Clinical Research Billing Compliance and The Billing Coverage Analysis:

The 5W's (and 1 H)

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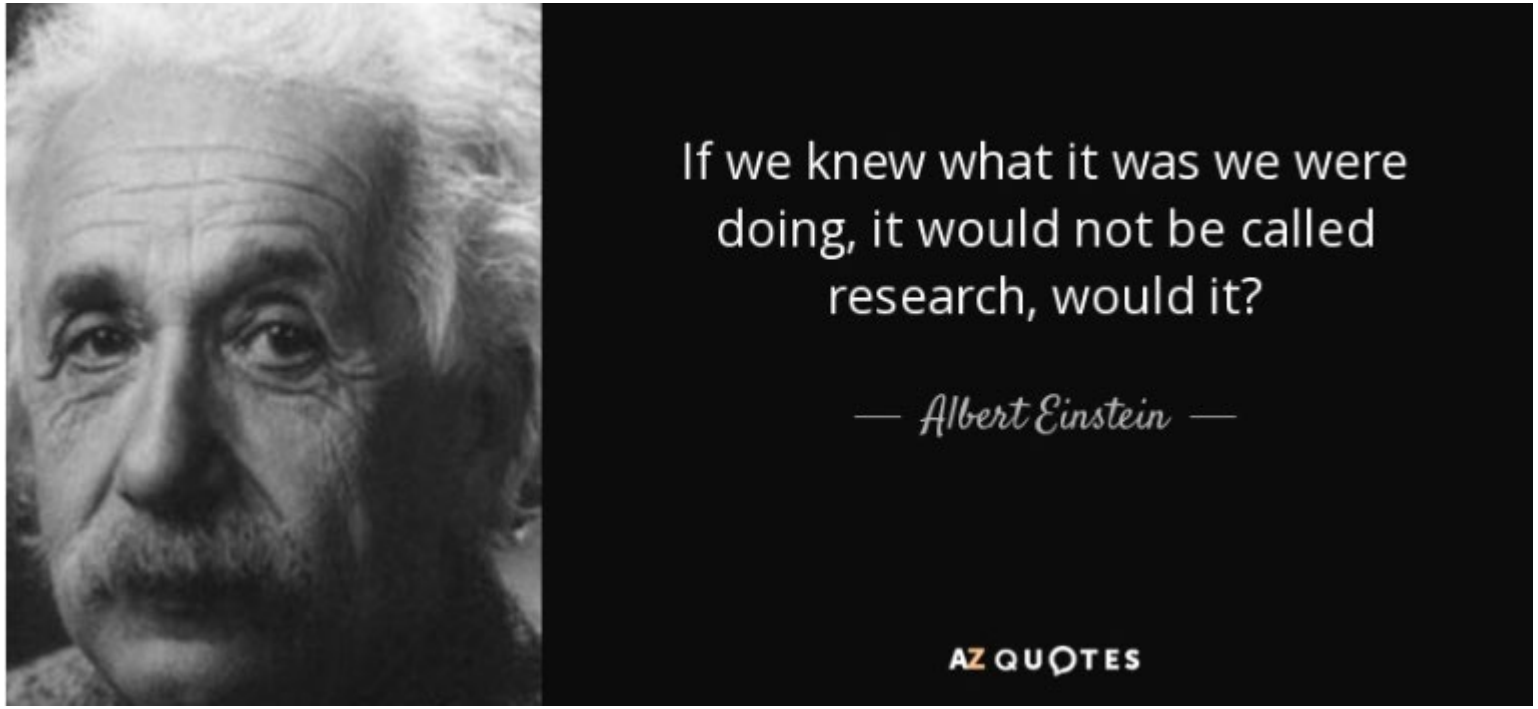
Clinical Research…



Objectives

1. To understand what **clinical research billing compliance** is and why it is important.

2. To learn about important **guidelines** and **rules** and why we must follow them.

3. To learn what a **Billing Coverage Analysis** (**BCA)** is, when it is needed, what its purpose is, and steps for obtaining one.

Meet the Team

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Clinical Research Billing Compliance

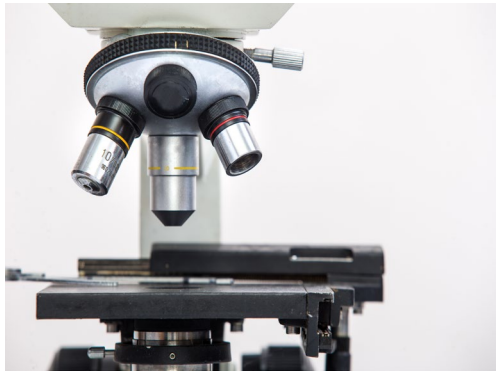
Clinical research billing (CRB) compliance is the **processes** and **tools** that are used to ensure that an institution utilizes billing practices **to ensure that services associated with a clinical research study are billed to the appropriate payor.**

Clinical Research Billing Compliance

Risks

Billing for services that are already paid by the sponsor (double billing)

Billing for services promised free in the informed consent



Billing for services that are for research-purposes only

Billing for certain services that are part of a non-qualifying clinical trial

Providing the correct coding, modifiers, and NCT number on each claim

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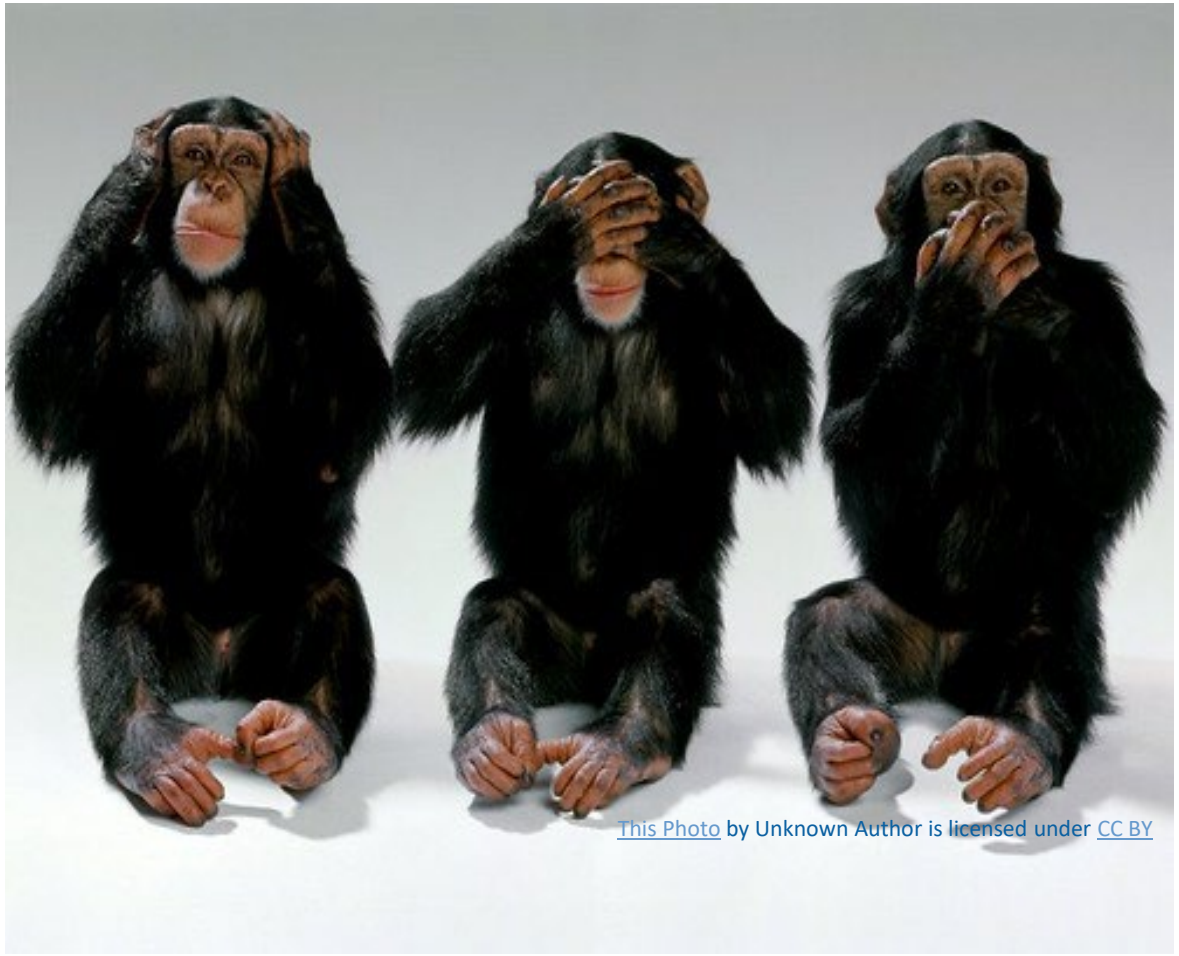
Clinical Research Billing Compliance

Practical Consequences

1. Erroneous claims can result in overpayments
2. Overpayments that are not returned could result in False Claims Act penalties and/or Civil Monetary Penalties
3. Overpayments that are the result of significant systemic problems could result in government imposed corrective actions
4. Federal funding and participation in federal programs can be jeopardized



Clinical Research Billing Compliance

What if the rules are not followed?

Settlements involving overbilling related to clinical trials illustrates how things can go awry, sometimes resulting in multi-million-dollar losses.

Clinical Research Billing Compliance

Rush University 2005	$1.0 million settlement
Emory University 2013	$1.5 million settlement
Tenet Norris-Cancer Center 2010	$1.9 million settlement
New Jersey Medical 2009	$2.0 million settlement
Johns Hopkins 2004	$2.6 million settlement
University of Alabama 2005	$3.4 million settlement
Cornell University 2005	$4.3 million settlement
Northwestern University 2003	$5.5 million settlement
Mayo Clinic 2005	$6.5 million settlement
Yale University 2008	$7.6 million settlement
H. Lee Moffitt Cancer Center 2022	$19.5 million settlement

Clinical Research Billing Compliance

Challenges

1. Insufficient understanding of compliance risk and research billing best practices.
2. “Unicorn” skill set for coverage analyst; lack of training.
3. Lack of documentation of reasoning/support for billing.
4. Silos and lack of communication: research ops, rev cycle, compliance, legal, etc.
5. Decentralized research operations, and/or inconsistent processes.
6. Lack of accountability and insufficient auditing and monitoring.

Clinical Research Billing Compliance

The law does not require a particular way to manage this risk but there is an industry standard:

Billing Coverage Analysis (BCA)

Billing Coverage Analysis

One of the most important pieces to opening a clinical trial from the business operations end is the BCA:

- The BCA allows for accurate billing under Medicare rules
- Protects the site, hospital, and health system

Billing Coverage Analysis

What Billing Coverage Analysis **is**

- A CA is a systematic review of research related documents to determine the Medicare billing status of both the study itself and the items and services provided to the research subjects that are required by the study.
- A CA is required for all studies that will enroll human subjects in which they will receive medical services that are potentially billable to the participant or their insurer.

Billing Coverage Analysis

What a Billing Coverage Analysis **does**

- The BCA documents the considerations, reasoning, and determinations made by the organization.
- The BCA translates the study services into the billing and claims environment.
- The BCA consolidates multiple study documents that impact payment into a single unified “source of truth.”
- The BCA is a tool to coordinate information for purposes of budgeting, claims review, auditing, and business assessment.

Billing Coverage Analysis

What a Billing Coverage Analysis is **Not**

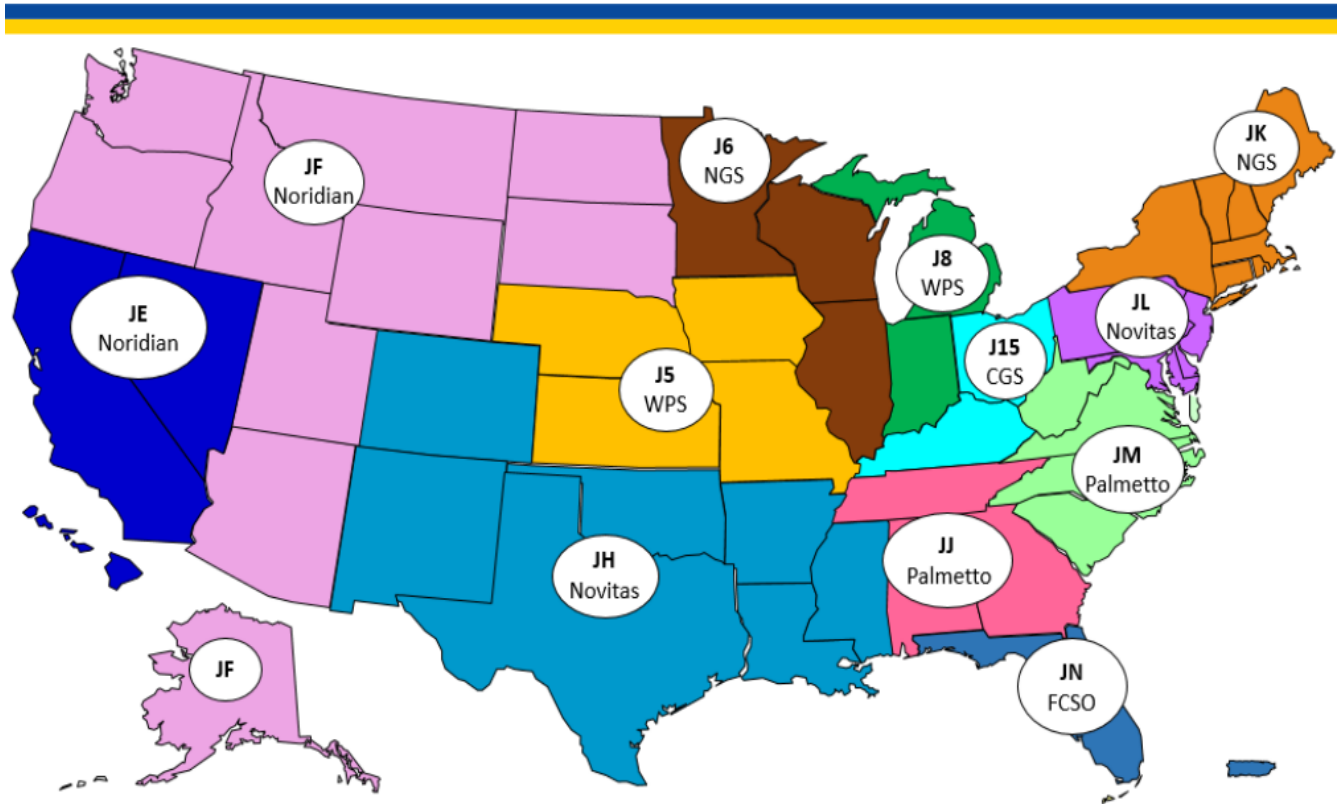
- A guarantee of coverage in all cases
- A substitute for the pre-authorization process
- Based on individual investigators' decisions or billing practices
- A substitute for the practices of medicine or physician judgement
- A treatment plan
- "Black and white" or a "perfect translation"

Medicare Rules

Structure of Medicare

- Federal program that is administered by local contractors
- To determine coverage providers must look to:
- Federal rules from
  - CMS; and
  - Local rules from “Contractor”

A/B MAC Jurisdictions



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Medicare Rules

Why use Medicare Billing Rules?

1. Medicare is the driver of reimbursement in the U.S.
    a. Many payers follow Medicare rules.
    b. Billing operations are often geared to Medicare rules as the most efficient way to accommodate reimbursement rules.
2. Medicare has the most sophisticated approach to clinical research billing (i.e., National Coverage Determination [NCD] 310.1) of all payers.
3. Medicare considers itself to have a “most favored nation” status – it wants the best deal. Medicare billing presents the most significant compliance risk.

Medicare Rules

National Coverage Determination (NCD) 310.1

In 2000 the Medicare National Coverage Determination 310.10 was adopted:

[Effective September 19, 2000; updated 2007]

This national coverage policy is based upon the authority found in §1862(a)(1)(E) of the Social Security Act (Act). It is binding on all Medicare carriers, fiscal intermediaries, Peer Review Organizations, Health Maintenance Organizations, Competitive Medical Plans, Health Care Prepayment Plans, and Medicare+Choice organizations (§1852(a)(1)(A) of the Act). In addition, an administrative law judge may not disregard, set aside, or otherwise review a national coverage decision issued under §1862(a)(1) of the Act. 42 C.F.R. §405.860.

Medicare Rules

NCD 310.1

ALL OTHER MEDICARE RULES APPLY- very important- medical necessity should be documented for every procedure, for each timepoint.

i.e., a CT Scan required at Cycle 3, Day 1 is NOT documenting medical necessity.

Medicare Rules

NCD 310.1

CMS.gov | Centers for Medicare & Medicaid Services

About Us | Newsroom | Data & Research

MCD Medicare Coverage Database

Search | Reports | Downloads | Archive | API

Back to National Coverage NCD Report Results

Contents

National Coverage Determination (NCD)

Routine Costs in Clinical Trials

310.1

Expand All | Collapse All

Tracking Information

Publication Number
100-3

Manual Section Number
310.1

Manual Section Title
Routine Costs in Clinical Trials

Version Number
2

Effective Date of this Version
07/09/2007

Implementation Date
10/09/2007

Medicare Rules

Medicare Coverage

Medicare requires a three-part process for clinical research services coverage:

1. Does the study “qualify” for coverage?
2. What items and services are “routine costs”?
3. Do Medicare rules allow/limit coverage of specific “routine costs” within a clinical trial?

Plus, the application of:

1. Informed consent form
2. Funding document

Medicare Rules

Qualifying Status

Does the study "qualify" for coverage?

The study must meet CMS "qualifying" criteria for any items and services in the study to be covered.

- Drug (non-device) Trials: CMS Clinical Trial Policy (NCD 310.1)
- Device Studies: Device study coverage rules from regulations (21 CFR 812) and Medicare Benefit Policy Manual Ch. 14

Medicare Rules

Qualifying Status (non-device)

2 PART TEST:

Part 1 – Does the study have all 3 necessary requirements?

Part 2 – Is the study “deemed”?

Medicare Rules

Qualifying Status (non-device)

Part 1 – Does the study have all 3 necessary requirements?

Must meet **all three** of the following necessary requirements:

1. The study must investigate an item or service that falls in a benefit category (i.e., it is investigating the type of thing that Medicare pays for)
2. The study must enroll patients with diagnosed disease
3. The study must have therapeutic intent

Medicare Rules

Qualifying Status (non-device)

Part 2 – Is the study "deemed"?

Must meet at least **one** of the following:

1. Studies funded by NIH, CDC, AHRQ, CMS, DOD, or VA;
2. Studies supported by centers or cooperative groups funded by NIH, CDC, AHRQ, CMS, DOD, and VA;
3. Studies being conducted under an IND application; or
4. IND exempt studies.

Medicare Rules

Qualifying Status (non-device)

What is billable in a Non-Qualifying Clinical Trial (non-QCT)?

Services that would be performed to manage the patient's disease

- ✓ Nothing related to the study item
- ✓ Nothing related to the administration/provision of the study item

However, treatment of complications as a result of non-QCT is covered

- But this would generally occur OUTSIDE of the trial/protocol-required items/services, so would not likely impact analysis

Medicare Rules

Qualifying Status (device)

Device Trial qualifying status is determined by CMS, not by same process as Drug Trials

- 21 CFR 812
- Medicare Benefit Policy Manual Chapter 14

Qualifying status for device trials is based on CMS IDE approval and CMS regulations regarding IDE or FDA status of device.

https://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies.html

After determination of QCT based on IDE/FDA status, analyze items and services in accordance with NCD 310.1.

Billing Coverage Analysis

NCD 310.1

What items and services are “routine costs”?

Billing Coverage Analysis

NCD 310.1

What items and services are limited?

The investigational item itself, unless it is otherwise covered outside of the trial

Items and services provided solely for data collection, that are not used in direct clinical management

Items and services provided free-of-charge by the sponsor

Medicare Rules

NCD 310.1: Conventional Care

CMS regulations refer to “conventional care” not “standard of care”

Clinical guidelines provide objective support for determining if an item or service is conventional care (i.e., Professional association guidelines, Peer-reviewed literature, Disease associations).

Consider which timepoints are medically necessary; which timepoints are for clinical management and not just data collection

Medicare Rules

Myth Buster:

The rule IS:

*Medicare covers **routine costs** during **qualifying clinical trials***

The rule is NOT:

Medicare covers standard of care services during research studies

Medicare Rules

NCD 310.1: Provision of the Investigational Item

1. What is required to administer the investigational item?
   - Surgery
   - Infusion
   - Other items and services required to provide/administer investigational item
2. Would the procedure or therapy required to administer be covered outside the study (i.e., coverage of infusions)?
3. NCD 310.1 supports coverage of administration of investigational item

Medicare Rules

NCD 310.1: Detecting and Preventing Side Effects

Known potential side effects or complications

- Informed Consent
- Product Label
- Lexi-Drugs
- Up to Date
- Investigator's Brochure

Prevention of Complications

- Anti-emetic to prevent vomiting after chemo
- IV steroid to prevent known reaction

Billing Coverage Analysis

“All Other Medicare Rules Apply”

National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs)

- NCD Index on CMS website
- Medicare Coverage Database
- LCDs via CMS website or MAC website

Medicare Manuals

When no Rules: Medical Necessity

- Reasonable and necessary for the treatment of an illness or injury
- Screening absent signs or symptoms

Billing Coverage Analysis

“All Other Medicare Rules Apply”

NCDs & LCDs

- Even if service is recommended by a clinical guideline, it is not billable if NCD/LCD does not support coverage
- If there is an NCD and an LCD for an item or service, BOTH the NCD and LCD must support coverage in order to bill

Consolidated Appropriations Act

The Consolidated Appropriations Act (Act)

(SEC. 210. PROMOTING ACCESS TO LIFE-SAVING THERAPIES FOR MEDICAID ENROLLEES BY ENSURING COVERAGE OF ROUTINE PATIENT COSTS FOR ITEMS AND SERVICES FURNISHED IN CONNECTION WITH PARTICIPATION IN QUALIFYING CLINICAL TRIALS.),

requires state Medicaid programs to cover certain costs in certain clinical trials.

North Carolina Clinical Coverage Policy

Per NC Medicaid Clinical Coverage Policy, No: 1A-39 (CCP):

Routine patient costs must be covered for a beneficiary participating in a QCT.

The CCP requires that the Principal Investigator (and the healthcare provider if applicable) sign the Attestation Form, for each participant who is enrolled in a QCT and receives Medicaid benefits.

The CCP states that NC Medicaid will recoup all associated costs if the Attestation Form is not completed and, in the beneficiary's medical record, prior to participation in the study

Medicaid Qualifying Clinical Trial

As defined by The Act and CCP, a QCT is:

- Must meet **this** criterion:
    1. "…a clinical trial in any clinical phase of development that is conducted in relation to the **prevention**, **detection**, or **treatment** of any **serious** or **life-threatening disease** or **condition** and is described in any of clauses (i)-(iii) of section 1905(gg)(2)(A) of the Act"

- Must **also** be **one** or more of the following:
    1. A study or investigation that is **approved, conducted, or supported** (including by funding through in-kind contributions) by one or more of the following: **NIH, CDC, AHRQ, CMS, DOD, VA**, or **qualified non-governmental research entity** identified in the guidelines issued by the NIH for center support grants.
    2. **Approved** or **funded** by any of the following entities: **Department of energy, VA, DOD.**
    3. One that is conducted pursuant to an **IND exemption** under section 505(i) of the Federal Food, Drug & Cosmetic Act, or exemption for a biological product undergoing investigation under section 351(a)(i) of the Public Health Service Act.
    4. **Drug trial exempt from being required to have one of the exemptions in the prior bullet**.

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Note: Consult your study's Billing Coverage Analysis (BCA) for the QCT determination.

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Billing Coverage Analysis

What studies need a BCA review?

The study protocol requires clinical items/services that will generate charges in the Electronic Medical Record (ERM) (Epic).

- This applies regardless of funding source
- This applies to all sponsor-paid studies

Billing Coverage Analysis

What studies DO NOT need a BCA?

The study protocol does not require clinical items/services that will generate charges in the EMR.

For example:

- No participants will be enrolled at a UNC (or UNC affiliate) location
- The entire study consists of nonbillable procedures (i.e., interview/questionnaire survey-only studies)
- IRB-exempt studies
- Observational/prospective/retrospective chart review studies **that do not require clinical items/services to be performed that will generate charges in the EMR**

Billing Coverage Analysis

Documents needed for a BCA:

1. Protocol (and TC Protocol if available)
2. Informed Consent Form
3. Funding Documents
    a. i.e., budget, funding sheet, contract

Other Useful Documents:

1. Investigator's Brochure
2. FDA Documents

Billing Coverage Analysis

Application of Informed Consent Form (ICF)

OHRP Rules:

45 CFR 46.116: “The information that is given to the subject or the representative shall be in language understandable to the subject or the representative.”

Standard Practice for IRBs: Language in 6th to 8th grade reading level

Billing Coverage Analysis

Application of Clinical Trial Agreement (CTA)

A CTA is a type of service agreement between the sponsor and the site.

A CTA is a contract (nothing special about that!) set in a research context between the Institution and the Sponsor.

The “budget” is typically set out as an exhibit, and is just as much part of the CTA as any other term in the CTA.

Billing Coverage Analysis

When to request a BCA Review

- New
- Amendment
- Correction

Billing Coverage Analysis

How to request a BCA

- ServiceNow
  - What should be included in/with the ticket submission?
  - Communication expectations via the ticket?
  - https://uncch.service -now.com/sp?id=sc_cat_item&sys_id=152e6d194708b910b9114f58436d436c
- (to come: Team Dynamix)

Billing Coverage Analysis

BCA Process Overview:

Create Billing Grid

- Build the calendar of all Protocol-required items and services

Analysis and Determinations

- QCT determination, analyze services, application of Medicare Rules

Delivery & Dialogue

- Email draft CA to the study team/PI and discuss determinations and clinical reasonings

Finalization

- Final PI approved BCA is harmonized with the finalized funding documents and approved ICF, and made available for revenue cycle

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Billing Coverage Analysis

Why is a BCA important

- Performing a coverage analysis is key to ensure correct billing.
- Coverage analysis is a review to determine if a research study is eligible to receive Medicare coverage, outlining what items and services performed as part of the research study should be billed to Medicare.
- The coverage analysis is a vital component of the study activation process and can save sites time, money, and their reputation in the future.

TEAMWORK!

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Contact Information

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Questions?

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