Clinical Research Billing and Related Compliance Issues

BMC/BU Medical Campus – Clinical Research Seminar

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PRESENTATION OVERVIEW

• Describe the nexus between research and clinical care activities and the operational and compliance challenges

• Set out the regulatory framework for these activities and the applicability of the False Claims Act to clinical research

• Overview of Medicare Clinical Trials Billing Policy and related rules for compliant billing and for the protection of study participants

• Highlight the requirement of collaboration to facilitate compliance to protect the integrity of clinical research on the Boston Medical Center – Boston University Medical Campus
THE BMC – BU MEDICAL CAMPUS
ACADEMIC MEDICAL CENTER

• BMC and BU are separate legal entities

• Shared mission to provide healthcare, teaching and research

• Healthcare and research are each supported by government programs

• BMC and BU each receive NIH and other federal funding for research
60-80% of BMC’s patients are beneficiaries of Medicare/Medicaid programs

Healthcare and research are heavily regulated

Rules are designed to prevent fraud and abuse, to protect the patient or the research subject, and to preserve integrity through transparency

The Department of Health and Human Services has primary oversight of government funded research and healthcare programs
HHS OFFICE OF INSPECTOR GENERAL (OIG)

- Charged with overseeing nearly $1 trillion dollars in HHS spending (~1/4 of every Federal dollar spent)
- Oversight of Medicare and Medicaid and other programs under HHS institutions, NIH, CDC, FDA
- Uses advanced data analytics to eliminate fraud, waste and abuse
- First half of FY 2016, OIG reported expected recoveries of more than $2.77 billion, 428 criminal actions against individuals or entities that engaged in crimes against HHS programs, and 383 civil actions, which include CMP settlements, false claims and unjust-enrichment lawsuit

FALSE CLAIMS ACT

• Healthcare fraud is a top enforcement priority of government agencies
• Federal government recovered nearly $16.5 Billion from healthcare fraud enforcement January 2009 –2015
• FCA establishes liability for anyone who submits a false claim for payment to the government - specific intent not required
• Federal penalties for violating the FCA are severe and include fines up to 3x the amount of each claim, plus a penalty of up to $21,562 per claim - possible exclusion from federal health care programs
• Obligation to respond promptly when there is a reason to suspect potential overpayment (potential liability for reverse false claim)
NO INDUCEMENTS TO USE HEALTH CARE PROGRAMS

- Anti-kickback laws are designed to prevent fraud and abuse of public funds that are used to support health care programs
  - Criminal liability for anyone who knowingly and willfully receives, gives, solicits or offers any payment or other form of remuneration with the intent to induce or influence the purchase, order, or referral of drugs, devices, products, services or other items reimbursable under a federal health care program – **NO BRIBES**

- Civil monetary penalties against any person who offers or transfers to a Medicare or Medicaid beneficiary any remuneration that the person knows or should know is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier of Medicare or Medicaid payable items or services
  - “Remuneration” defined to include “**waivers of copayments and deductible amounts** (or any part thereof) and **transfers of items or services for free** or for other than fair market value” [https://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf](https://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf)
RESEARCH RELATED FALSE CLAIMS SETTLEMENTS

University of Alabama at Birmingham paid $3.39 M to settle claims that it overstated the percentage of effort devoted to grants and that it billed Medicare for trials that were also billed to the sponsor (April 2005)

Medtronic paid $23.5 M to settle claims that it had violated the False Claims Act by using physician payments related to post-market studies and device registries as kickbacks to induce doctors to implant Medtronic pacemakers and defibrillators (December 2011)

Emory paid $1.5 M for billing Medicare and Medicaid for clinical trial services that sponsor had agreed to pay for and in some cases, had paid, resulting in being paid twice for the same service (August 2013)

University of Florida paid $19.87M to settle claims that it had overcharged salary and administrative costs on hundreds of federal grants (November 2015)

Columbia University paid $9.5M to settle claims that it sought and received excessive cost recoveries (July 2016)
THE CONVERGENCE OF HEALTHCARE AND RESEARCH

• Although funded and regulated by agencies within the Department of Health and Human Services, research and healthcare activities are typically separate.

• The activities converge when either BMC or BU’s research activities involve BMC patients and BMC clinical infrastructure.

• The separation between research and clinical care reimbursement poses operational and compliance challenges.
CLINICAL TRIAL BILLING

• Depending on the study, Medicare will pay for certain services for beneficiaries that participate

• The rules are fairly straightforward:
  – Do not bill for services the sponsor is already paying for (double billing)
  – Do not bill for services that were promised free to the participant
  – Do not bill for services that are for research purposes only
  – Only bill for services that have no external funding source and are medically necessary

• Academic medical centers have developed centralized processes to create connections between research and billing departments to ensure that study costs are billed properly

To encourage clinical trial participation by older Americans, on June 7, 2000, the President issued an executive memorandum, which directed the Secretary of Health and Human Services to authorize Centers for Medicare & Medicaid Services (CMS) to cover the routine costs.

On September 19, 2000, CMS issued National Coverage Decision (NCD) 310.1 Routine Costs in Clinical Trials, which was last reviewed in 2007.

CMS NCD 310.1 states:

“Medicare covers the routine costs of qualifying clinical trials, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. **All other Medicare rules apply.**”

“Routine costs of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries that are provided in either the experimental or the control arms of a clinical trial” with specific exceptions.

http://www.cms.gov/medicare-coverage-database/
CMS NCD 310.1 ROUTINE COSTS OF QUALIFYING CLINICAL TRIALS

• All items and services typically covered absent a clinical trial (conventional care)

• Items or services required solely for the provision of the investigational item or service (e.g. administration of a non-covered chemotherapeutic agent)

• Items and services provided for the clinically appropriate monitoring of the effects of or prevention of complications from the investigational item

• Items or services needed for reasonable and necessary care arising from the provision of the investigational item or service – in particular for the diagnosis or treatment of complications

NOT ROUTINE COSTS

- The *investigational item or service*, itself unless otherwise covered outside of the clinical trial

- Items and services provided solely to satisfy data collection and analysis needs and that are **not used in the direct clinical management of the patient** (e.g., monthly CT scan for a condition that usually requires only one scan)

- Items and services **provided by the research sponsors free of charge** for any enrollee in the trial

QUALIFYING CLINICAL TRIAL MUST MEET THREE REQUIREMENTS

- The trial must involve the evaluation (investigation) of an item or service that falls within a Medicare benefit category and is not statutorily excluded from coverage.

- The trial must have therapeutic intent and not be exclusively designed to test toxicity or disease pathophysiology.

- The trial must enroll patients with diagnosed disease rather than healthy volunteers (trials of diagnostic interventions may enroll healthy patients as controls).

QUALIFYING CLINICAL TRIAL MUST ALSO HAVE SEVEN DESIRABLE CHARACTERISTICS

- Principal purpose is to test whether the intervention potentially improves participants’ health outcomes

- Well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use

- Does not unjustifiably duplicate existing studies

- Design is appropriate to answer the research question being asked

- Sponsored by a credible organization or individual capable of executing the trial successfully

- In compliance with Federal regulations related to the protection of human subjects

- Conducted according to appropriate standards of scientific integrity

4 TYPES OF TRIALS AUTOMATICALLY DEEMED TO MEET 7 DESIRABLE CHARACTERISTICS AND ARE QUALIFIED

• Funded by NIH, CDC, AHRQ, CMS, DOD, VA

• Supported by center or cooperative groups that are funded by NIH, CDC, AHRQ, CMS, DOD and VA

• Conducted under an investigational new drug application (IND) reviewed by the FDA

• Exempt from having an IND under 21 CFR 312.2(b)(1)

ALIGN BILLING WITH IRB APPROVAL OF RESEARCH

• 45 CFR 46.116 and 21 CFR 50.20 General Requirements of Consent. Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject’s legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence…” (no inducements)

• 45 CFR 46.116(a) and 21 CFR 50.25(a) Basic Elements of Informed Consent, which includes at (a)(6) for research involving more than minimal risk, the requirement that the ICF include: “an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.” (must include subject injury language in the ICF)

• 45 CFR 46.116(b) and 21 CFR 50.25(b) Additional elements of informed consent, which includes at (b)(3), when appropriate ICF must include “any additional costs to the subject that may result from participation in the research.” (co-pays and deductibles if billing insurance for routine care)
QUALIFYING CLINICAL TRIAL CODING AND BILLING REQUIREMENTS – ALL OTHER MEDICARE RULES APPLY

- Claims must be accurate, supported by the medical record, be for medically necessary services that were actually performed.

- For QCT, beneficiary’s medical record must contain: trial name, sponsor, and sponsor-assigned protocol number.

- ICD-9 diagnosis code V70.7/ICD-10 diagnosis code Z00.6 (in either the primary/secondary positions).

- HCPCS modifier Q0 or Q1 as appropriate.

- Mandatory clinical trial number (NCT) for claims of items and services submitted on or after January 1, 2014.

Clinicaltrials.gov was launched in 2000 in response to FDA Modernization Act of 1997, which required HHS, through NIH, to establish a clinical trials registry.

The registration requirements were expanded by the FDA Amendments Act of 2007, which required result reporting for trials involving FDA regulated products.

On September 16, 2016, HHS issued the final rule for Clinical Trials Registration and Results Information Submission, which clarified and expanded the registration and results submission requirements (compliance date 90 days after January 18, 2017)

- Grant funding can be withheld
- CMP of up to $10,000/day

NIH Policy requires registration and result reporting of all NIH funded studies

- Suspend or terminate grant funding
- Noncompliance may be considered in future funding decisions

CMS will be able to use NCT number to evaluate claims being made for payment under the Clinical Trials Policy.
Number of Registered Studies Over Time and Some Significant Events (as of September 15, 2016)

Source: https://ClinicalTrials.gov
CREATE THE CONNECTION BETWEEN THE STUDY AND BILLING

• Rush University Medical Center paid $1 M after self-disclosing that it had billed Medicare for services performed in cancer research studies that were not reimbursable (December 2005) (double billing and promised free)

• Accurate Billing is Driven by Coverage Analysis
  – Coverage Analysis (CA) is a detailed review of clinical research items, services, procedures and Medicare billing rules to determine the appropriate payer/funding source for each

• Align the study documents and the billing process
  – Synchronize the coverage analysis, clinical trial agreement, and the informed consent to ensure compliance with clinical trial billing rules and the regulations that govern protection of human subjects
# Coverage Analysis

## Clinical Trial Office
### Billing Grid Template

<table>
<thead>
<tr>
<th>Code</th>
<th>Name</th>
<th>CPT Code</th>
<th>Use Q1/Q2 modifiers if the items or services to the right will be charged to SOC</th>
<th>Screen</th>
<th>C1V1</th>
<th>C2V1</th>
<th>C3V1</th>
<th>C3V2</th>
<th>C4V1</th>
<th>C5V1</th>
<th>C6V1</th>
<th>EOT</th>
<th>F1U</th>
<th>COMMENTS</th>
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<td>99205</td>
<td>Initial Visit w Hst, Phys &amp; Vitals</td>
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<td>SP</td>
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<td>SP</td>
<td>SP</td>
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<td>85027</td>
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<tr>
<td>80053</td>
<td>Comprehensive Metabolic Panel: Glucose, Sodium, Potassium, BUN, Creatinine,AST, ALT, v-ET</td>
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<td>SP</td>
<td>SP</td>
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<td>83615</td>
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<td>Spec Handling (simple), Dry Ice-Lab Supplies- 10lb Pack, Shipping</td>
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<td>*WTR</td>
<td>Tumor Response Criteria, RECIST WHO</td>
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**Study Key Codes**

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<th>Code</th>
<th>Description</th>
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<tr>
<td>SP</td>
<td>Standard of Care</td>
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<tr>
<td>SOC</td>
<td>Invoiced to Sponsor</td>
</tr>
<tr>
<td>INV</td>
<td>Invoice to Sponsor</td>
</tr>
</tbody>
</table>

Financial Analyst Signature: ________________________

CTO Director Signature: ________________________

PI Signature: ________________________
BMC’s Clinical Trial Office (CTO) was set up to support clinical research for BMC and BU that uses any of BMC’s clinical infrastructure to ensure that costs are billed properly.

The CTO performs the coverage analysis, reviews budgets to address cost recovery for BMC services and negotiates clinical trial agreements for BMC.

The IRB routes to the CTO studies that do not have outside funding, but contemplate use of BMC clinical infrastructure.

The IRB also routes ICF language to CTO for approval of cost and subject injury language, and to facilitate synchronization by CTO of CA, CTA and IRB approved ICF.
The PI is responsible for making sure that each study that uses any BMC infrastructure, which leads to the generation of patient care charges for clinical or professional services, is set up in VelosCT.

To facilitate accurate billing, the PI is responsible for making sure each participant is added to VelosCT, associated with the appropriate study calendar, and that each activity is marked in the calendar as it occurs.

The finance department (Revenue Integrity) uses VelosCT to determine which patients are enrolled and then flags them all in SDK as being part of a research study.

Revenue Integrity reviews all claims for the flagged patients and processes them in accordance with the CA to determine which items and services may be billed to insurance or which must be billed to the study.
PRESENTATION SUMMARY

• False Claims Act applies to clinical research activities and failure to comply with the rules may lead to fines and penalties.

• Study documents and coverage analysis must be aligned to assure compliance with clinical trial billing rules and the regulations that protect human subjects.

• Everyone who uses BMC clinical infrastructure for clinical research must do their part to facilitate compliance for the benefit of our patients and our research enterprise as a whole.
FINAL THOUGHTS FROM THE BMC COMPLIANCE DEPARTMENT

• The Government expects us to have an effective compliance program
• We work to make sure that everyone follows the laws that govern our activities and that we behave ethically
• Investigate reports and solves problems
• Provide training and education programs
• Conduct auditing and monitoring of BMC departments and programs
• Please report any concerns – no retaliation
  • The Research Compliance Officer: 617-638-7990
  • The Compliance Hotline: 800-586-2627
  • Compliance Email: ComplianceHelp@bmc.org
  • Visit the Compliance Department located in the DOB, 6th Floor