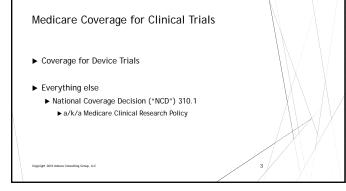


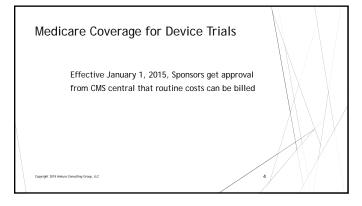
Overview

- 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

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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

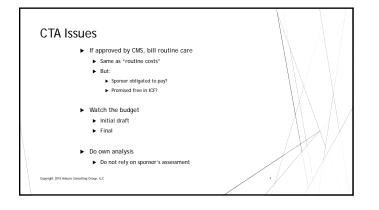
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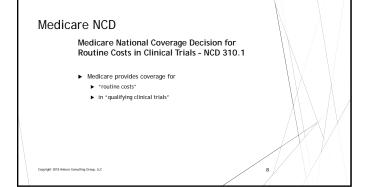
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CTA Issues

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- 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 Problem: out of date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





Qualifying Clinical Trials: 4-Part Test

- Trial must study an item or service that falls within a Medicare benefit 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

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- Exempt from having an IND under 21 CFR 312.2(b)(1) drug studies not intended to change indications, labeling, or dosage, or patient population
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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 OCT test

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- ► Self-certification process never developed by CMS CMS has no intention of doing so
- ► Do not consider the 7 desirable characteristics
- ▶ Do not rely on self-certification

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Routine Costs

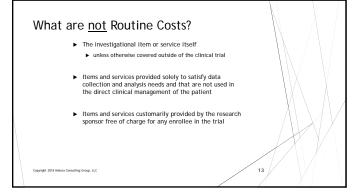
- Items or services required solely for the provision of the investigational item or service;
- Clinically appropriate monitoring of the effects of the item or service, or prevention of complications; and
- Items or services typically provided absent a clinical trial (i.e., conventional care)

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)"

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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



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

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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 prohibits

 - 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 concalling 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.

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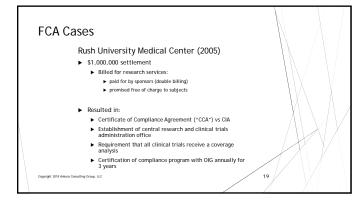
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Proof of specific intent to defraud <u>not</u> required.

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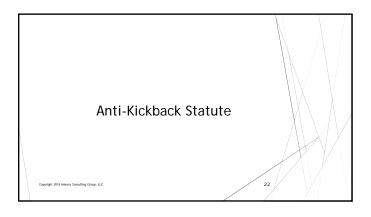
False Claims Act

- 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 UAB (2005) Pata 3.39 million Complaint alleged UAB billed Medicare and sponsors for sames. Also, overstated percentage of work effort devoted to grant You whistleblowers received \$395,000, collectively Physician formerity on staff Research compliance officer I Bequired to: Adhere to certain compliance program at or above then-current staffing and unding levels Aghere to certain compliance program requirements for 3 eases

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





- ► 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.

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Criminal and civil penalties

Exclusion from federal health care programs.

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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

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AKS Example

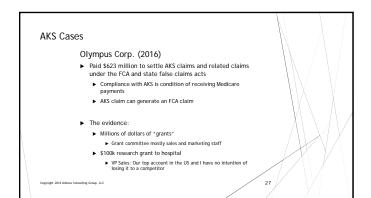
- In September 2009, Biovail Pharmaceuticals pleaded guilty to conspirady and AKS charges
 paid \$24M for allegedly conducting a sham study Also FCA violations
 - Caused false claims to be submitted
- Payments to PIs exceeded reasonable FMV of physician time to enroll subjects and complete questionnaires
- Stated objectives for the study included increasing number of prescriptions for the drug among primary care physicians

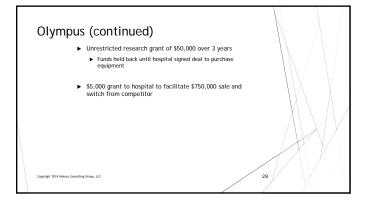
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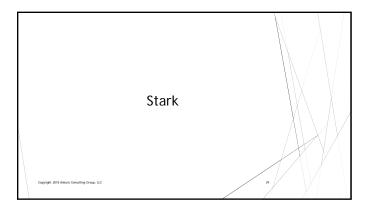
Study not designed to provide new data on how the drug worked

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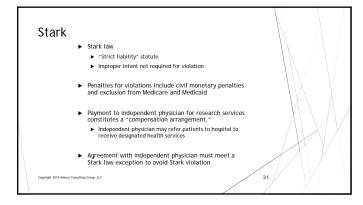
AKS Cases St. Jude Medical (2011) ▶ Paid \$16 million settlement Allegedly used postmarket studies and a registry study to pay kickbacks to physicians to induce them to use the company's pacemakers and defibrillators Allegedly paid PIs up to \$2,000 per subject enrolled to retain their business or convert business from another device manufacturer Whistleblower filed False Claims Act Qui Tam recovered \$2.84M Copyright 2018 Ankura Consulting Group, LLC 26







Stark Law Prohibits a physician Comeratoring Medicare and Medicaid patients Comeratoring Medicare and Medicaid patients



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

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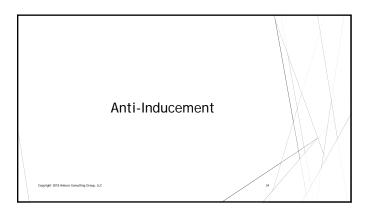
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Stark - Hypothetical

- 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?





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

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Anti-Inducement Hypothetical

Investigator initiated trial

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- 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

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Question: would an IRB approve this study?

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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

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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

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