Research Billing I: The *Most Basic* Basics

Clinical Research Resources Office
14 February 2024

Poll 1: What description best fits your role?

1. Clinical research coordinator
2. Clinical research financial analyst/manager
3. Regulatory specialist, study team or department
4. IRB administrator
5. Department administrator
6. Investigator
7. Other

Poll 2: Does your role include attention to research billing?

1. Yes, directly
2. Yes, indirectly
3. No
4. I am not sure

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Primary objectives*

1. Understand basic research billing compliance (RBC) requirements
2. Identify the range of studies subject to them
3. Consider the role of RBC in protecting participants and providers

**Discussion of the BMC/BUMC RBC process is Part II, 13 March*

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Contextualizing research billing compliance

- Scope of relevance: any study that includes **≥1 clinical provisions**
- In the last 16 years: graduated from hot topic to perennial **top risk***
  - In response to federal rulings in 1995, 2000
  - Initial codification: **~30 years after human subjects protections'**
  - Centers for Medicare and Medicaid Services (CMS) has primary oversight**
    - Some CR clinical items are "routine," – billable to federally insured patients***
  - Non-compliance is subject to **significant penalties**
  - (How) does research billing risk relate to **research ethics**?

**https://assets.hcca-info.org/Portals/0/PDFs/Resources/ResourceOverview/650_0_TopRiskAreasResearchComp.pdf*

***CMS rules span across many federal payers; often "Medicare" is employed as a synonym*
**** "Standard of care" is frequently used as a synonym for "routine"*

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Scope of relevance: clinical research

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For RBC purposes, clinical research = ≥1 clinical item

- Whenever protocol includes **≥1 clinical "procedures, services, or other items"***
- **Interventional or observation** studies
  - Intended or not to affect health outcomes
  - Sponsored internally or externally
- **Range of study's clinical services:** buccal swab to organ transplant
  - IRB requirement tends to conform with RBC need but is neither necessary nor sufficient
  - FDA-regulated and federally sponsored CR are subject to extra requirements
- Context paradigm: services provided in BMC clinic and documented, coded, and billed in electronic medical record (EMR)
  - Exceptions do not exempt provider from RBC
  - Services are billed separately as **practitioner** (professional) or **institutiona**l (technical) to same CMS administrator
    - Match is expected

CMS terminology to cover all billables; includes surgeries, office visits, labs, images, drugs, devices, sutures:* everything *is coded

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Some studies are excluded from coverage; most require special RB claims modifications

Routine care **includes** items provided, in an active or control arm, that are:

- Conventional care (= the care that the patient would receive anyway)
- Needed "solely" to provide the investigational item
  - E.g., chemotherapy administration charges
- Used for "clinically appropriate" patient monitoring
- Needed to diagnose, prevent, or treat complications

Routine care ***excludes*** item(s) provided:

- For **data-collection** purposes only (beyond clinical management of the patient)
- As the **object of the investigation**, unless it is "conventional care

Content paraphrased from National Coverage Determination 310.1, issued in 2000, modified in 2007

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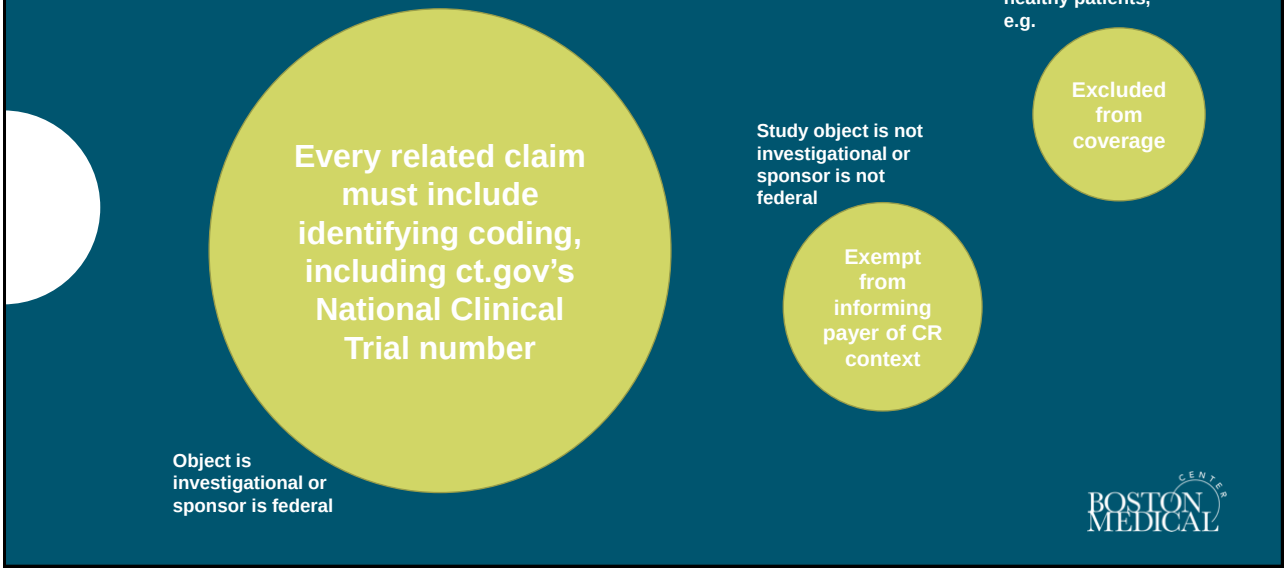
Federal allowance of routine items ultimately results in three categories of clinical research, relative to RBC



Risks of non-compliance

Misbilling and its discontents

Research billing non-compliance = **misbilling**

- Most egregious: charge participant when sponsor is the required payer
- Times two: charging participant *and* sponsor = **double billing** (and double credit to professional provider)

Challenges

- Billing is frequent
- Electronic medical record: not designed to manage RB's twin oddities
  - **Alternative payer**: sponsor
  - **Alternative reason for service**: data collection
- Medical coding = identification of exact services provided = intricate with pitfalls
  - Special research claims modifications for most; absence of them for others
  - **Clinical documentation** must support submitted claims

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Misbilling federal payers violates the False Claims Act*

- Individuals (eg, clinicians) and institutions are liable
- Civil and criminal penalties
  - **Criminal**: requires "knowingly" committing fraud but systemic negligence counts
- Every instance of discovered federal overpayment faces
  - **Penalties**, adjusted annually, 2/12/2024: **$13,946-$27,894****
  - Damages, trebled: overpayment amount x 3
- Quickly adds up
  - Moffitt Cancer Center agrees to pay **$19.5m**, 4 January 2024***
    - Items "provided during research studies that were not eligible for reimbursement"
- Note: the FCA is invoked in effort violations with similar high settlements

**** Also possible: exclusion from participation in federal insurer payments***

*** https://www.federalregister.gov/documents/2024/02/12/2024-02829/civil-monetary-penalties-inflation-adjustments-for-2024*

**** https://www.justice.gov/opa/pr/florida-research-hospital-agrees-pay-more-195-million-resolve-liability-relating-self*

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Following standard medical billing, RBC = no free services!

*Without positive financial needs assessment, no service may be provided without charge**

- CMS demands that beneficiaries receive the lowest price
- If a provider does not charge a patient, or documents a lower service but provides a higher service, a new Medicare beneficiary price is established
- Applies to:
  - **Every patient**, including study participants
  - **Every service**, direct or ancillary, professional or technical
- Research presents a susceptible context:
  - Failure to bill the participant or the sponsor = **free service**

Or at a rate lower than the applicable federal rate

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Beyond billing patient/insurance

Services provided outside of standard BMC clinic (external to Epic, may or may not employ medical coding)

1. **Research cores/recharge centers**
   - Cannot misbill participants: no routine services apply
   - Nevertheless, strong documentation required to prevent audit alerts, establish compliance with federal cost principles

2. **Effort instead of medical coding: rife with violation** potential
   - Professional (pro) and technical services are tandem charges
   - Effort = pro service only; technical applies even when use of effort is compliant
     - Somewhat distinct electronic pathways but audit-susceptible
     - Absence of pro charges raises flags
     - NIH: accepts pro services as effort; requires routine tech services to be billed as routine

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Do the responsibilities of RBC fall within research ethics?

-- Most violations appear to go undetected
-- Healthcare institutions vary in formal diligence
-- Research-related regulations are disparate
-- …

Summary

Research billing basics: recap

- **Relevant whenever a study includes ≥1 prospective clinical services**
- **Narrow context**: in play whenever a patient-care charge is generated in the context of research
  - Protocol-specified or for treatment of a study-related adverse event
  - At BMC, the required clinical documentation and charging occur through Epic
  - May be billable to the patient/insurance or to the sponsor
  - If the study is a clinical trial, most likely requires special claims modification
  - Failure to add complete set of modification results in claims rejection (= loss of revenue)
- **Larger context, less understood**: whenever a study-related clinical item occurs
  - Recharge center/core billing by federal requirements
  - Charged to sponsor as time and effort
  - Should have been billed or charged as time and effort but wasn't
- **Penalties** for non-compliance **are significant**
- **Ethical research stewardship** includes commitment to RBC(?)

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Appendix: background for Part II

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Allowance of research-related routine services fundamentally altered CR compliance

1. Analysis at the item level: **routine or research-only**
   - Inexact, time-consuming: robust documentation needed
   - Frequency and extent of service matter
   - Clinicians vary in clinical practice history
2. Analysis of **study characteristics**
   - Relatively simple determination:
   - Follow-through is complex
3. Identification of **study participants/visits**, including documentation of:
   - exact items provided (and not provided)
   - treatment of study-related adverse events
4. Charge "segregation" for billing review and, for most CR, claims modification
5. **Back-end confirmation** of correct payer for each clinical item
6. Over time, **standard process** features evolved and were shared

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Upcoming presentation March 13th on the BMC RBC Process including:

- **Coverage Analysis**
  - Analysis at the item level
  - Analysis of study characteristics
- Identification and documentation of **study participants/visits**
- Charge **"segregation"** for billing review
- RBC **Systems**
  - Clinical Trial Management System
  - Electronic Health Record System
- Charge **"segregation"** for billing review
- **Back-end confirmation** of correct payer for each clinical item

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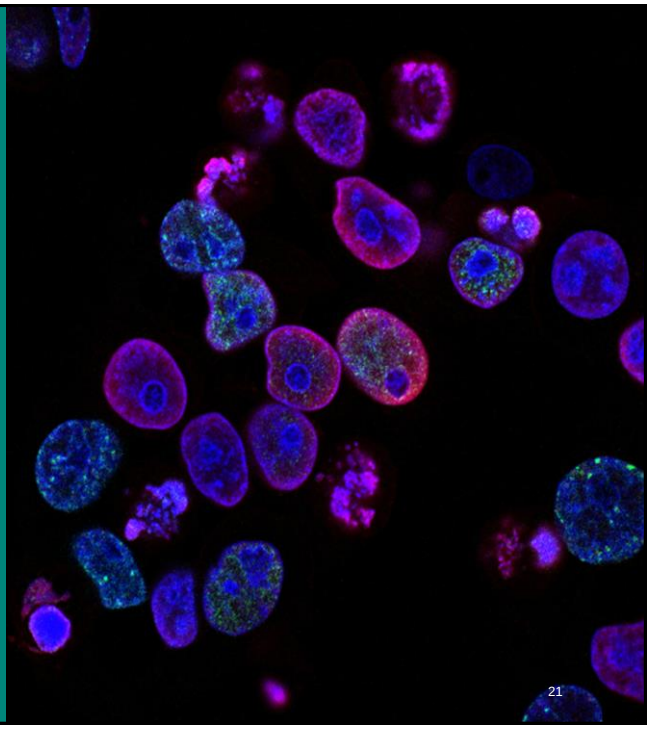
References

- 1995: U.S. allows Medicare billing related to investigational devices: 42 CFR 405.201-213 Medicare Services Coverage Decisions That Related to Health Care Technology (amended 2004, 2013, 2021)
- 2000: Medicare extends billing to "clinical trials", National Coverage Determination 310.1 (amended 2007)
- Medicare Claims Processing Manual, Chapter 32, especially §§68-69 (investigational devices; qualifying clinical trials)



Contact the speakers

Mike Porreca
Senior Manager, Clinical Trial Office
Research Operations
Boston Medical Center
michael.porreca@bmc.org

Kaye Mottola
Research Policy, Education, and Communications
Research Operations
Boston Medical Center
kaye.mottola@bmc.org