### HCCA Research Compliance Conference

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

June 6, 2018

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



Copyright 2018 Ankura Consulting Group, LLC

## 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

Copyright 2018 Ankura Consulting Group, LLC

# Medicare Coverage for Clinical Trials

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

Copyright 2018 Ankura Consulting Group, LLC

.

# Medicare Coverage for Device Trials

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

Copyright 2018 Ankura Consulting Group, LLC

# 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

Copyright 2018 Ankura Consulting Group, LLC

5

## **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    - ▶ Problem: out of date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

Copyright 2018 Ankura Consulting Group, LLC

# **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

Copyright 2018 Ankura Consulting Group, LLC

# 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"

Copyright 2018 Ankura Consulting Group, LLC

# 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

Copyright 2018 Ankura Consulting Group, LLC

9

# Seven Desirable Characteristics and Self-Certification

- ▶ NCD includes a self-certification process to qualify trials based on 7 desirable characteristics in lieu of 4<sup>th</sup> 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

Copyright 2018 Ankura Consulting Group, LLC

# **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)"

Copyright 2018 Ankura Consulting Group, LLC

11

# 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

Copyright 2018 Ankura Consulting Group, LLC

# What are <u>not</u> 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

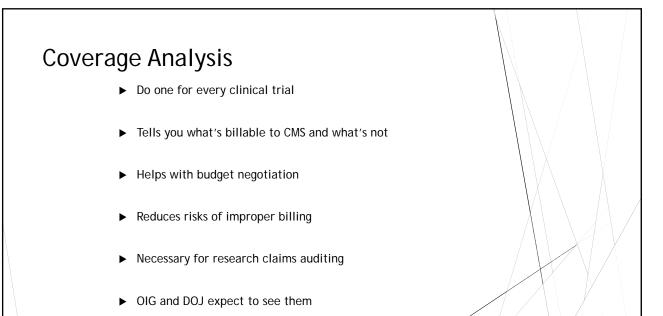
Copyright 2018 Ankura Consulting Group, LLC

13

# **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

Copyright 2018 Ankura Consulting Group, LLC



15

Copyright 2018 Ankura Consulting Group, LLC

False Claims Act

Capyright 2018 Ankura Consulting Group, LLC

16

# 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 <u>deliberate ignorance</u> of the truth or falsity of the information; <u>or</u>
  - Acts in <u>reckless disregard</u> of the truth or falsity of the information.
- ▶ Proof of specific intent to defraud <u>not</u> required.

Copyright 2018 Ankura Consulting Group, LLC

17

# 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

Copyright 2018 Ankura Consulting Group, LLC

### **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

Copyright 2018 Ankura Consulting Group, LLC

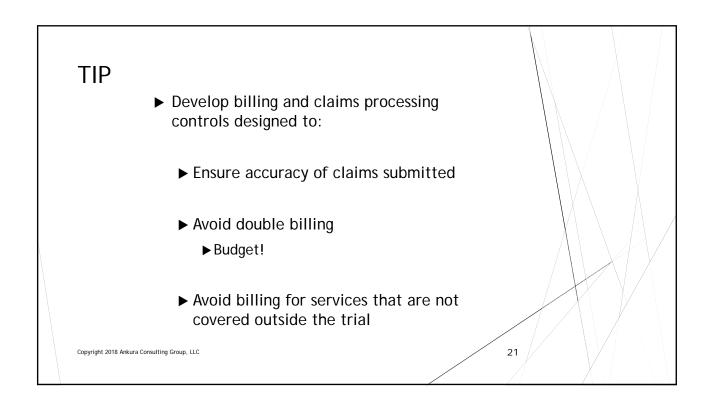
19

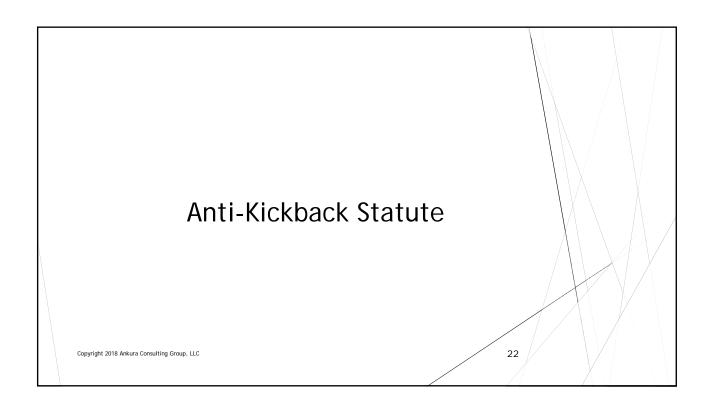
# **FCA Cases**

### 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

Copyright 2018 Ankura Consulting Group, LLC





### 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.

Copyright 2018 Ankura Consulting Group, LLC

23

# **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

Copyright 2018 Ankura Consulting Group, LLC

# **AKS Example**

- In September 2009, Biovail Pharmaceuticals pleaded guilty to conspirady 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

Copyright 2018 Ankura Consulting Group, LLC

25

### **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 Pls 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

Copyright 2018 Ankura Consulting Group, LLC

### **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

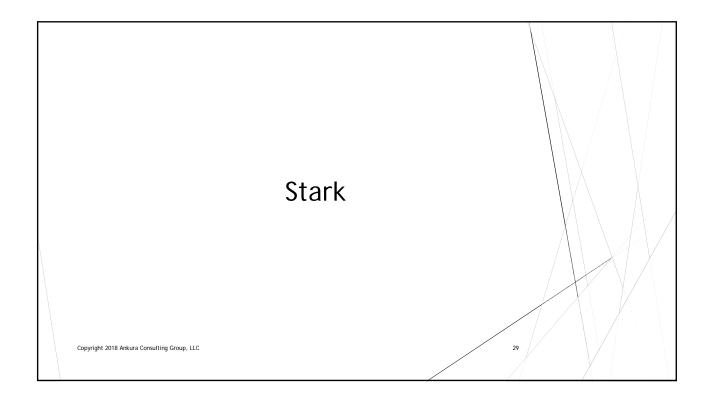
Copyright 2018 Ankura Consulting Group, LLC

27

# 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

Copyright 2018 Ankura Consulting Group, LLC



# 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

Copyright 2018 Ankura Consulting Group, LLC

31

# 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

Copyright 2018 Ankura Consulting Group, LLC

# 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?

Copyright 2018 Ankura Consulting Group, LLC

33

# Anti-Inducement Copyright 2018 Ankura Consulting Group, LLC 34

# 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

Copyright 2018 Ankura Consulting Group, LLC

35

# 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

Copyright 2018 Ankura Consulting Group, LLC

# 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?

Copyright 2018 Ankura Consulting Group, LLC

37

# 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

Copyright 2018 Ankura Consulting Group, LLC

# 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 protocolrequired items and services for financially needy beneficiaries.
- ▶ OIG found no violation of anti-inducement statute or the antikickback 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

Copyright 2018 Ankura Consulting Group, LLC

39

### 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

Copyright 2018 Ankura Consulting Group, LLC



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



Copyright 2018 Ankura Consulting Group, LLC