

# CASE STUDIES IN CLINICAL RESEARCH BILLING RISK

Ryan Meade, JD, CHRC, CHC-F

Director, Regulatory Compliance Studies/Loyola University Chicago

Visiting Scholar in Law and Ethics/University of Oxford

Senior Managing Director, Ankura Consulting



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## OVERVIEW

- Case Study Theme: "It Depends"
- Case Study 1: Confusing Language
- Case Study 2: Screening Labs
- Case Study 3: Variable Billing

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“It Depends”

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## THEME: IT DEPENDS

- Baseline:
  - Medicare pays for “routine costs” during “qualifying clinical trials.”
  - But remember... “All other Medicare rules apply.”
    - NCD 310.1

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## THEME: IT DEPENDS

- Baseline:
  - And don't forget:
    - What is the sponsor paying for?
    - What is promised free in the informed consent?

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## THEME: IT DEPENDS

- What is covered by Medicare during a clinical trial?
  - **It depends!**
- What is covered during a clinical trial is not a straight answer and it definitely is not as simple as "standard of care."

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## THEME: IT DEPENDS

- It depends on:
  - The design of the study
  - What is being studied
  - Whether Medicare has a non-coverage rule on an item or service
  - Whether you can identify a “typical” enrollee
  - Institutional policies
  - Risk tolerance (is the organization going through any compliance investigations?)
  - What the sponsor wants to pay for

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## THEME: IT DEPENDS

- The coverage analysis needs to address:
  1. Qualifying clinical trial status (“approved” status for IDE device trial)
  2. Which services are “routine costs”
    - Conventional care guidelines
    - Detect or treat side effects
    - Administration of the investigational article
  3. “All other Medicare rules apply”
  4. Funding document
  5. Informed consent form

These feed into an answer on what is covered – not an easy thing to explain (or do)

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## THEME: IT DEPENDS

- The #1 issue in interacting with P.I.'s is getting them to understand that Medicare rules are different from clinical care terminology
- In other words, what is medically necessary is different from what is covered by Medicare
- Medicare covers a subset of medically necessary services.

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## THEME: IT DEPENDS

- A powerful statement....
- OIG:
  - "Physician practices should remember that "necessary" does not always constitute "covered.""
  - OIG Compliance Program for Individual and Small Group Physician Practices

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## EXPLAINING THE RULE TO PHYSICIANS

- Medicare covers “items and services” that are “reasonable and necessary to diagnose or treat illness or injury....” (Social Security Act Sec, 1862(a)(1)(A))
- **“Reasonable and necessary” does not mean whatever a physician believes is medically necessary**
- Medicare decides what is “reasonable and necessary,” not the physician
  - Remember that Medicare is just an insurer

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### Case Study 1:

### The Case of “You Know What it Means”

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## CONTRACT LANGUAGE

### Example 1

- "All of the study visit costs are included in the costs outlined above. The Per Patient Visit Costs Section of the budget represents procedures required to be performed on every patient."

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## CONTRACT LANGUAGE

### Example 2

- "Per Study Subject includes all participant-related costs and participant compensation, as well as non-participant costs such as overhead expenses and administration costs."

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## CONTRACT LANGUAGE

### Example 3

- “Neither Institution nor Principal Investigator shall bill any third party for any Study Drug or other items or services furnished by Sponsor in connection with the Study, or any services provided to patients in connection with the Study for which payment is made as part of the Study including, but not limited to, Laboratory Tests, ECG evaluations, CT scans, Bone Marrow Biopsy, and MRI.”

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## Case Study 2:

### The Case of “I Always Order That Lab”

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# SCREENING

- Myth: whenever a physician orders something, it is paid
- "Always ordering a lab" does not mean the lab is always paid or even makes it through the revenue cycle edit system
- ...and even if it is paid, that does not mean it should have been paid
  - Medicare Official Policy: "pay and chase"

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# SCREENING

- Study Screening:
  - CBC
  - CMP
  - EKG
  - Glucose
  - PT
  - PTT
  - Lipid
  - HIV

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## SCREENING

- NCD 310.1 allows coverage for "routine costs" including conventional care and detecting and treating complications but NCD 310.1 does not over-rule others NCDs
- The most powerful and forgotten sentence in NCD 310.1"
  - **"All other Medicare rules apply."**

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## SCREENING

- The Medicare program generally groups all services into three categories and can be described as follows:
  - **Therapeutic** – an intervention to improve outcomes or manage condition
  - **Diagnostic** – a test for symptomatic patients or to monitor for progression of disease
  - **Screening** – a test for asymptomatic patients
- Although there can be many rules which limit coverage for therapeutic and diagnostic tests, there is general coverage for medically necessary therapeutic and diagnostic services but Medicare does not cover what it considers "screening" services.
- Different notion of the term "screening" than is used in general medical terminology or in a research protocol.

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## SCREENING

- **“CMS interprets these provisions to prohibit coverage of ‘screening’ services, including laboratory test services furnished in the absence of signs, symptoms, or personal history of disease or injury, except as explicitly authorized by statute.”**
  - CMS National Coverage Determination Coding Policy Manual ([January 2019](#))

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## SCREENING

- **“A test service might be considered medically appropriate, but nonetheless might be excluded from Medicare coverage by statute.”**
  - CMS National Coverage Determination Coding Policy Manual ([January 2019](#))

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## SCREENING

- MAC awareness even if the MAC lacks edits
- **“The use of diagnostic testing as part of a pre-operative examination, where there is an absence of signs or symptoms indicating a need for the test, is not covered under the Medicare benefit. Such studies will be considered not reasonable and medically necessary.”**
  - NGS LCD 33629 (October 2018)

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## SCREENING

- Example: Lipid Test
- “Routine screening and prophylactic testing for lipid disorder are not covered by Medicare. **While lipid screening may be medically appropriate**, Medicare by statute does not pay for it...**Lipid testing in asymptomatic individuals is considered to be screening** regardless of the presence of other risk factors such as family history, tobacco use, etc.”
  - NCD 190.23;

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## SCREENING

- Example: PTT
- **“Hospital/clinic-specific policies, protocols, etc., in and of themselves, cannot alone justify coverage.”**
  - NCD 190.16

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## SCREENING

- **Example: EKG**
- “EKG services are covered diagnostic tests when there are documented signs and symptoms or other clinical indications for providing the service. Coverage includes the review and interpretation of EKGs only by a physician. **There is no coverage for EKG services when rendered as a screening test** or as part of a routine examination unless performed as part of the one-time, “Welcome to Medicare” preventive physical examination under section 611 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.”
  - NCD 20.15 (emphasis added)

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# SCREENING

- **Example: EKG**
- "An ECG may help identify cardiac disorders **as part of a preoperative clinical evaluation**. A preoperative ECG may be reasonable and necessary under one of the following conditions:
  - In the presence of pre-existing heart disease such as congestive heart failure, prior myocardial infarction (MI), angina, coronary artery disease, or dysrhythmias;
  - In the presence of known comorbid conditions that may affect the heart, such as chronic pulmonary disease, peripheral vascular disease, diabetes, or renal impairment; or
  - When the pending surgery requires a general or regional anesthetic."
- "An ECG is not a covered benefit when used for screening purposes or as part of a routine physical examination. Routine physical examinations (screening) are evaluation and management services supplied in **the absence of associated signs, symptoms or complaints**. These services are denied as not a benefit of the Medicare program. Patients may choose to pay privately for these services. ."
  - Noridian LCD 34315 (emphasis added)

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## Case Study 3:

### The Case of "But Everybody Does It"

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# VARIABLE BILLING

- Variable billing: billing insurance differently for different subjects in the same study
- Example:
  - The sponsor pays for X-service for Subject 1 in Study A
  - The site bills insurance for X-service for Subject 2 in Study A

CMS's assertion on the law in play: "No Legal Obligation to Pay":

The statute sets out exclusion from coverage "for which the individual furnished such items or services has no legal obligation to pay, and which no other person (by reason of such individual's membership in a prepayment plan or otherwise) has a legal obligation to provide or pay for, except in the case of Federally qualified health center services."

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# VARIABLE BILLING

## Example 1

- Subject 1 is Blue Cross and Subject 2 is Medicare.
- Subject 1 receives X-service at a specific time point but Blue Cross denies coverage for X-service.
- The sponsor's budget allows invoicing to the sponsor for services that are denied coverage by the subject's insurer. The site invoices the sponsor for Subject 1.
- When Subject 2 receives X-service, it is covered by Medicare so the site bills Medicare.

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## VARIABLE BILLING

- Under CMS's view, billing Medicare for X-service for Subject 2 would be inappropriate.
- Although X-service is generally covered by Medicare, a non-Medicare subject has received the service without charge to the subject (paid by the sponsor) and therefore Medicare should have no obligation to pay because the sponsor has taken on the risk of paying for subjects for X-service.

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## VARIABLE BILLING

### Example 2

- Subject 1 is Blue Cross and Subject 2 is Medicare.
- Subject 1 is scheduled for X-service under the protocol and presents with no signs and symptoms so that X-service is not medically necessary and may be invoiced to the sponsor.
- Subject 2 presents for X-service under the protocol but has signs and symptoms such that the service is medically necessary and would otherwise be covered by Medicare.

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# VARIABLE BILLING

## Example 2

- Medicare would assert that it has no legal obligation to pay because the sponsor has taken on the risk of paying for X-service under the budget and has indeed already paid for a non-Medicare patient.

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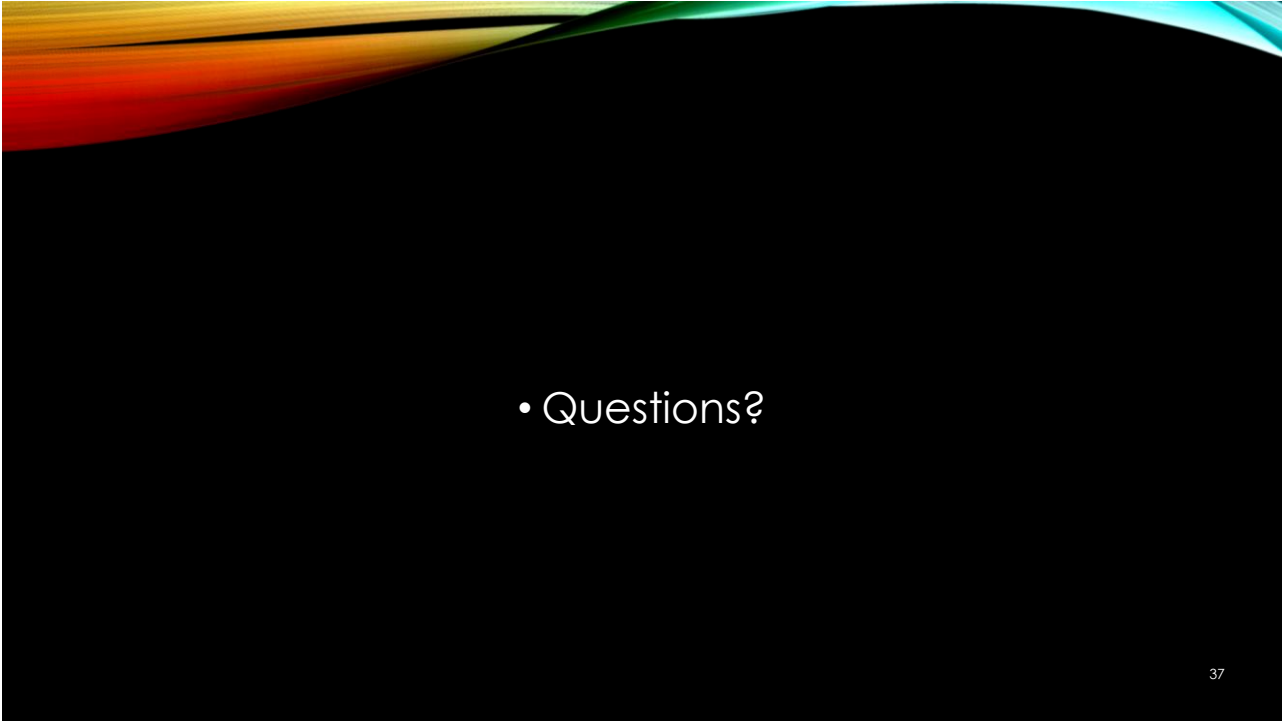
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# VARIABLE BILLING

- Note exception:
  - Indigency
  - "Medical indigency"
  - MLN Matters Article SE0822

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• Questions?

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