS or specific intent to violate AKS
- Criminal liability
- Failure to fit within a safe harbor is not fatal, instead case-by-case call

## Stark Law

- Limited to physician referrals
- Does NOT require bad intent (i.e. strict liability)
- Civil liability
- Must meet an exception

# CIVIL MONETARY PENALTY LAW

# Beneficiary Inducements Civil Monetary Penalties (CMP) Law

- Prohibits a PERSON from
  - Offering or transferring remuneration to a patient
  - That the person knows or should know
  - Is likely to induce the patient
  - To order or receive items or services covered by a government healthcare program
  - From a particular provider, practitioner, or supplier
- Exceptions available
- Penalties
  - Fines for improper claims
  - Exclusion from federal healthcare programs

# AKS and CMP Protections

# 2019 Proposed Rule

- New Value-Based Safe Harbors
- New Patient Engagement and Support Safe Harbor
- Safe Harbor Modifications:
  - Personal Services and Management Contracts
  - Warranty
  - Local Transportation

# Value-Based Safe Harbor

- Largely mirrors CMS value-based exceptions
- Safe harbors for value based arrangements
  - Care coordination arrangements to improve quality, health outcomes, and efficiency
  - Arrangements with substantial downside financial risk
  - Arrangements with full financial risk
- Designed to protect certain arrangements entered into with or by a VBE
- Not all entities are eligible to be a VBE participant

# Patient Engagement and Support Safe Harbor

- Protects patient engagement tools and support services furnished by VBE participants
- Provides both CMP and AKS protection
- Example tools and support services
  - Smart watch monitoring a patient's health and transmitting health data to the patient's physician
  - Smart pill bottle dispensing medications at preset times
  - Parking voucher during medical appointments
  - Free childcare during medical appointments

# Safe Harbor Modifications

- Personal Services and Management Contracts
  - Remove requirements for part-time arrangements
  - Modify set in advance requirement
  - Permit outcome-based payments
  - Better alignment with the personal arrangements exception to the Stark Law
    - Protect services provided on an as-needed basis
    - No longer required to specify total compensation paid over the duration of an arrangement



# Safe Harbor Modifications

- Warranty
  - Expand protection to bundled items and services
  - Safeguards
  - Does not protect free or reduced-priced items or services
  
- Local Transportation
  - Increase distance residents of rural areas may be transported from 50 to 75 miles
  - Remove mileage limit when a patient is discharged from a healthcare facility to her or his home
  - Clarify safe harbor has always applied to ride-sharing services

# COVID-19 Waivers

# COVID-19 Stark Law Waivers

- Blanket waivers for remuneration and referrals solely related to COVID-19 purposes
- Effective March 1, 2020
- Blanket waivers apply if:
  - 1) Providers are acting in good faith to provide care in response to the COVID-19 pandemic;
  - 2) Financial relationship or referral is protected by 1 of 18 enumerated relationships; and
  - 3) Government does not determine that the financial relationship creates fraud and abuse concerns.
- [1877CallCenter@cms.hhs.gov](mailto:1877CallCenter@cms.hhs.gov)

# COVID-19 Stark Law Waivers

- COVID-19 Related Purposes
  - Diagnosis or treatment of COVID-19
  - Securing the services of physicians and other healthcare practitioners
  - Ensuring ability of healthcare providers to address patient and community needs due to COVID-19
  - Expanding the capacity of healthcare providers to address patient and community needs due to COVID-19
  - Shifting diagnosis and care to appropriate alternative settings due to COVID-19
  - Addressing medical practice or business interruption resulting from COVID-19 to maintain the availability of medical care and related services

# COVID-19 Stark Law Waivers

- Permissible Forms of Remuneration
  - Compensation for a physicians personally performed services *above or below* FMV
  - Office space and equipment rent payments *below* FMV
  - Payments for the purchase of items or services *below* FMV
  - Additional incidental benefits to medical staff
  - Nonmonetary compensation to a physician
  - Low interest or interest free loans

# COVID-19 Stark Law Waivers

- Permissible Referral Relationships
  - Referrals by owners of physician-owned hospitals that temporarily expand facility capacity
  - Referrals by owners of ambulatory surgery centers that temporarily convert to hospitals
  - Referrals by owners of home health agencies
  - Referrals for in-office ancillary services at additional locations
  - Referrals to immediate family members for patients located in rural areas
  
- Waiver of writing requirements for compensation arrangement exceptions

# COVID-19 Stark Law Waivers

- Post COVID-19 Considerations
  - Maintain appropriate documentation (1) detailing the appropriate COVID-19 purpose and (2) specifying the blanket waiver used
  - Return any items provided to a physician or entity under a blanket waiver
  - Terminate financial relationships that will not meet a Stark Law exception
  - Ensure any continuing relationships are structured to satisfy a Stark Law exception

# COVID-19 AKS Enforcement

- Protection from administrative sanctions under the AKS for remuneration solely related to COVID-19 purposes
- Provider must meet all conditions and definitions applicable to the Stark Law blank waivers.
- Effective April 3, 2020
- Differences from the Stark Law blanket waivers
  - Only protects remuneration
  - No retroactive effective date
  - No protection for pharmaceutical or device manufacturers



# Best Practices for COVID-19 Waivers

- Don't abandon the Stark Law framework
- Document, document, document
- Enter with an exit plan

# Questions or Comments?

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