Fair Market Value, Anti-kickback, and Stark Risks in Clinical Research

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Compliance Risks in Clinical Research

- Key concerns
  - Relationships between pharmaceutical companies and providers have always been heavily scrutinized
  - Focus on marketing, costs to federal programs
- Research relationships present special concerns
  - True research vs. sham "research"
  - Integrity of results
  - Payments to providers and physicians
  - Sunshine Act disclosures lead to increased scrutiny

Compliance Risks in Clinical Research

- Key statutory provisions
  - Medicare/Medicaid Anti-kickback statute
  - Stark Medicare self-referral prohibition
  - Federal False Claim Act
  - Sunshine Act

Anti-Kickback Statute

- Anti-Kickback Statute (AKS): 42 U.S.C. § 1320a-7b(b)
  - Prohibits intentional exchange of remuneration (anything of value) for referrals or to induce the purchase of items or services covered by Medicare, Medicaid and other federal health care programs
    - Criminal penalties
    - Civil money penalties
    - False Claims Act exposure
  - Safe Harbors

Stark Self Referral Prohibitions

- Physician Self-Referral Law ("Stark"): 42 U.S.C. § 1395nn
  - Prohibits Medicare referrals to "entities" for designated health services (DHS) by physicians where the entity has financial relationship with the physician (or an immediate family member)
  - Exceptions
  - Sanctions
    - Denial of Medicare reimbursement
    - Civil penalties
    - False Claims Act liability

Comparison of Stark and AKS

- Key distinctions between Stark and the AKS
  - Stark is strict liability/AKS requires intent
  - Stark only covers "entities" that provide DHS
    - Hospitals and other providers covered
    - Manufacturers not covered
  - Stark only covers relationships involving physicians and immediate family/AKS covers all persons

Comparison of Stark and AKS

- Key distinctions between Stark and the AKS
  - Exceptions
    - Stark exceptions are mandatory
    - AKS safe harbors are optional
- "Fair Market Value" and "Commercial Reasonableness" are key concepts in both Stark exceptions and AKS Safe Harbors

Civil False Claims Act

- Civil False Claims Act: 31 U.S.C. § 3927
  - Prohibits filing, or causing to be filed
    - "false or fraudulent" claims
    - Using false statement to "conceal, avoid or decrease" a government obligation
  - Intent
    - "Intent to defraud" not required
    - Filing claims with "reckless disregard" of their truth or falsity is sufficient
      - "Honest mistakes"

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Civil False Claims Act

- Civil False Claims Act
  - Potential liability
    - Treble damages
    - $5,500 to $11,000 *per claim*
  - *Qui Tam* Provisions
    - "private attorney generals"
    - Can proceed even if Government declines
    - Can receive up to 30% of recovery

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Civil False Claims Act

- Civil False Claims Act
  - Claims for services 'tainted" by a Stark or AKS violation generally are actionable under the Civil False Claims Act
    - Where an improper Stark relationship exists ***all*** Medicare referrals from the "tainted" physician are actionable, not just those related to the research
    - Where trials involve federal funds, claims on those funds involving a AKS "tainted" relationship may also be actionable

Sunshine Act

- Sunshine Act (42 U.S.C. § 1320a-7h)
  - Requires "applicable manufacturers" to disclose payments to physicians and academic medical centers ("covered recipients")
  - Applicable manufacturers have prescription drug, device, biologic, or medical supply that is covered by Medicare, Medicaid, or CHIP
  - Includes payments related to research, defined as:
    - "a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social sciences research. This term encompasses basic and applied research and product development." 42 C.F.R. § 50.603 (PHSA)

Sunshine Act

- Sunshine Act (42 U.S.C. § 1320a-7h)
  - Research payments use different template than other payments—requires reporting of any payment, even to non-covered recipient, if passed on to covered recipient
  - Even funds paid to non-teaching hospitals must be reported
  - Report aggregate amount paid for services covered under the written clinical trial agreement/research protocol
  - Separately report consulting payments to physicians

Sunshine Act

- Sunshine Act
  - Physicians and academic medical centers may review entries for accuracy before they are made public
  - Important to take this ability seriously
  - Check against recorded payments and expenditures

Sunshine Act

- Sunshine Act
  - Provides both government and relators increased insight into payments between sponsors and providers
  - Could lead to increased scrutiny of clinical research arrangements
  - State laws
- Impact on FCA cases
  - Public disclosure?

OIG Focus

- OIG-identified “suspect practices”
  - 1994 Special Fraud Alert on Pharmaceutical Marketing Practices http://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html

- A ``research grant'' program in which physicians were given substantial payments for de minimis recordkeeping tasks. The physician administered the drug manufacturer's product to the patient and made brief notes, sometimes a single word, about the treatment outcome.
- Grants to physicians and clinicians for studies of prescription products when the studies are of questionable scientific value and require little or no actual scientific pursuit.

OIG Focus (cont’d)

- 2003 OIG Compliance Program Guidance for Pharmaceutical Manufacturers
  - http://oig.hhs.gov/compliance/compliance-guidance/index.asp
  - When manufacturers contract with physicians to provide research services on a fee-for-service basis payments for research services should be
    - Fair market value
    - For legitimate, reasonable, and necessary services.

OIG Focus (cont'd)

- OIG "suspect" practices
  - Research that originates through the sales or marketing functions
  - Indicia of questionable research
    - Research that is not transmitted to, or reviewed by, a manufacturer's science component;
    - Research that is unnecessarily duplicative or is not needed by the manufacturer
    - Post-marketing research used as a pretense to promote product.

OIG Focus (cont'd)

- OIG "suspect" practices re grants
  - OIG recognizes that many grant-funded activities are legitimate and beneficial.
  - Funding cannot be based, expressly or implicitly, on usage or referral of the manufacturer's product.
  - The funding must be for *bona fide* educational or research purposes.

Enforcement Activity

- Boston Scientific Corp
  - $22 million False Claims Act settlement in 2009
    - Payments of $1,000-$1,500 to physicians per implanted pacemaker or defibrillator as part of 4 post-market studies
    - Alleged the studies were a sham to disguise payments to induce the use of Guidant pacemakers and defibrillators
    - "Although medical-device and pharmaceutical manufacturers can use post-market studies legitimately to obtain information about how their products work in the field, they cannot use those studies, and the honoraria associated with them, to induce physicians to use their products."
      - » DOJ Press Release

Enforcement Activity

- Medtronic, Inc.
  - $23 million False Claims Act settlement of whistleblower case in 2011
    - Payments of $1,000-$2,000 to physicians per implanted Medtronic pacemaker as part of a post-market study and device registry
    - Alleged the study and registry were sham to disguise payments to induce the use of Medtronic pacemakers
  - In 2006, Medtronic had paid $40 million to settle claims that it had entered into sham consulting agreements and sham royalty agreements to pay doctors to use spinal implants

Enforcement Activity

- St. Jude Medical
  - $16 million False Claims Act settlement in 2011
    - Payments of $1,000-$1,500 to physicians per implanted pacemaker or defibrillator as part of 3 post-market studies and a device registry
    - Alleged the studies were a sham to disguise payments to induce the use of St. Jude pacemakers and defibrillators

Industry Guidance

- PhRMA Guidance on Clinical Trials (rev. June 2015)
  - http://www.phrma.org/principles-and-guidelines-clinical-trials
  - Require written contract and budget for research services
  - Compensation may not be tied to outcome
  - Investigators should not have an interest in the studied drug or device
  - No compensation in stock or stock options
  - Compensation for time spent enrolling patients only when enrollment is particularly difficult
  - Reimbursement for travel to clinically necessary meetings at appropriate locations ("resorts are not appropriate") only

Industry Guidance

- AdvaMed Code of Ethics
  - http://advamed.org/issues/1/code-of-ethics
  - Written consulting agreements and research protocols required
  - Legitimate need for service should be defined and documented in advance
  - Investigators selected based on qualifications, not referrals
  - Sales staff may provide ***limited*** input in selecting participants
  - All compensation reasonable, FMV

Scenario 1

- A sponsoring pharmaceutical manufacturer enters into a clinical trial agreement (CTA) with an academic medical center (AMC) whereby AMC will conduct clinical trials and one of the AMC's employed physicians, Dr. Jones, will act as the Principal Investigator
  - AKS issues?
    - How to address?
  - Stark issues?
    - How to address?

Scenario 1-CTA Analysis

- Analysis
  - Potential issues in the CTA between the Sponsor and the AMC
    - Potential AKS issue because presumably the AMC and its employed physicians are in a position to drive usage of the sponsor's products
      - Note that not only the drugs subject to the CTA are an issue
    - No Stark issue, because no physician party to the agreement

Scenario 1-CTA Analysis

- AKS Personal Services Safe Harbor
  - Written, signed agreement
  - Term of at least a year
  - Covers all the services to be provided
    - Part-time interval issue
  - Compensation
    - set in advance in the aggregate,
    - consistent with fair market value in an arms-length transaction
    - does not take volume or value of referrals or other business into account
  - Contracted services do not exceed what is reasonably necessary to achieve the "commercially reasonable" purpose of the agreement

Scenario 1-CTA Analysis

- Written, signed agreement
  - Easily accomplished
- One year term
  - Potentially problematic
    - Shorter term permitted, if agreement clearly states that there can be no new arrangement during the remainder of the one year term
- Covering all services
  - Problematic in part-time arrangements because of requirement for specific schedule

Scenario 1-CTA Analysis

- Compensation issues
  - Safe harbor requires fixed ***aggregate*** compensation
    - Often impractical, and more honored in the breach
  - Compensation may not take the volume or value of referrals or other business into account
    - Generally not problematic

Scenario 1-CTA Analysis

- Compensation (cont'd)
  - FMV=General market value between parties without the ability to refer business
  - Determining fair market value
    - Site-specific
    - Medicare rates for clinical services?
    - Commercial insurance rates?
    - Cost of administrative services?
  - What costs should be included in the budget?
    - Start-up costs (communication with IRB, protocol review)
    - Clinical and administrative costs (direct and indirect)
    - Overhead

Scenario 1-CTA Analysis

- Ensuring fair market value
  - OIG CIA requirements on manufacturers relating to FMV in CTAs
    - Centrally managed, pre-set rate structure
    - Documented fair market value analysis
  - Use of outside valuation experts
  - Published compensation surveys, e.g. MGMA

Scenario 1-CTA Analysis

- Commercial reasonableness
  - » Contracted services may not exceed what is reasonably necessary to achieve the "commercially reasonable" purpose of the agreement
  - Particularly acute in post-market studies
    - » Key component in prior enforcement cases
  - Key issues
    - » Documented scientific need for the study
    - » Origination in the clinical group of the manufacturer, not Sales and Marketing

Scenario 1-PI Analysis

- Analysis
  - Potential issues in the PI arrangement between the between the AMC and Dr. Jones
    - Potential AKS issue because presumably Dr. Jones refers patients to the AMC
    - Potential Stark issue because payments to Dr. Jones create a financial arrangement between a physician and an "entity" to which she refers Medicare patients

Scenario 1-PI Analysis

- AKS analysis
  - No AKS issue because of a statutory exception and safe harbor that protects all bona fide W-2 employment arrangements, with no other requirements

Scenario 1-PI Analysis

- Stark analysis
  - Stark employment exception requirements
    - Bona fide employment relationship
    - For identifiable services
    - Compensation consistent with fair market value
      - except for certain permitted productivity bonuses, does not take into account the volume or value of referrals
    - Commercially reasonable even if no referrals were made to the employer.
  - No requirement for a writing

Scenario 1-PI Analysis

- Stark analysis
  - Exception easily met
  - Potential pitfall
    - Ensure that any additional compensation arising from Dr. Jones role as PI does not cause her compensation to exceed fair market value
      - Analysis requires consideration of all employment compensation, not just that arising from PI role

Scenario 2

- This scenario is the same as Scenario 1, except that Dr. Jones is not employed by the AMC. She is a member of the AMC's medical staff and will act as PI as an independent contractor to the AMC.

Scenario 2-Analysis

- CTA analysis is unchanged
- PI analysis
  - AKS
    - Employment exception no longer available
  - Stark
    - Employment exception no longer available
    - Analyze compliance with Personal Services exception

Scenario 2-Analysis

- Stark Personal Services Exception
  - In writing, signed by the parties
  - Specifies the covered services
  - Covers all services to be provided by physician to entity.
  - Aggregate services contracted for do not exceed those reasonable and necessary for the legitimate business purposes of the arrangement.

Scenario 2-Analysis

- Stark Personal Services Exception
  - One year term
    - Issue of shorter term
  - The compensation is set in advance at fair market value and does not take into account referrals or other business generated between the parties
    - ***Aggregate*** compensation does ***not*** have to be set in advance
  - The services do not involve the counseling or promotion of an unlawful business arrangement or other activity.

Scenario 2-Analysis

- Compliance should be readily achievable, but…
  - Significant exposure if even one is not met, e.g. lack of a signature
  - A few words about the CMS Stark Self Disclosure protocol
    - https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self_Referral_Disclosure_Protocol.html

Scenario 3

- The manufacturer also enters in to a Consulting Agreement directly with Dr. Jones to provide a variety of services, including making presentations to other PIs at manufacturer-organized conferences, identifying other potential PIs, making instructional videos about the protocol, etc. She is paid $400 per hour plus any out-of-pocket expenses, including travel.

Scenario 3-Analysis

- AKS analysis
  - Same as with CTA with AMC
  - Stark analysis
    - No Stark issue because Manufacturer is not an "entity" under Stark
  - Potential pitfalls
    - Ensuring that rate is FMV
    - Ensuring that the tasks are actually performed
    - Ensuring that the services are commercially reasonable
    - Expense issues

Things to watch in CTAs

- Be wary of investigator selection based more on use of manufacturer's products rather than clinical acumen
- Make sure the CTA clearly defines the services to be provided
  - Be cognizant of duties outside the protocol, like attending meetings, etc.
- Define the expected time commitment under the CTA

Things to watch in CTAs

- Document the fair market value of payments under the CTA
  - Use of compensation surveys
  - Use of out valuation experts
  - Documented budgets
- Be wary of enrollment bonuses
- Avoid compensation in stock or other forms that may increase in value contingent on the results of the study
- Scientific basis for study should be well-understood and clearly documented

Government Funded Clinical Research

- Government-funded research poses additional risks
  - Inaccurate claims for reimbursement can be false claims if inaccuracies are intentional
  - Requires close monitoring of both institutional claims and claims by individual physicians
    - Submitting bad claim for reimbursement on behalf of physician can create institutional liability

QUESTIONS?

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