The New Stark and AKS Final Rules:
Implications and Considerations for Laboratories

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Opinions expressed in this presentation are those of the speaker and do not express the views or opinions of Cardinal Health

Learning Objectives

Our Presentation is intended to help you:

- Recognize the basic regulatory framework for the federal Physician Self-Referral "Stark" Law and the Anti-Kickback Statute (AKS).
- Identify the areas where these laws most often impact clinical laboratories.
- Learn about New Stark and AKS Final Rules and how they impact clinical laboratories.
- Recognize potential Stark and AKS concerns in new opportunities and proposed arrangements so that you can analyze and/or escalate as appropriate.

The Basics

Questions to Consider:

- What is the difference between the federal Stark Law and AKS?
- Where is the Stark Law and AKS most often implicated in clinical laboratory operations?
- Are the risks different depending on the type of clinical laboratory?
- Should clinical laboratories that are part of a hospital be focused on different issues?

Comparing the Stark Law and the AKS

	Stark Law (42 U.S.C. § 1395nn)	Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b))
Prohibits	Physicians from referring Medicare Patients for designated health services (including lab services) to an entity which the physician (or a family member) has a financial interest	*Any person* from offering, paying, soliciting, or receiving anything of value to induce or reward referrals or induce referrals for services paid for by a Federal healthcare program
Referrals	From physicians	To or from anyone
Items / Services	Designated health services (DHS)	Any items or services reimbursed by a federal healthcare program
Penalties	Civil: overpayment obligation, False Claims Act Liability, civil monetary penalties and program exclusion for known violations, fines can be up to $22,000 per violation or up to 3x amount	Criminal: fines up to $25,000 per violation or up to 5-year prison sentence Civil: False Claims Act Liability, civil monetary penalties and program exclusion, potential $50,000 fine per violation, civil assessment up to 3x amount
Exceptions	Mandatory compliance exceptions and ALL elements must be met	Voluntary safe harbors
Federal Health Programs	Medicare / Medicaid	All federal healthcare programs
Intent	No intent required except for civil monetary penalties on *knowing* violations (strict liability)	Intent must be proven

NOTE: This chart is adapted from the OIG's website (not identical): https://oig.hhs.gov/compliance/provider-compliance-training/files/starkandakscharthandout508.pdf

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Stark and AKS Impact on Laboratories

Common Regulatory Compliance Implications

- Sales and marketing efforts; customer service
  - Situations where the lab is providing goods/services for free or below FMV, examples include:
    - Non-monetary compensation
    - On-site collectors
    - Interfaces v. EHR
    - Specimen collection supplies
    - Patient billing policies

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Stark and AKS Impact on Laboratories

Regulatory Compliance Implications

- Non-Monetary Compensation – Stark Law Exception exists
  - Not solicited by the physician
  - Does not take into account volume/value of referrals
  - No more than $429/physician (for 2021)

- In-Office Collectors – arrangements may be scrutinized
  - OIG Special Fraud Alert
    - Phlebotomist or collector services may violate the AKS if any services are not directly related to the collection/processing of the specimens for the laboratory provider

- Interfaces permissible SOLELY to transmit orders and results between laboratory/pathology provider and client

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Stark and AKS Impact on Laboratories

Regulatory Compliance Implications

- Specimen Collection Supplies
- Government Guidance
  - Certain supplies may be provided free or below-market cost IF:
    - *Used solely to:*
      - *Collect specimens*
      - *Transport specimens*
      - *Process specimens*
      - *Store specimens*
  - Permissible (examples):
    - Cups for urine collection
    - Vials to hold and transport blood
  - Impermissible (examples):
    - Gloves
    - Biopsy needles and snares
  - Other Supplies
    - High risk if provided free or below-market cost:
      - Alcohol pads
      - Examination gowns
      - Gauze
      - Hazardous material labels
      - Table paper
      - Test kits
      - Point of care collection cups

Stark and AKS Impact on Laboratories

Regulatory Compliance Implications

- Patient Billing Policies
  - Routine waiver or reduction of co-pays, deductibles, etc. for federal government work is a violation of AKS.
  - In the past, labs may have waived all commercial out of network patient responsibility so that the patient was not penalized for obtaining services out of network.
  - We continue to see this issue with out of network labs.
  - Primary issue with out of network service relates to patient responsibility – physician and patient satisfaction.
  - Private payors are aggressively attempting to discourage the practice and have proceeded against labs engaging in the practice.

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Stark and AKS Impact on Laboratories

Regulatory Compliance Implications

- Patient Billing Policies
  - General Considerations:
    - Across the board full waivers are improper (whether policy or practice)
    - Exception is often recognized for patients with inability to pay
    - General practice should be to make good faith effort to collect — send multiple bills

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Recent Federal Activity

HHS Releases New Final Rules for Stark and AKS

- On November 20, 2020, the Department of Health and Human Services (HHS), Centers for Medicare and Medicaid Services (CMS) and the Office of the Inspector General (OIG) released final rules for the federal Stark Law and the federal AKS.
  - Majority of changes took effect on January 19, 2021 (exception - Physician Group Practice Compensation changes - delayed until January 1, 2022).
  - Shift toward patient care coordination and value-based arrangements with levels of risk-sharing.
  - Key terms and concepts revised and newly defined in an effort to provide more clarity to providers.
  - Renewed focus on electronic health record (EHR) and cybersecurity donations.
  - Clinical laboratories expressly excluded from certain Stark exceptions and AKS safe harbors.

The New Stark and AKS Final Rules

Changes for 2021 and Beyond

- As part of HHS' "Regulatory Sprint to Coordinated Care," the Final Rules modify regulations viewed as impediments to healthcare providers' efforts to advance value-based, coordinated care in federal or commercial settings:
  - The CMS final rule clarifies and modifies existing Stark Law guidance with the intent to ease regulatory burdens on providers while still curbing acts of physician self-interest.
  - The OIG final AKS rule facilitates better coordinated and value-based patient care and improves providers' care efforts while protecting against fraudulent or abusive activity toward patients.

- These HHS regulatory reforms are intended to:
  - Allow more innovative arrangements
  - Increase value for patients and providers
  - Leverage digital technology for efficiency
  - Continue during the COVID-19 pandemic and in years to follow

The New Stark Final Rule

New and Revised Features Likely to Impact Laboratories in the Short Term*

- Revised Stark Definitions (42 CFR 411.351)
  - "Commercially Reasonable"
  - "Fair Market Value"

- Modifications to Financial Relationships (42 CFR 411.354)
  - Volume or Value standards
  - Modification of compensation during the course of arrangement
  - Signature requirement (90-day grace period)

** This is not an exhaustive summary of the New Stark Final Rule*

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The New Stark Final Rule

New and Revised Features Likely to Impact Laboratories in the Short Term*

- Exceptions related to Compensation Arrangements (42 CFR 411.357)
  - Limited physician remuneration
  - Isolated transactions
  - Electronic Health Records and Cybersecurity Technology donations
    - *EHR exception expressly excludes lab companies as donors; Cybersecurity and Technology exception does not*
  - Value-based arrangements

- Prohibition on Billing for Certain Referrals (42 CFR 411.353)
  - Grace period for reconciling payment discrepancies

** This is not an exhaustive summary of the New Stark Final Rule*

The New AKS Final Rule

New and Revised Features Likely to Impact Laboratories in the Short Term*

- AKS Exceptions (42 CFR 1001.952)
  - Personal Services and Management Contracts Safe Harbor
    - *But note, this safe harbor includes new outcomes-based payments and labs are excluded from the outcomes-based arrangement component of the safe harbor*
  - CMS-Sponsored Models Safe Harbor
  - EHR versus Cybersecurity and Technology Services Safe Harbors
    - *EHR safe harbor expressly excludes lab companies as donors; Cybersecurity and Technology safe harbor does not*

** This is not an exhaustive summary of the New AKS Final Rule*

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The New AKS Final Rule

New and Revised Features Likely to Impact Laboratories in the Short Term*

- AKS Exceptions continued (42 CFR 1001.952)
  - Other Lab-Ineligible AKS Safe Harbors
    - Value-Based Arrangements
      - Care Coordination Arrangements
      - Substantial Downside Risk
      - Full Financial Risk
    - Patient Engagement and Support
    - Outcomes-Based Payments
      - *The above safe harbor exclusions reflect OIG concerns that laboratories and other Ineligible Entities rely heavily on provider referrals. In fact, the Stark value-based exceptions do not have similar limitations for labs; however, CMS acknowledged that while the Stark value-based exceptions do not exclude labs, from CMS' perspective, AKS would serve as a backstop for value-based arrangements.*

** This is not an exhaustive summary of the New AKS Final Rule*

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Stark and AKS Impact on Laboratories

New Arrangement Best Practices

- Consult with a valuation expert on whether financial arrangements satisfy the new Stark Law fair market value and commercial reasonableness standards.
- Consult with healthcare counsel to review compensation arrangements to identify any structures that take into account the volume or value of referrals or business generated between the parties.
- Processes exist to seek OIG Advisory Opinion (AKS) and CMS Advisory Opinion (Stark) in certain instances.

Beyond Stark and AKS

Additional Regulatory Compliance Considerations

- Outside of Stark and AKS Laws:
  - The Eliminating Kickbacks in Recovery Act (EKRA)
  - False Claims Act
  - Anti-markup/billing
  - State fraud and abuse laws
  - Payor policies / contract restrictions
  - Covid-19 emergency prohibitions (surprise/balance billing)

Enforcement Trends

- Financial incentives are everywhere for providers, suppliers, and patients but medical judgment should not be improperly influenced by these forces.
  - Labs remain under intense scrutiny from government authorities (federal and state).
  - Fraud, waste, and abuse initiatives are expected to increase as a result of the COVID-19 provider relief programs and various HHS waivers.
  - Imperfect alignment exists between the Stark and AKS Final Rules.
  - OIG active work plan: Medicare Part B Payments for Laboratory Services.

QUESTIONS?

Thank you for attending

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