HCCA Research Compliance Conference

Session W4 – Dissecting the Clinical Trial Agreement: Avoiding Compliance Pitfalls in Clinical Trial Agreements

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Michael C. Roach, JD, MHSA, MA, CHRC, CIP

Overview

- Medicare coverage for clinical trials
  - Coverage for Device Trials
  - National Coverage Decision
- Federal False Claims Act
- Federal Anti-Kickback Statute
- Stark Law
- Beneficiary Anti-Inducement

Medicare Coverage for Clinical Trials

- Coverage for Device Trials
- Everything else
  - National Coverage Decision ("NCD") 310.1
    - a/k/a Medicare Clinical Research Policy

Medicare Coverage for Device Trials

Effective January 1, 2015, Sponsors get approval from CMS central that routine costs can be billed

Medicare Coverage - Device Trials

- What does Medicare cover?
  - For Category A device trial: routine care
    - Not the device itself
  - For Category B device: routine care and the investigational device
- Device category determinations made by CMS
  - along with determination of trial eligibility for coverage of routine costs
- Approved device trials:

https://www.cms.gov/Medicare/Coverage/IDE/index.html

CTA Issues

- Get copy of CMS approval
  - Or, confirm trial is approved on CMS website
    - Problem: out of date
- Category A devices
  - Sponsor provides free
  - Cannot bill it
- Category B devices
  - If sponsor provides, site cannot bill

CTA Issues

- If approved by CMS, bill routine care
  - Same as "routine costs"
  - But:
    - Sponsor obligated to pay?
    - Promised free in ICF?
- Watch the budget
  - Initial draft
  - Final
- Do own analysis
  - Do not rely on sponsor's assessment

Medicare NCD

Medicare National Coverage Decision for Routine Costs in Clinical Trials – NCD 310.1

- Medicare provides coverage for
  - "routine costs"
  - in "qualifying clinical trials"

Qualifying Clinical Trials: 4-Part Test

- Trial must study an item or service that falls within a Medicare benefit category
  - e.g., drugs, DME, diagnostic tests
- Trial must have therapeutic intent
- Trial must enroll patients with a diagnosed disease
- Trial must be:
  - Funded by NIH, CDC, AHRQ, CMS, DOD or VA
  - Supported by centers or cooperative groups funded by NIH, CDC, AHRQ, CMS, DOD, or VA
  - Conducted under an investigational new drug application (IND); or
  - Exempt from having an IND under 21 CFR 312.2(b)(1)
    - drug studies not intended to change indications, labeling, advertising, route of administration or dosage, or patient population

Seven Desirable Characteristics and Self-Certification

- NCD includes a self-certification process to qualify trials based on 7 desirable characteristics in lieu of 4th criteria in QCT test
  - Self-certification process <u>never</u> developed by CMS
  - CMS has no intention of doing so
- Do <u>not</u> consider the 7 desirable characteristics
- Do <u>not</u> rely on self-certification

Routine Costs

- Items or services required solely for the provision of the investigational item or service;
- Clinically appropriate monitoring of the effects of the item or service, or prevention of complications; and
- Items or services typically provided absent a clinical trial (i.e., conventional care)

NCD includes: "Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service (such as diagnosis or treatment of complications)"

What's Missing?

- "Standard of Care"!
  - Some SOC not covered by Medicare outside trials
    - self-administered drugs
    - Screening EKGs
    - Some lab tests, absent signs or symptoms
- Term is "conventional care"
  - As stated in accepted guidelines (e.g., NCCN guidelines) or journals

What are not Routine Costs?

- The investigational item or service itself
  - unless otherwise covered outside of the clinical trial
- Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient
- Items and services customarily provided by the research sponsor free of charge for any enrollee in the trial

CTA Issues

- Sponsor template budget:
  - Services designated as SOC
  - Services for which sponsor offers to pay
- Make sure final budget synchs with:
  - Final coverage analysis
  - IRB approved ICF

Coverage Analysis

- Do one for every clinical trial
- Tells you what's billable to CMS and what's not
- Helps with budget negotiation
- Reduces risks of improper billing
- Necessary for research claims auditing
- OIG and DOJ expect to see them

False Claims Act

False Claims Act

- False Claims Act prohibits
  - knowingly filing a false claim
  - causing the filing of a false claim
  - creating a false record to get a claim paid, or
  - concealing an obligation to repay money to the federal government.
- "Knowingly" means:
  - Has actual knowledge of the information;
  - Acts in deliberate ignorance of the truth or falsity of the information; or
  - Acts in reckless disregard of the truth or falsity of the information.
- Proof of specific intent to defraud not required.

False Claims Act

- Violations subject to:
  - Treble damages
  - Civil penalties up to $11,000 per claim
  - Exclusion from Medicare and Medicaid
- *Qui Tam* suits (whistleblowers)
  - Plaintiff can receive 15% - 30% of the total recovery from the defendant
  - Big incentive

FCA Cases

Rush University Medical Center (2005)

- $1,000,000 settlement
  - Billed for research services:
    - paid for by sponsors (double billing)
    - promised free of charge to subjects
- Resulted in:
  - Certificate of Compliance Agreement ("CCA") vs CIA
  - Establishment of central research and clinical trials administration office
  - Requirement that all clinical trials receive a coverage analysis
  - Certification of compliance program with OIG annually for 3 years

FCA Cases

UAB (2005)

- Paid $3.39 million
  - Complaint alleged UAB billed Medicare and sponsors for same services
  - Also, overstated percentage of work effort devoted to grant
- Two whistleblowers received $395,000, collectively
  - Physician formerly on staff
  - Research compliance officer
- Required to:
  - Maintain compliance program at or above then-current staffing and funding levels
  - Adhere to certain compliance program requirements for 3 years

TIP

- Develop billing and claims processing controls designed to:
  - Ensure accuracy of claims submitted
  - Avoid double billing
    - Budget!
  - Avoid billing for services that are not covered outside the trial

Anti-Kickback Statute

Anti-Kickback Statute

- The Anti-Kickback Statute ("AKS") prohibits
  - knowingly and willfully
  - offering, paying, soliciting, or receiving
  - any remuneration, directly or indirectly,
  - in return for
    - referring an individual for the furnishing or arranging for the furnishing of an item or service for which payment may be made under a federal health care program, or
    - purchasing, leasing, ordering an item, good, or service for which payment may be made under a federal health care program.

- Criminal and civil penalties
  - Exclusion from federal health care programs.

AKS Research Hypothetical

- Physician employed by hospital
- PI on industry-sponsored trial
- His tasks:
  - Enroll subjects
  - Prescribe one FDA-approved heart medication to subjects
  - Make sure they filled the prescription
  - Complete a 10-question multiple-choice questionnaire for each subject
- Enrolled 15 subjects
- Practice paid $15,000 by sponsor

AKS Example

- In September 2009, Biovail Pharmaceuticals pleaded guilty to conspiracy and AKS charges
  - paid $24M for allegedly conducting a sham study
  - Also FCA violations
    - Caused false claims to be submitted
- Payments to PIs exceeded reasonable FMV of physician time to enroll subjects and complete questionnaires
- Stated objectives for the study included increasing number of prescriptions for the drug among primary care physicians
- Study not designed to provide new data on how the drug worked

AKS Cases

St. Jude Medical (2011)

- Paid $16 million settlement
  - Allegedly used postmarket studies and a registry study to pay kickbacks to physicians to induce them to use the company's pacemakers and defibrillators
  - Allegedly paid PIs up to $2,000 per subject enrolled to retain their business or convert business from another device manufacturer
- Whistleblower filed False Claims Act Qui Tam
  - recovered $2.84M

AKS Cases

Olympus Corp. (2016)

- Paid $623 million to settle AKS claims and related claims under the FCA and state false claims acts
  - Compliance with AKS is condition of receiving Medicare payments
  - AKS claim can generate an FCA claim
- The evidence:
  - Millions of dollars of "grants"
    - Grant committee mostly sales and marketing staff
  - $100k research grant to hospital
    - VP Sales: Our top account in the US and I have no intention of losing it to a competitor

Olympus (continued)

- Unrestricted research grant of $50,000 over 3 years
  - Funds held back until hospital signed deal to purchase equipment
- $5,000 grant to hospital to facilitate $750,000 sale and switch from competitor

Stark

Stark Law

- Prohibits a physician
  - from referring Medicare and Medicaid patients
  - to an entity
  - for designated health services (e.g., lab, imaging, hospital OP)
  - if the physician (or an immediate family member) has a financial relationship with the entity
    - Ownership
    - Compensation arrangements
- Entity cannot submit claims for services furnished due to a referral prohibited by Stark

Stark

- Stark law
  - "Strict liability" statute
  - Improper intent not required for violation
- Penalties for violations include civil monetary penalties and exclusion from Medicare and Medicaid
- Payment to independent physician for research services constitutes a "compensation arrangement,"
  - Independent physician may refer patients to hospital to receive designated health services
- Agreement with independent physician must meet a Stark law exception to avoid Stark violation

Stark – Personal Services Exception

- Arrangement set out in writing specifying services covered
  - Signed by both parties
  - Cover all of the services to be provided
- Services must be reasonable and necessary to accomplish legitimate business purposes of the arrangement
- Term for at least one year
  - if terminated prior to that, cannot enter the same or substantially the same arrangement during the first year of the agreement
- Compensation must be FMV and set in advance
  - cannot take volume or value of referrals or other business generated between the parties into account when determining compensation

Stark - Hypothetical

- Independent member of medical staff is PI on a study
- She is also your hospital CMO for which hospital pays her a stipend
- Entered into CTA directly with sponsor
  - Hospital is not a party to CTA
- Needs to send subjects to your hospital for required OP services
- Negotiates with your Director of Research for "research rates" well below Medicare rates for same services
- Exchange of emails documenting arrangement

Problems?

Anti-Inducement

Beneficiary Anti-Inducement Statute

- Civil monetary penalties for
  - giving something of value to Medicare/Medicaid beneficiary,
  - that person knows or should know is likely to influence the beneficiary,
  - to select a particular provider, practitioner, or supplier of item or service paid for by Medicare or Medicaid
- Civil monetary penalties up to $10,000 for each item or service

Anti-Inducement Hypothetical

- Investigator initiated trial
- PI wants to use department money to pay subjects for time and inconvenience
- Proposes $500 per 2-hour study visit plus $50 for lunch

Beneficiary Anti-Inducement – Case Study

- Payments to subjects
  - Must be reasonable pay for time, inconvenience, out-of-pocket expenses
  - Excessive compensation viewed as inducement to obtain services from the research site or investigator that are reimbursable by Medicare
- Question: would an IRB approve this study?

Beneficiary Anti-Inducement – Examples

OIG Advisory Opinion 11-16 (2011)

- Non-profit children's hospital
- Providing free transportation, meals, and lodging, to subjects
- OIG found no violation of anti-inducement statute:
  - Most funding came from philanthropic sources, not federal health care programs
  - Unlikely a patient would self-refer for unneeded care due to nature of services
  - Services designed with infection control in mind due to subjects' compromised immune systems
  - Subjects told of free services only after being accepted into the study
    - no inducement to participate

Beneficiary Anti-Inducement – Examples

OIG Advisory Opinion 17-02 (2017)

- Hospital conducting Medicare Coverage with Evidence Development ("CED") study of a FDA-approved wound care system
- Wants to waive co-pays/cost-sharing amounts for protocol-required items and services for financially needy beneficiaries.
- OIG found no violation of anti-inducement statute or the anti-kickback statute because:
  - Cost-sharing reduction/co-pay waiver not advertised
  - Study staff would mention possible reduction/waiver only after a potential study participant indicated lack of resources
  - Reduction/waiver contingent on submitting application and meeting criteria in Center's financial need policy

TIP

- Have someone not involved in the research looking at the financial arrangements of all research being conducted at your institution
- Have a mechanism designed to assure the institution is aware of all research being conducted there

Questions?

Michael C. Roach
Senior Managing Director
Ankura Consulting Group, LLC
Michael.Roach@Ankura.com