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102 – Tricky Clinical Trial Budget and Research Billing Compliance Issues Inherited from Mergers & Acquisitions

Mercy Research

*Insert SCCE/HCCA slide for instructions on obtaining & accessing polling app

Session Overview

What follows is a series of simple, mock debates around three independent research billing compliance scenarios.

Presentation Disclaimer:

Material presented, statements of opinion, and comments by presenters do not necessarily reflect the viewpoint, policies, or practices of themselves, or their organization. The positions presented are intended to present arguments, and challenge attendees to choose an option based on session arguments along with personal opinions.

Introductions

- **JoAnne Levy, JD**
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  St. Louis, MO
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  Madison, WI
- **Ray Heller**
  Senior Director
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Audience Composition Poll #1

Organizations represented

- Academic Medical Center
- Integrated Healthcare Delivery System (multiple points of care/research)
- Community Hospital (single site)
- Physician Group
- Sponsor/CRO
- Other

Audience Composition Polls #2

Your primary perspective you bring to research compliance:

- Clinical
- Compliance / Legal
- Finance
- HRPP (IRB) / Ethics
- Research operations

Audience Composition Polls #3

How would you characterize your “expertise” on research billing compliance challenges?

- High (i.e. “expert” or well-versed)
- Intermediate
- Low (novice or relatively new to the world of research billing)

Assumptions Throughout Scenarios

- The challenges uncovered were identified as part of due diligence review upon two organizations coming together. The organizations are committed to the acquisition/merger and solutions must be found.
- Studies are already underway and the option of "declining to participate" in the trial(s) is not an option.
- Principal Investigators for the studies identified are respected, successful, influential, and operating under a spirit of good intent. There is no reason to infer motive(s) as anything less than trying to conduct a successful clinical trial.
- No PI will accept closure of her/his Study.

Debate #1: Background

- Both organizations have the same trial open, and currently enrolling in geographic areas that do not compete for participants.
- FDA approved meds for the disease are currently oral administration, but do not have great response rates.
- Study Drug is an infused med, and Sponsor is providing drug free of charge.
- Study budget covers drug infusion/administration (both tech & prof) fees for all treatment cycles.

Background #1 continued

- Protocol makes suggestions on possible patient comfort meds for side effects (i.e. anti nausea, etc.), but specifically indicates decisions are up to Investigator.
- Study budget has no monies specifically allocated for comfort meds, and no provision for “reimbursement by invoice”.
- Comfort meds are not extremely expensive, but there is low predictability on frequency they will be needed or how long subject will be on Study.

Debate #1: The Challenge

- The two organization handle comfort med charges differently:
  - Organization A bills comfort meds to Study
  - Organization B bills for comfort meds as SOC based on side effects from the infused Study Drug
- **Finance has requested establishment of a single methodology, and for it to be implemented for the remainder of the current Study.**

Debate #1

- Bill Comfort Meds

- Study absorbs cost of Comfort Meds

Debate #1 Audience Poll

Which position do you agree with?

Bill Comfort Meds

Comfort Meds cost absorbed by Site

Debate #2: Pediatric Research

- Both organizations have a large portfolio of clinical trials for pediatric patients, and are providers of choice for family medicine.
- Org A considers its children's hospital a "research hospital", with the perspective that participation in clinical trials **is its standard of care** and therefore billable to all payors.
- Org B "carves out" pediatric studies from Coverage Analysis review of CMS decisions, and strictly focuses on ensuring nothing paid for by Sponsor is also billed to 3rd party payor.

The Plot Thickens…

- Org A does not bill patients (families) copays, coinsurance, or deductibles if a research participant.
- Org A has an “opinion letter” from a federal review agency in 2001, indicating this practice is non-compliant but indicating OIG will take no action against UM for this practice.
- The new organization wants a single methodology for handling pediatric clinical trials research billing. What is the solution?

Debate #2 Audience Poll

Time to vote again! Which solution do you prefer?

Org A solution is preferred

Org B solution is preferred

Debate #3: Background

- M. Mouse, MD is a preeminent PI on a recently opened trial at Magic Kingdom Health.
- Currently there is only a **single subject** enrolled, with three study visits completed. Study drug has been administered at each of the three visits.
- Charges for the visits (a mix of Sponsor paid and SOC) are currently in the billing queue and have not been processed.
- Disease is almost certainly fatal, and FDA approved therapies only extend survival period; they are not curative.

Background 3 (continued)

- Earlier study publications are gaining notoriety due to a reasonable “cure rate” shown. As such, patients are beginning to contact Sites to be screened for the current trials.
- **Enrollment is expected to boom.**
- The Sponsor – a small bio-pharma company – has authorization from FDA to charge for the direct costs of Study Drug manufacture. It is substantial, but not exorbitant.
- There is room in the Study Budget to absorb Study Drug cost, for up to four visits per participant.

To complicate matters…

- Dr. Mouse's organization (MKH) does not routinely perform Coverage Analysis on trials; your team's review identified the following:
  - Appendix in the CTA for Site ***purchase*** of Study Drug from Sponsor.
  - Notes in Study Folder re: creation of a charge code for Study Drug, and question of whether drug will be billed or charged to the Study. **No decision has been made yet.**
  - IRB approved Informed Consent indicates Site is purchasing Study Drug from Sponsor, but does not explicitly state whether will be billed to insurance.
  - "….services not covered by Sponsor, and determined to be billable to insurance may be submitted for reimbursement….services not covered by insurance…."

DEBATE #3: To bill, or not to bill…

- Study Drug cost absorbed by Site

- Study Drug billed to 3rd Party Payor (insurance)

Debate #3 Audience Poll

Time to vote! Which argument do you agree with?

Bill Study Drug

Study Drug cost absorbed by Site

THANK YOU for joining us!

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