

Compliance Considerations for Clinical Laboratories

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Learning Objectives



Interpret how the Stark Law framework, Anti-Kickback Statute, and related exceptions and safe harbors apply to laboratory testing

Discuss the developments in compliance requirements for client account billing for laboratory testing

Identify risks and issues commonly associated with payor audits

Agenda



Background & Legal Framework

Non-monetary Compensation

Free Services/Payment for Collection Services

Equipment and Supplies

EHRs & Interfaces

Account Billing

Payor Audits

Background



- Legal Framework for Pathology and Clinical Laboratory Providers
 - Federal
 - Anti-Kickback Statute (AKS)
 - Physician Self-Referral Law (Stark law)
 - False Claims Act
 - Anti-markup/account billing regulations
 - State
 - Fraud and abuse laws
 - Anti-markup/account billing regulations
 - Others
 - Payor contract restrictions

Background



- The World Outside
 - Commercial Incentives are everywhere
 - Cash back credit cards; Frequent flyer miles; Free gift with a purchase; One free with the purchase of three etc.
 - Why Are Health Care Entities Treated Differently?
 - Inappropriate arrangements in health care have the potential to result in overutilization, increased program costs, improperly influenced medical decision making, patient steering and unfair competition.
 - Judgments about medical care should not be influenced by financial incentives.

Background



- Anti-Kickback Statute (AKS)
 - Prohibits knowing and willful
 - Intent
 - Payment or receipt of remuneration
 - Remuneration = anything of value (cash, free rent, meals, etc.)
 - Judgments about medical care should not be influenced by financial incentives.
 - To induce patient referrals
- Penalties
 - Fines, jail, exclusion from Federal health care programs

Background



- Elements of AKS
 - Referral Source (unlike Stark, not limited to physicians)
 - Payment (direct or indirect) in return for referrals
 - Intent to engage in the activity to induce referrals
 - Applicable safe harbor?

Background



- Physician Self-Referral Law
 - The Stark Law prohibits:
 - A physician from referring to an entity furnishing designated health services with which the physician (or a family member) has a financial relationship unless meet all requirements of an exception.
 - (No intent element!)
 - Penalties:
 - Fines, exclusion from Federal health care programs

Background

- Stark Designated Health Services (DHS)
 - *Clinical laboratory and anatomic pathology services (both technical and professional components)*
 - Physical therapy, occupational therapy, and outpatient
 - Speech-language pathology services
 - Radiology and certain other imaging services
 - Radiation therapy services and supplies
 - DME and Supplies
 - Home Health services
 - Inpatient and outpatient hospital services

** Note that this is not a comprehensive list.*

Background

- What is a “Financial Relationship?”
 - Compensation Arrangements
 - Essentially any form of direct/indirect remuneration
 - Includes compensation from an entity that has a compensation arrangement with entity that furnishes DHS
 - Ownership/investment interests
 - May be debt, equity, stock, membership interests (LLC)
 - Includes interest in another entity that holds an ownership/investment interest in the entity that furnishes DHS

Background



- False Claims Act (FCA)
 - Illegal to submit a false claim to Medicare/Medicaid
 - Civil FCA
 - Criminal FCA
- Penalties
 - Fines, exclusion from Federal health care programs, jail (criminal FCA)

Non-Monetary Compensation



- Examples
 - Meals
 - Trips
 - Pens
 - Coffee mugs
- Implicates
 - AKS
 - Stark law
 - State law

Non-Monetary Compensation



- Stark Law
 - Stark Law Exception
 - Not solicited by the physician
 - Does not take into account volume/value of referrals
 - No more than \$398/physician (for 2017)
- Tracking
 - Documentation is key
 - Avoid anything that has a value on the open market
 - (e.g. tickets)
 - Caution: non-monetary compensation to physicians in group practice
 - Allocate to each physician

Payment for Services

- AKS Safe Harbor & Stark Exception
 - For services provided to a referral source that benefit the referral source
 - Written agreement
 - Fixed fair market value compensation
 - Other elements of the safe harbor and exception

Payment for Services

- AKS Safe Harbor & Stark Exception (continued)
 - For reimbursement of referral source performance of services
 - Written agreement
 - Fixed fair market value compensation
 - Only for actual time spent
 - Payment over Medicare rate could be found in excess of FMV
 - Other elements of the safe harbor and exception
 - Documentation of actual time spent by physician or physician's personnel

Free Services/Payment for Collection Services



- State Restrictions
 - Some states specifically prohibit or restrict placement of laboratory personnel in physician offices
 - For Example:
 - Florida has a specific regulation prohibiting a laboratory from placing any personnel in a physician's office
- Compliance for Free Services
 - Always have a written agreement
 - Specimen Collector: only for samples where laboratory will be performing the pathology services
 - Only where permissible under state law

Free Services/Payment for Collection Services



- OIG Fraud Alert
 - Phlebotomist or collector services provided, could violate the AKS if any services are not directly related to the collection/processing of the specimens for the laboratory provider
- OIG Advisory Opinion (2005)
 - Payments by a lab to a physician of \$3-\$6/patient for phlebotomy service potentially violated AKS
- OIG Special Fraud Alert (2014)
 - Also on the topic of payments for services, determination that AKS was implicated by such arrangements

Equipment and Supplies



- Compliance for Donating Equipment
 - Should remain owned by laboratory
 - Remove when relationship terminates
 - No other independent value to the referral source
 - Written agreement
 - Referral Source with its own laboratory:
 - Responsible for equipment at its own expense

Equipment and Supplies



- Equipment: Government Guidance
 - OIG Fraud Alert (1994)
 - Computers and Fax Machines
 - Suspect under AKS
 - Unless
 - Integral to and exclusively used for laboratory's work
 - Also applies to electronic interfaces
 - OIG Advisory Opinion, 2012

Equipment and Supplies

- 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
 - Permitted (examples):
 - Cups for urine collection
 - Vials to hold and transport blood

Equipment and Supplies

- Supplies: Government Guidance (continued)
 - Not Permitted (examples):
 - Disposable single-use Speculums
 - Gloves
 - Biopsy needles and snares
 - Endometrial brushes

Equipment and Supplies



- Other Supplies
 - Potentially 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

EHRs & Interfaces



- EHR Donations
 - Stark law exception and AKS safe harbor for all donors except laboratory and pathology providers – no EMR donations permissible from laboratory and pathology providers
- Interfaces
 - Interfaces are permissible if SOLELY to transmit orders and results between laboratory/ pathology provider and client, and no transfer of client EHR expense to laboratory/pathology provider

Account Billing

- Account Billing/Client Billing Arrangements
 - Physician purchases professional and/or technical component pathology services at a discount and bill the payor. Typically excludes government work.
 - OIG Advisory Opinion 99-13 explains that pathology providers and the physicians who purchase pathology services risk violating the Medicare and Medicaid anti-kickback law if they have deeply discounted pricing arrangements.

Account Billing

- Medicare Anti-Markup Regulations
 - Medicare payment to physician must be LESSER of:
 - Performing provider's charge to physician
 - Physician's actual charge
 - Medicare allowable amount

Account Billing



- Federal Law Considerations
 - Anti-kickback Statute
 - OIG Advisory Opinion (1999)
 - Deeply discounted price arrangements could violate AKS
 - Must comply with safe harbor – fair market value pricing
- Stark Law
 - Exception for purchase of pathology and lab services IF
 - Fair Market Value

Account Billing

- State Prohibitions
 - Several with statutory restrictions including:
 - Anti-markup
 - Disclosure of price and identify of pathology provider
 - Direct Billing by pathology provider

Account Billing

- Other Payors
 - Medicare Advantage Plans
 - Generally incorporate compliance with Medicare regulations
 - Medicaid and Medicaid HMOs
 - Most do not permit physicians to bill for purchased pathology services
 - May impose anti-markup restrictions
 - May prohibit billing for purchased services

Payor Audits



- Audits are increasing in frequency
- Payers are using more aggressive tactics
- Amounts sought in recoupment actions are increasing significantly

Payor Audits



- Elements of Documentation
 - Evidence of documentation of performance of service, as well as proper ordering of any ancillary services.
 - Required documentation can vary by payer and type of test/service. Medical chart must describe all elements of medical service provided to support CPT and ICD-10 coding.
 - Documentation of order for ancillary services could include:
 - Signed requisition
 - Electronic signature through e-mail
 - Signed documentation in patient chart

Payor Audits



- Elements of Documentation (continued)
 - Documentation of Medical Necessity
 - Documentation of medical necessity of the medical service provided or ancillary service in medical record.
 - For ancillary services, such as dermatopathology services, documentation of medical necessity is important not only for the ancillary service, but also any associated underlying procedure (such as a biopsy).

Payor Audits



- Elements of Documentation (continued)
 - Usage of Results of Ancillary Services:
 - Increasingly, payers want to see documentation of review and/or use of the information by the ordering physician

Summary



- To prevent over-utilization of healthcare services, control healthcare expenditures, and ensure ethical decision making by physicians, numerous Federal and State laws exist
 - Penalties for non-adherence can include monetary fines, jail, and exclusion for Federal healthcare programs
- Each element of a contemplated service arrangement (which may include financial relationships, non-monetary compensation, and or other elements) needs to be carefully analyzed for compliance and if determined to be permissible, appropriately documented
- Laboratory specific considerations include, but are not limited to:
 - Free services/payment for collection services
 - Providing equipment and supplies
 - Interfaces
- In addition to Federal law considerations, many states have statutes and regulations limiting account billing arrangements between laboratories and ordering providers
- Government and private payors are increasing the level of scrutiny related to audits and requesting recoupment of payments for non-compliance

Questions?

The information in this presentation is provided for educational purposes only and is not legal advice. It is intended to highlight laws you are likely to encounter, but is not a comprehensive review. If you have questions or concerns about a particular instance or whether a law applies, you should consider contacting your attorney.



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