

# Clinical Research Billing Compliance

BMC/BU Medical Campus – Clinical Research Seminar

*Joyce S. Samet, JD, CHRC*

*December 13, 2017*



Boston Medical Center is the primary teaching affiliate  
of the Boston University School of Medicine.

# 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 protection of study participants

# THE BMC – BU MEDICAL CAMPUS ACADEMIC MEDICAL CENTER

- BMC and BU are separate legal entities
- Shared mission to provide healthcare, teaching and research
- BMC and BU are each federal grant recipients and each perform clinical trials
- Healthcare and research are each supported by government programs (Department of Health and Human Services)
  - Medicare and Medicaid and other programs under HHS institutions (NIH, CDC, FDA)
- Although funded and regulated by HHS agencies, research and healthcare activities typically operate separately within the academic medical center

# THE CONVERGENCE OF HEALTHCARE AND RESEARCH

- Research and clinical care reimbursement converge when either BMC or BU research activities involve BMC patients and BMC clinical infrastructure
- The convergence poses operational and compliance challenges
- 60-80% of BMC's patients are beneficiaries of Medicare/Medicaid programs
- Prevention of health care fraud and abuse in government health care programs is a major initiative of HHS, OIG, CMS and DOJ
  - FY 2016, recovered >\$3.3B from health care fraud (ROI \$5 for each \$1 invested) <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-01-18-2.html>
  - Health care fraud enforcement has remained a priority under the Trump administration (called for a new \$70M investment in Health Care Fraud and Abuse Control) <https://www.justice.gov/opa/pr/national-health-care-fraud-takedown-results-charges-against-over-412-individuals-responsible>

# FALSE CLAIMS ACT

- Federal False Claims Act (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 violation, plus a penalty of up to \$21,916 per violation
  - 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 offense to knowingly and willfully offer, pay, solicit or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. NO BRIBES
- Civil monetary penalty statute prohibits any person from giving remuneration to a Medicare or Medicaid beneficiary 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/advisoryopinions/2004/ao0401g.pdf>

# RESEARCH RELATED FALSE CLAIM SETTLEMENTS

- University of Alabama at Birmingham paid \$3.39 M to settle claims that 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)

# CREATE THE CONNECTION BETWEEN THE STUDY AND BILLING TO ASSURE COMPLIANCE

- Depending on the study, Medicare will pay for certain services for beneficiaries that participate in clinical trials
- 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
- 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**)
- Academic medical centers have developed centralized processes to create connections between research and billing departments to ensure that study costs are billed properly

Boyd, C.E. and Meade, R.D.(2007) *Clinical Trial Billing Compliance at Academic Medical Centers* 82(7), 646-653

# PROCESS TO ASSURE COMPLIANCE

- **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

### Trial Information

Study Title:  
Phase:  
PI Name:  
Sponsor:  
Protocol Version Date:  
Study Duration:

Code	Name	CPT Codes	Use Q0/Q1 modifiers if the items or services to the right will be charged to SOC	Screen	C1V1	C2V1	C3V1	C4V1	C5V1	C6V1	EOT	FU1	COMMENTS
*ADVE	Adverse Events Assessment	N/A		SP	SP	SP	SP	SP	SP	SP	SP	SP	This will be paid for by the sponsor.
99205	Initial Visit w Hist, Phys & Vitals	99205		SP									This will be paid for by the sponsor.
*INCO	Informed Consent Process	N/A		SP									This will be paid for by the sponsor.
*INEX	Inclusion/Exclusion Criteria	N/A		SP	SP								This will be paid for by the sponsor.
99212	Follow-Up Visit w Phys/Vitals	99212	Q1 for the SOC procedures		SOC	SP	SOC	SP	SOC	SP	SOC		For the SOC visits, physical exams at that frequency appear reasonable and necessary for the optimal management of the patient and to monitor for potential complications related to the study drugs. Coverage supported by NCD §10.1
*RANDO	Randomization	N/A			SP								This will be paid for by the sponsor.
84703	Urine Pregnancy Test, Qualitative	84703		SP	SP		SP		SP		SP		This will be paid for by the sponsor.
99211	Brief Visit w/ Vitals	99211										SP	This will be paid for by the sponsor.
93000	ECG w/ Interpret. & Report	93000		SP	SP	SP	SP	SP	SP	SP	SP	SP	This will be paid for by the sponsor.
85027	Hemogram (CBC) w/ Plate. & No Diff	85027	Q1 for the SOC procedures	SP	SOC	SOC	SOC	SOC	SOC	SOC	SOC		The study drug has known toxicities that according to the consent form (page ...) will decrease white blood cells, neutrophil and platelet levels during on-treatment. Therefore, for the visits labeled SOC, the tests appear reasonable and necessary to detect, monitor and treat potential toxicities associated with study drug(s). Coverage supported by NCD §10.1
80053	Comprehensive Metabolic Panel: Glucose, Sodium, Potassium, BUN, Creatinine, AST, ALT, γ-GT,	80053	Q1 for the SOC procedures	SP	SOC	SOC	SOC	SOC	SOC	SOC	SOC		The study drug has known toxicities that according to the consent form (page ...) has known increases in liver enzymes (AST, ALT, γ-GT) on-treatment. Therefore, for the visits labeled SOC, the tests appear reasonable and necessary to detect, monitor and treat potential toxicities associated with study drug(s). Coverage supported by NCD §10.1
83615	Lactate Dehydrogenase (LD, LDH)	83615	Q1 for the SOC procedures	SP	SOC	SP	SOC	SP	SOC	SP	SOC		For the visits labeled SOC, the tests appear reasonable and necessary to detect, monitor and treat potential toxicities associated with study drug(s). Coverage supported by NCD §10.1.
N/A	Spec Handling (simple), Dry Ice-Lab Supplies- 10lb Pack, Shipping	N/A		SP	SP	SP							This will be paid for by the sponsor.
EOCG	EOCG	N/A		SP	SP	SP	SP	SP	SP	SP	SP	SP	This will be paid for by the sponsor.
<b>Tumor Assessment:</b>													
70551	MRI- Brain	70551	Q1 for the SOC procedures	SOC							INV	INV	Per NCCN guidelines, page ...; brain MRI can be performed at pre-treatment. Therefore, it is reasonable to have the patient's insurance pay for the screening visit and involve the sponsor for the scans at EOT and FU1. Coverage supported by NCD §10.1
71250	CT- chest	71250	Q1 for the SOC procedures	SOC							INV	INV	Per NCCN guidelines, page ...; chest CT or PET (if not previously done) can be performed at pre-treatment. Therefore, it is reasonable to have the patient's insurance pay for the screening visit and involve the sponsor for the scans at EOT and FU1. Coverage supported by NCD §10.1
70470	CT- brain	70470	Q1 for the SOC procedures	SOC							INV	INV	Per NCCN guidelines, page ...; brain CT or PET (if not previously done) can be performed at pre-treatment. Therefore, it is reasonable to have the patient's insurance pay for the screening visit and involve the sponsor for the scans at EOT and FU1. Coverage supported by NCD §10.1
*WTR*	Tumor Response Criteria, RECIST WHO	N/A		SP							SP	SP	This will be paid for by the sponsor.
	Tumor Biopsy (fresh))			SP									This will be paid for by the sponsor.
	Tumor Archiving			SP									This will be paid for by the sponsor.
Medication Dispensing	Medication Dispensing	N/A		SP	SP	SP	SP	SP	SP	SP			This will be paid for by the sponsor.
*CUSD	Collection of Unused Study Drug	N/A			SP	SP	SP	SP	SP	SP	SP		This will be paid for by the sponsor.
*EQSD	QOL	N/A		SP		SP	SP	SP	SP	SP	SP	SP	This will be paid for by the sponsor.

Study Key Codes	
SPONSOR PAID	SP
STANDARD OF CARE	SOC
INVOICE TO SPONSOR	INV.
Not Billable	NB

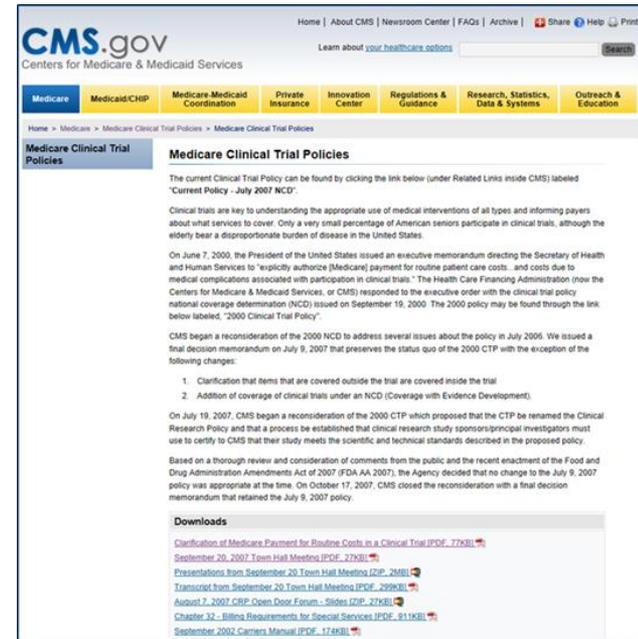
Financial Analyst Signature: \_\_\_\_\_  
 CTO Director Signature: \_\_\_\_\_  
 PI Signature: \_\_\_\_\_

# MEDICARE CLINICAL TRIALS POLICY

## 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.



The screenshot shows the CMS.gov website with the following content:

- Navigation bar: Home | About CMS | Newsroom Center | FAQs | Archive | Share | Help | Print
- Search bar: Learn about your healthcare options
- Menu: Medicare, Medicaid/CHIP, Medicare/Medicaid Coordination, Private Insurance, Innovation Center, Regulations & Guidance, Research, Statistics, Data & Systems, Outreach & Education
- Breadcrumbs: Home > Medicare > Medicare Clinical Trial Policies > Medicare Clinical Trial Policies
- Section: Medicare Clinical Trial Policies
- Text: The current Clinical Trial Policy can be found by clicking the link below (under Related Links inside CMS) labeled "Current Policy - July 2007 NCD".
- Text: Clinical trials are key to understanding the appropriate use of medical interventions of all types and informing payers about what services to cover. Only a very small percentage of American seniors participate in clinical trials, although the elderly bear a disproportionate burden of disease in the United States.
- Text: On June 7, 2000, the President of the United States issued an executive memorandum directing the Secretary of Health and Human Services to "explicitly authorize [Medicare] payment for routine patient care costs... and costs due to medical complications associated with participation in clinical trials." The Health Care Financing Administration (now the Centers for Medicare & Medicaid Services, or CMS) responded to the executive order with the clinical trial policy national coverage determination (NCD) issued on September 19, 2000. The 2000 policy may be found through the link below labeled, "2000 Clinical Trial Policy".
- Text: CMS began a reconsideration of the 2000 NCD to address several issues about the policy in July 2005. We issued a final decision memorandum on July 9, 2007 that preserves the status quo of the 2000 CTP with the exception of the following changes:
  1. Clarification that items that are covered outside the trial are covered inside the trial
  2. Addition of coverage of clinical trials under an NCD (Coverage with Evidence Development).
- Text: On July 19, 2007, CMS began a reconsideration of the 2000 CTP which proposed that the CTP be renamed the Clinical Research Policy and that a process be established that clinical research study sponsors/principal investigators must use to certify to CMS that their study meets the scientific and technical standards described in the proposed policy.
- Text: Based on a thorough review and consideration of comments from the public and the recent enactment of the Food and Drug Administration Amendments Act of 2007 (FDA AA 2007), the Agency decided that no change to the July 9, 2007 policy was appropriate at the time. On October 17, 2007, CMS closed the reconsideration with a final decision memorandum that retained the July 9, 2007 policy.
- Section: Downloads
  - Clarification of Medicare Payment for Routine Costs in a Clinical Trial (PDF, 77KB)
  - September 20, 2007 Town Hall Meeting (PDF, 27KB)
  - Presentations from September 20 Town Hall Meeting (ZIP, 2MB)
  - Transcript from September 20 Town Hall Meeting (PDF, 209KB)
  - August 7, 2007 CRP Open Door Forum - Slides (ZIP, 27KB)
  - Chapter 32 - Billing Requirements for Special Services (PDF, 911KB)
  - September 2002 Carriers Manual (PDF, 174KB)

<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**

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R74NCD.pdf>

## 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

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R74NCD.pdf>

# 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)

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R74NCD.pdf>

# 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**

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R74NCD.pdf>

## 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)

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R74NCD.pdf>

# ALIGN BILLING WITH IRB APPROVAL OF RESEARCH

- 45 CFR 46.116 (a)(2) General Requirements for Informed Consent. “An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or **undue influence**...” (no inducements)
- 45 CFR 46.116(b)(6) For research involving more than minimal risk, the ICF must include 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 (subject injury language in the ICF)
- 45 CFR.116(c)(3) When appropriate the ICF must include a statement that describes any additional costs to the subject that may result from participation in the research. (co-pays and deductibles if billing insurance for routine care)

<https://www.gpo.gov/fdsys/pkg/FR-2017-01-19/html/2017-01058.htm>

# 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
  - Sponsor-assigned protocol number
- 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

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c32.pdf>

<https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM8401.pdf>

# CMS CTP DOES NOT INCLUDE DEVICES

- Category A IDE Device Studies
  - Category A devices include experimental devices
  - The cost of the device is not covered by Medicare
  - Providers may only submit claims for routine care items and services
- Category B IDE Device Studies
  - Category B devices are non-experimental
  - The cost of the device may be covered by Medicare
  - Providers may submit claims for routine care items and services and the Category B IDE device if approved by the local Medicare fiscal intermediary

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c14.pdf> (Chapter 14 of the Medicare Benefit Policy Manual)

# THE CLINICAL TRIAL OFFICE AND THE IRB

- 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

# CLINICAL TRIAL MANAGEMENT SYSTEM

- 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
- BMC Revenue Integrity uses VelosCT to determine which patients are enrolled and then flags them all in SDK as being part of a research study (no one should remove these flags!)
- 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

# FINAL THOUGHTS FROM THE BMC COMPLIANCE DEPARTMENT

- BMC is committed to adherence to all federal and state laws and regulations concerning health care billing and claims submission
- Accuracy and integrity in BMC's billing practices is an essential part of "Exceptional Care" at BMC
- Anyone engaged in research that involves health care billing for BMC clinical services is expected to adhere to the applicable laws, regulations and BMC's policies
- Please report any concerns – no retaliation
  - The Research Compliance Officer: 617-638-7990
  - **The Compliance Hotline: 800-586-2627**
  - Compliance Email: [ComplianceHelp@bmc.org](mailto:ComplianceHelp@bmc.org)
  - Visit the Compliance Department located in the DOB, 6<sup>th</sup> Floor