

Two-Headed Beast: Compliance and Research Billing

Kelly Willenberg, DBA, RN, CHRC, CHC, CCRP

Ryan Meade, JD

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Two Headed Beast



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How Does Compliance and Research Billing Intersect



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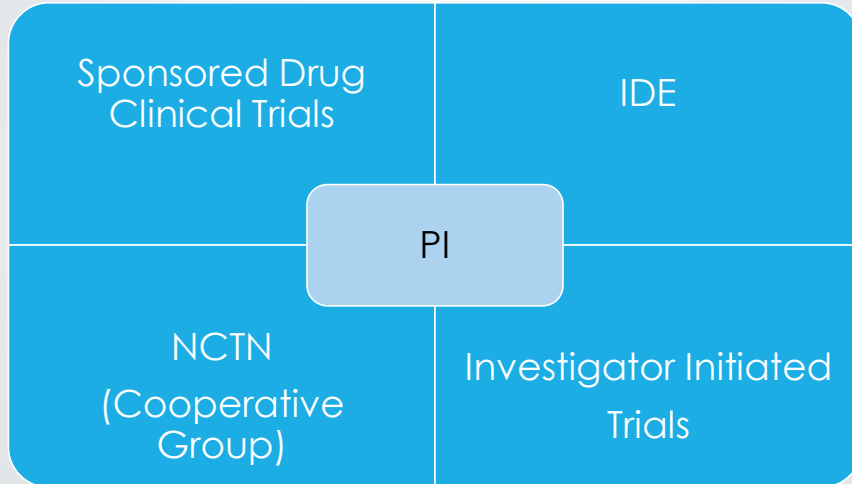
Business Function of Billing

- Coverage Analysis
- Budgeting and Contracting
- Charge Segregation
- Invoicing to Sponsors
- Reconciliation of Accounts Receivable
- Payer Management Controls
- Denial and Appeals Management
- Write Offs or Research Off the Books

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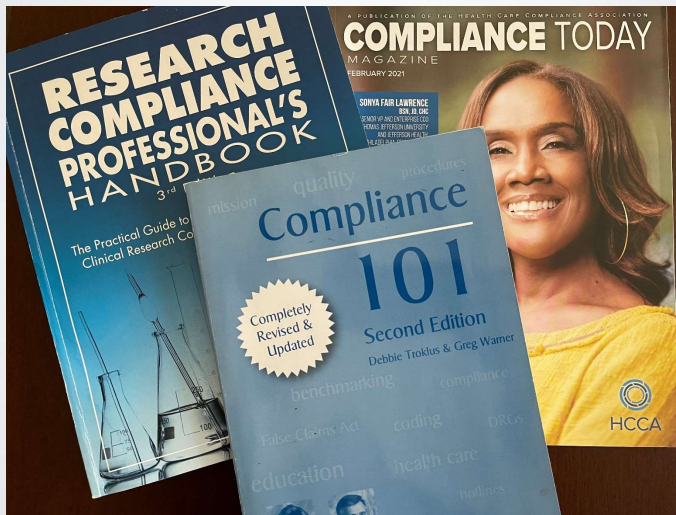
The Beast is Different with Types of Studies



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Compliance



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Mitigating Risks – A Do-it-Yourself Quick Check

Foundational Questions

KNOWING is the first step to risk mitigation

1. Know the process flow – how does information get from A to B
 2. Is your organization doing a Coverage Analysis? (pivotal risk question)
 3. Is your organization using a Coverage Analysis? (pivotal risk question)
- These questions can help assemble the information for compliance reviews and operations' risk management

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Mitigating Risks – A Do-it-Yourself Quick Check

Foundational Questions

1. Know the process flow – how does information get from A to B?
 - A. Who is doing what?
 - B. Are studies triaged for Coverage Analysis needs?
 - C. Where are the study documents stored?
 - D. Where are the Coverage Analyses stored?
 - E. Who identifies enrolled subjects to the billing process?
 - F. Is a subject identified to the billing process and all charges reviewed or are study teams flagging specific encounters as related to the study?
 - G. Is the process “consistent” and auditable?

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Mitigating Risks – A Do-it-Yourself Quick Check

Foundational Questions

2. Is your organization *doing* a Coverage Analysis?

- A. Who does the Coverage Analysis?
 - Centralized office?
 - Decentralized, done by study teams?
- B. Does your Coverage Analysis development have a quality review check?
- C. Has the Coverage Analysis format been vetted by the billing office? (it needs to be usable)
- D. Are the following included in the Coverage Analysis?
 - Clear billing designations
 - Reasoning for decisions
 - Reasoning that links back to NCD 310.1 and other Medicare billing rules?
- E. Is the final Coverage Analysis that goes to the billing office “synced” with the final study documents?
 - Final/executed Clinical Trial Agreement (including budget)
 - IRB-approved Informed Consent Form

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Mitigating Risks – A Do-it-Yourself Quick Check

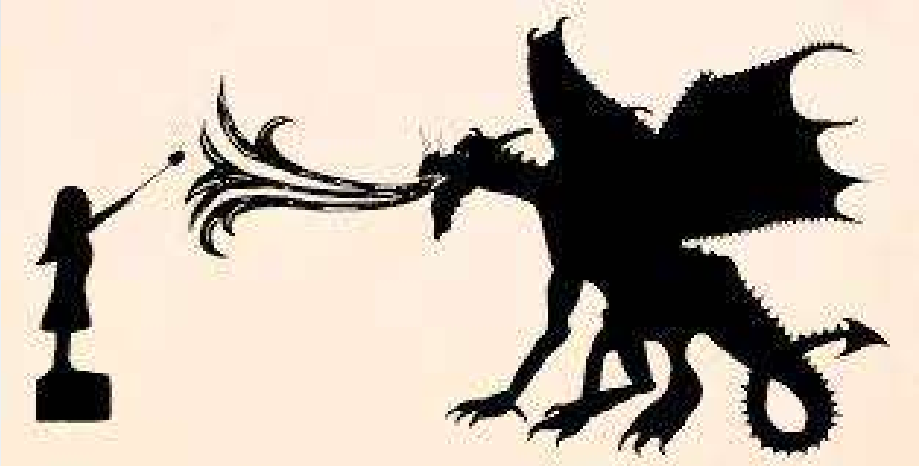
Foundational Questions

3. Is your organization *using* a Coverage Analysis?

- A. Who does claims review? (identify a *human!*)
- B. Do they have access to the Coverage Analysis?
- C. How does the claims reviewer know where the subject “is” on the study calendar?
- D. Are Q1/Q0 modifier, Z00.6 Dx code, NCT# placed on claims?
- E. Are research-related claims directed to the MAC instead of the Medicare Advantage plan for patients with Part C services? (only applies to non-device studies that are QCTs under NCD 310.1)
- F. Are charges that are not billable to insurance *written off/adjusted or charged to the study account?*
- G. Are invoiceable items and services actually invoiced to the sponsor?

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*Now you have collected information
to begin taming the beast!*

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Discussion and Questions?

- ▶ Kelly Willenberg, DBA, RN, CHRC, CHC, CCRP
 - ▶ Kelly@kellywillenberg.com
 - ▶ 864-473-7209
 - ▶ kellywillenberg.com
- ▶ Ryan Meade, JD
 - ▶ ryan.meade@bfriars.ox.ac.uk
 - ▶ Faculty of Law, University of Oxford

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