



# **Introduction to Clinical Research Billing Compliance**

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Human Research Protection Program**

# Topics

- Clinical Research Billing Compliance
- Overview of Billing Rules
- Medicare Coverage Analysis (MCA)
- Billing Compliance Plan (BCP)
- Post Award
- Post Approval Monitoring

# Clinical Research Billing Compliance

# New at MSU



Within the Compliance Office Clinical Research Coverage Analysts can provide support to the research community and others involved in patient care activities to ensure the proper billing of health care services and items according to federal, state, and local regulations for clinical research.

# Who We Are

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# Clinical Research Billing Compliance

- If insurance is proposed to be billed, there are rules on what can be billed to a subject's insurance
- Determinations need to be made on who pays for what  
Who is covering the cost . . . sponsor, department, subject, insurance, etc.?
- The function of clinical research billing compliance is to help ensure proper billing of health care services and items according to federal, state, and local regulations

# What We Do

- Conduct the required prospective Medicare Coverage Analysis (MCA) in accordance with the [Centers for Medicare and Medicaid Services \(CMS\) National Coverage Determination 310.1](#)
- Develop detailed study budgets for clinical research studies generating billable events
- Identify applicable CPT/HCPCS codes for billable events for the clinical team to review
- Negotiate budgets directly with Sponsors and/or Clinical Research Organizations

# What We Do, Continued

- Review informed consent cost language to ensure clarity and consistency with other study documents
- Review and negotiate payment terms in funding agreements (*as applicable*)
- *Words matter – how you can ensure that the words in the contract say what your are actually doing when a bill drops*



# Current Services Offered

- Includes Budget Development, Coverage Analysis and Budget Negotiation

## Development

- Receive CRBC Registration Form and essential study documents
- CRBC develops the initial Clinical Research Billing Compliance Plan, which includes the coded billable events

## Coverage analysis

- CRBC reviews the initial billing designations from the clinical team and looks up supporting documentation for Routine Care items
- CRBC Office updates the Billing Compliance Plan with coverage analysis notes for the clinical team to review/update

## Budget Negotiation

- Upon PI's approval to proceed with negotiations, CRBC begins budget negotiations
- Once negotiations are concluded, the study's Billing Compliance Plan is finalized per the final budget.

# CRBC Registration Form

The completion of the Clinical Research Billing Compliance (CRBC) Registration Form is required when engaging in the support of the office.

The registration form ensures proper assignment of your study among CRBC staff and improves communication between other administrative offices during the project initiation.

Form Download: <https://ora.msu.edu/crbc-registration-form>

# Overview of the Billing Rules

# Overview of Billing Rules

- False Claim Act
- Stark
- Anti-Kickback Act
- Medicare Rules
- Patient Protection and Affordable Care Act (ACA)
- State Insurance Regulations
- Institutional Policies

Title	Brief Description	Source
False Claims Act	Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval to the Government	<u>31 U.S.C. § 3729</u>
Stark Law	Prohibits certain Physician referrals with financial gain	<u>42 USC § 1395</u> <u>42 CFR § 411.350</u>
Anti-kickback	Prohibits bribes and incentives for any item or service for payment in whole or in part under a Federal health care program	<u>41 U.S.C. § 51</u> <u>42 U.S.C. §1320</u>
CMS National Coverage Determination (NCD) for Routine Costs in Clinical Trials	Medicare regulations for qualifying clinical trials	<u>NCD 310.1</u>
Patient Protection and Affordable Care Act (ACA)	Provides coverage to a qualified individual in group plan to participate in the clinical trial	<u>Public Law</u> <u>111-148</u>

# False Claims Act

The False Claims Act was established in 1863. In general, the act holds individuals liable who *knowingly*:

- (1) presents, or causes to be presented, a false or fraudulent claim for payment or approval;
- (2) makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government;
- (3) conspires to defraud the Government by getting a false or fraudulent claim paid or approved by the Government

## False Claims Act (continued)

- Civil Penalties can include \$5,000 and not more than \$10,000 for each claim, plus **3 times** the amount of damages which the Government sustained
- Erroneously and/or double billing can trigger an investigation under the False Claims Act
- Federally funded studies carry significant risk

# Stark Law

- Prohibits physicians from ordering **designated health services** from entities with which the physician, or a family member, has a financial relationship unless an exception applies
  - e.g. self-referrals
- Exceptions exist in order to accommodate legitimate business arrangements
  - Hospitals in Rural locations
  - In-office ancillary services
  - Within group practice referrals

# Anti-Kickback Statute

- Prohibits any kickback (any money, fee, commission, credit, gift, gratuity, thing of value, rebate or compensation of any kind) that is provided to improperly obtain or reward favorable treatment for the any item or service for which payment may be made in whole or in part under a Federal program (e.g. Medicare, NIH)



- Safe harbor regulations allow financial transactions between potential referring parties be conducted at fair market value

# Affordable Care Act

- Patient Protection and Affordable Care Act (ACA)
  - Public Law 111-148,
  - Signed into law March 23, 2010
  - Also known as Obamacare
  - Comprehensive changes to health insurance coverage
  - Provisions take effect over multiple years
  - Impacts research
    - Amends 42 USC 300 to provide coverage for individuals with private insurance to participate in approved clinical trials with private insurance
    - Amends the Social Security Act to add a new part, Part D – Comparative Clinical Effectiveness Research

## Other ACA highlights

- Preventive services given an “A” or “B” rating by United States Preventive Services Task Force(USPSTF) must be reimbursed by insurers at no cost to patients under the [Affordable Care Act](#).
- No annual or lifetime coverage limits
- Health Insurance Marketplace
- Medicaid program expansion
  - Michigan is expanding its Medicaid program as of April 2014 to cover households with incomes up to 138% of the federal poverty level
    - \$16,105 a year for 1 person
    - \$32,913 for a family of 4

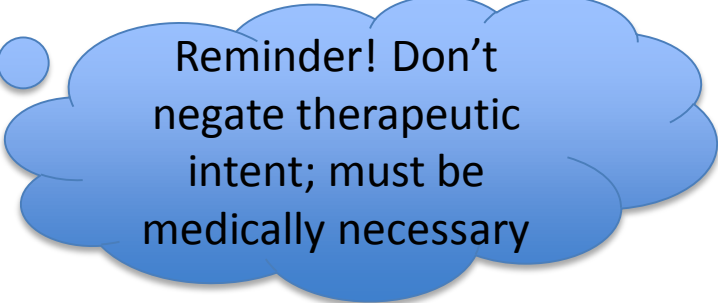
# CPT Codes

- **Current Procedural Terminology (CPT)**: a set of codes, descriptions, and guidelines that describe procedures and services performed by physicians and other qualified health care providers
- Developed by the **American Medical Association (AMA)**
- **5 digits**
- **Levels of Service**
  - Classification determined by:
    - Type of service
    - Place of service
    - Patient's status
- **Credentialed** coders are an invaluable resource
- Resource materials: CPT codebook or online tools (i.e. EncoderPro)



# Claim Submission Rules

- Medical record documentation:
  - clinical trial title
  - sponsor name
  - sponsor protocol number
- Secondary diagnosis code: ICD-9: **V70.7** ICD-10: **Z00.6**
  - Examination of participant in a clinical trial
  - Used for inpatient & outpatient
- Healthcare Common Procedure Coding System (HCPCS) modifier:
  - **Q0**: Investigational item/service
  - **Q1**: Routine care items/services
- 8 Digit clinical trial number (NCT#)
  - Now Required! Effective January 2014



Reminder! Don't negate therapeutic intent; must be medically necessary

# HIPAA

- Four New Health Care Related Crimes:
  - Health care fraud
  - Theft or embezzlement in connection with health care fraud
  - False statements relating to health care matters
  - Obstruction of criminal investigation of health care offense
- It is imperative that the Clinical Trial Agreement (CTA) requires the parties to ensure confidentiality of the subjects PHI.
- Requests for Social Security number also would fall under this.

# The Rush Settlement – First of its kind

- Rush University Medical Center – One Million settlement in December 2005
  - Improperly billed Medicare for physician and hospital cancer research services as routine costs.
  - Voluntary self-disclosure to DOJ in 2003
  - Among the first settlements related solely to Medicare's CTP on clinical trials
  - This resulted from offices not knowing what the other was doing.

## U of Alabama at Birmingham \$3.39 M settlement

- Falsely billed Medicare for researcher's time spent on patient care
- Falsely billed Medicare for clinical research trials that were also billed to the sponsor

## Emory University – 1.5 M settlement

- Falsely billed Medicare and Medicaid for clinical trial services that were not permitted by the rules.
- The sponsor agreed to pay for services which in some instances were not ever invoiced by Emory to the sponsor per contract.
- Some services promised for free in the informed consent.

# Georgia's Columbus Regional Healthcare System – 35 M settlement

- Excessive salary and directorship payments to a physician in violation of the Stark law. That law prohibits physicians from referring Medicare and Medicaid patients to entities, for certain services, with which they have financial relationships.
- The government and whistle-blower also alleged that from 2006 to 2013, Columbus billed federal healthcare programs for higher levels of services than supported by documentation.

# Clinical Trial Billing

- Clinical research studies with billable events must meet the federal billing compliance requirements:
  - No double billing
  - Documentation supports coding
  - Research modifiers, diagnosis codes, condition codes and CT.gov registration number for qualifying study.
  - Transparent and consistent documentation

# Medicare Coverage Analysis (MCA)

# Principal Payers in the USA

1. Medicare
2. Medicaid
3. Medicare and Medicaid Manage Care
4. Tricare
5. VA
6. Employer-Sponsored Health Plans
7. Commercial Plans
8. Misc. (e.g. County Medical Services)

# Standard of Care?

- Not mentioned in NCD310.1
- Medicare uses the term routine care
- What is routine care?
  - Reasonable assessment of normal care for a patient
  - Standard clinical management
  - Accepted imaging and laboratory parameters
  - National guidelines and benchmarks

# Brief History

Historically, Medicare has not paid for items or services on clinical trials.

- On June 7, 2000, the President of the United States issued an Executive Memorandum directing *Health Care Financing Administration (HCFA)* to “explicitly authorize (Medicare) payment for routine patient care costs...and costs due to medical complications associated with participation in clinical trials.”
- In keeping with this directive, Medicare issued a NCD (National Coverage Determination) that defined specific criteria for which payment should be made for clinical research studies

# What is Medicare?

“Medicare is our country’s health insurance program for people age 65 or older. Certain people younger than age 65 can qualify for Medicare, too, including those who have disabilities, permanent kidney failure or amyotrophic lateral sclerosis (Lou Gehrig’s disease). The program helps with the cost of health care, but it does not cover all medical expenses or the cost of most long-term care.

Medicare is financed by a portion of the payroll taxes paid by workers and their employers. It also is financed in part by monthly premiums deducted from Social Security checks.

The Centers for Medicare & Medicaid Services (CMS) is the agency in charge of the Medicare program.”



# Four Parts of Medicare

<b>Part A</b>	Hospital/Facility	Part A is paid for by a portion of Social Security tax. It helps pay for inpatient hospital care, skilled nursing care, hospice care and other services.
<b>Part B</b>	Provider	Part B is paid for by the monthly premiums of people enrolled and by general funds from the U.S. Treasury. It helps pay for doctors' fees, outpatient hospital visits, and other medical services and supplies that are not covered by Part A.
<b>Part C</b>	Medicare Advantage (Medicare + Choice)	Part C (Medicare Advantage) plans allow you to choose to receive all of your health care services through a provider organization. These plans may help lower your costs of receiving medical services, or you may get extra benefits for an additional monthly fee. You must have both Parts A and B to enroll in Part C.
<b>Part D</b>	Prescription Drug Coverage	Part D is voluntary and the costs are paid for by the monthly premiums of enrollees and Medicare. Joining the Medicare prescription drug plan is voluntary, and enrollees must pay an additional monthly premium for the coverage. Anyone who has Medicare coverage under parts A and B are eligible.

## Medicare vs. Medicaid

“**Medicaid** is a state-run program that provides hospital and medical coverage for people with low income and little or no resources. Each state has its own rules about who is eligible and what is covered under Medicaid. Some people qualify for both Medicare and Medicaid. For more information about the Medicaid program, contact your local medical assistance agency, social services or welfare office.”

<http://www.socialsecurity.gov/pubs/10043.html#a0=1>

# Medicare's Legal Structure

- To understand Medicare research billing rules, it is important to step back and understand the legal structure of Medicare
- Statutory basis for Medicare coverage follows this principle:
  - Medicare covers items and services that are “reasonable and necessary to diagnose or treat illness or injury”
  - Known as the “Reasonable & Necessary Rule”

# Medical Necessity

- Title XVIII of the Social Security Act (SSA):

Section 1862(a)(1)(A) excludes expenses incurred for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Section 1833(e) prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

# The Hierarchy of Medicare Rules

- The Statute
- National – CMS
  - National Coverage Determinations (“NCDs”)
    - [www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx](http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx)
  - Manuals (e.g., Medicare Benefit Policy Manual, Medicare Claims Processing Manual)
  - Transmittals
- Local - MACs
  - Local Coverage Determinations (“LCDs”)
  - Medical Director “articles” and “rulings”
- “Reasonable & Necessary Rule”
  - Document medical necessity when no coverage rule found; use peer reviewed clinical guidelines

# What is a coverage analysis?

- Determine whether the study qualifies for coverage according to the national Medicare Clinical Trial Policy (NCD310.1)
- Prospectively determine the eligibility of a clinical study's related tests, procedures or interventions for insurance coverage
- Detailed review of the clinical events specified in the protocol to document the funding source for billing intent

# MCA Basics



Questions that always need to be asked:

1. Does the study qualify for coverage?
2. Are the protocol-scheduled services “routine costs”?
3. What is paid/provided for by the sponsor?
4. What is promised free in the informed consent?
5. Do other Medicare rules impact billing?

# “All other Medicare rules apply”

- Complex and lengthy part in the coverage analysis process
- Based on study’s design and each individual items/service applicable to the patient
- A Medicare coverage analysis doesn’t dictate patient care, only determines what is anticipated as a covered benefit
- Refer to National guidelines if determinations are not present
  - An initial review of national guidelines is typically by an unbiased reviewer during the coverage analysis process
  - Feedback on findings is essential; Physicians are the experts!



# Medicare's General Exclusions

No payment can be made under either the hospital insurance or supplementary medical insurance program for certain items and services, when certain exclusions exist.

Selected examples:

- Not reasonable and necessary
- No legal obligation to pay for or provide
- Not provided within United States
- Personal comfort
- Excluded investigational devices

# Medicare Qualifying Clinical Trial (MQCT) Criteria

- Meet all three requirements
  - The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have **therapeutic intent**
  - The subject or purpose of the trial must be the evaluation of an item or service that falls within a **Medicare benefit category** and is not statutorily excluded from coverage
  - Trials of therapeutic interventions must enroll patients with **diagnosed disease** rather than healthy volunteers
- Must be one of these **deemed** categories:
  - Trials funded by NIH, CDC, AHRQ, CMS, DOD and VA
  - Supported by centers or cooperative groups that are funded by the above
  - Conducted under an IND reviewed by the FDA
  - IND exempt studies

# Medicare Coverage Analysis (MCA) Overview

- A MCA is designed to assist research personnel with any clinical research patient care billing concerns or budgeting issues prior to the start of the study
- Ideally, the MCA is prepared in tandem with the budget to ensure study costs are covered prior to enrollment of study subjects
- The MCA can then be used throughout the study's life cycle to ensure appropriate billing
  - *It is a communication tool!*

# NCD310.1 Clinical Trials Policy

- 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 in clinical trials include:**
  - Items and services typically provided absent a clinical trial (conventional care)
  - Items or services required solely for the provision of the investigational item or service (e.g., administration)
  - The clinically appropriate monitoring of the effects of the item or service, or the prevention of complications
  - Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service

# CMS National Coverage Determination (NCD) for Routine Costs in Clinical Trials

## NCD310.1 Simplified

- Medicare requires a three-part process for clinical trial coverage determination:
  1. Does the study “qualify” for coverage?
  2. What items and services are “routine costs”?
  3. Does Medicare rules allow coverage of specific “routine costs” within clinical trials?
- Plus:
  1. role of funding document
  2. role of informed consent

# Coverage with Evidence Development (CED)

- Medicare has issued several NCDs providing coverage for services and procedures of a complex nature
- For coverage eligibility, facilities providing these services must meet certain criteria
- An additional condition of coverage, required to collect additional patient data to supplement standard claims data

## For example...

- Being certified as a Medicare approved facility is required for performing the following procedures:
  - carotid artery stenting
  - ventricular assist device destination therapy
  - bariatric surgery
  - certain oncologic PET scans in Medicare-specified studies
  - lung volume reduction surgery

## Other commonly cited coverage determinations

NCD 150.1	Manual Manipulation
NCD 190.15	Blood Counts
NCD 220.1	Computed Tomography (CT)
NCD 220.2	Magnetic Resonance Imaging (MRI)
WPS LCD L30161	Flow Cytometry
WPS LCD L30489	Psychiatry and Psychology Services
WPS LCD L31078	Hemophilia Clotting Factors
WPS LCD L33219	Molecular Diagnostic Testing
WPS LCD L28576	Chemotherapy Drugs and their Adjuncts

# Refresher on Routine Costs

- 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 in clinical trials include:**
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# Medicare's General Exclusions

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Selected examples:

- Not reasonable and necessary
- No legal obligation to pay for or provide
- Not provided within United States
- Personal comfort
- Excluded investigational devices



# Drug studies vs. Device studies

- Starting January 1, 2015, Medicare centralized the approval process
  - Sponsors must submit to Medicare directly; not sites
  - Sponsors will need to provide sites with approval letter

# FDA Device Categories

An Investigation Device Exemption (IDE) permits a device that has not yet received market approval to be used in a clinical study designed to generate data on the safety and/or effectiveness of such a device. FDA categorizes devices into two categories:

- **Category A devices:** “Experimental” investigational devices where the “absolute risk” of the device type has not been established.
  - This category typically includes only FDA Class III devices.
- **Category B devices:** “Non-experimental” investigational devices where the “incremental risk” is the primary risk in question.
  - Class I, II or III can be classified as Category B devices.

# CMS Reimbursement Categories

- In addition to the risk class assigned by the FDA, they will determine the CMS reimbursement category:
  - Category A
  - Category B

# Local Medicare Administrative Contractor (MAC)

- Assigned based on regions/jurisdictions
- Responsible for processing Medicare claims
- Michigan's MAC is WPS Region J8



J8 MAC Part A



IN, MI Providers

J8 MAC Part B



IN, MI Providers



# Category B: Non-Experimental Devices

- These devices may be covered under Medicare
- FDA approved IDE study protocols restrict investigational devices shipment to a limited number of clinical sites for testing on a specific number of patients.
- Currently, must obtain local Medicare Administrative Contractor's (MAC) approval for coverage eligibility. In 2015, Sponsors will request approval centrally with CMS.
- Medicare coverage is based on the device continuing to meet criteria that led to the FDA category designation

# Category A: Experimental Devices

- Generally not covered
  - However, Medicare may cover routine costs, if the device is used for a life-threatening condition.
  - Medicare contractor decides
  - Device itself must be provided free

# Local MAC Submission Requirements

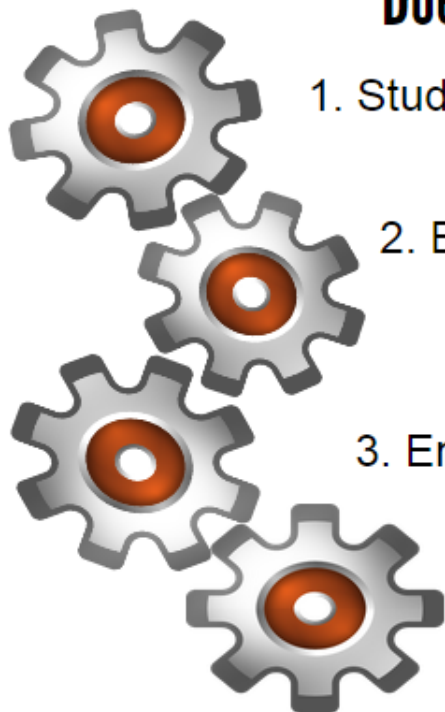
1. The FINAL Federal Drug Administration (FDA) letter (not redacted)
2. Copy of the Institutional Review Board approval letter
3. The informed consent form
4. A copy of the complete protocol.
5. Supporting articles ONLY if the IDE is a true new/unique technology.
6. Type of coverage requested; Medicare A, Medicare B, or both.
7. The site(s) of the hospital(s) is in our jurisdiction.
8. The name of the principle investigator and any sub-investigators
9. The hospital's provider number (if Medicare A).
10. Contact email address and telephone number for any questions we may have or to request missing documentation.

# Importance of Coverage Analysis

- Increased interest in clinical trial participation
- Participation provides several benefits for patients, physicians, hospitals and health systems
  - Provide the latest treatment and technology options to patients
  - Treat rare conditions
  - Discover new medical treatments
  - Prestige of conducting research
  - Alternative revenue source
- Minimize risk to all parties by conducting a coverage analysis
- Used as a communication tool during the life of the study

# Medicare's Qualifying Clinical Trial Criteria

## Does the study itself qualify?



1. Study includes therapeutic intent

2. Evaluates an item/service in a Medicare benefit category

3. Enrolls subjects with a diagnosed disease

4. Study falls within a deemed category



# Required documents for the MCA

In order to begin the MCA process with the CRBC Office, the following documents are typically needed:

- Signed CRBC Study Registration Form
- Study Protocol
- Informed Consent Form
- Funding agreement for externally funded studies
- Budget offer
- FDA letter(s)

Form Download: <https://ora.msu.edu/crbc-registration-form>

Submit to [CRBC@ora.msu.edu](mailto:CRBC@ora.msu.edu)

# Review of Determining a Qualifying Clinical Trial Hands on Exercise

# Billing Compliance Plan (BCP)



# Clinical Research Billing Compliance Plan

- Primary output document from the CRBC Office
- The Billing Compliance Plan is a **hybrid** between a budget and billing grid
- Provides documentation of billing intent, including an assessment of the routine care costs that are billable to insurance
- Used throughout the study's lifecycle

# Primary Risk Areas

- Ignoring clinical research billing rules can lead to increased risks
- Billing for items/services that are:
  - Services that are for research-purposes only
  - Billed to Medicare but not covered under Medicare rules (i.e. non-qualifying clinical trial, statutorily excluded, etc.)
  - Payable/Paid by the Sponsor
  - Promised for free in the informed consent
  - Not supported by required documentation
    - Proper order, documentation of medical necessity, NCT#, modifiers, etc.

# Additional Risk Areas

- Waiving, paying or reimbursing subject co-pays and/or deductibles
- Not determining fair market value upfront
- Not conducting a prospective Medicare coverage analysis
- Consider each subject's situation upon enrollment
  - A prospective Medicare coverage analysis does not replace the patient pre-authorization process

# Common delays

- Receiving incomplete information and/or missing essential study documents
- Late notification
- Additional sub-sites that require contracting
- Amendments needed ( e.g.. consent language)
- Poor communication

# Clinical Research Billing Compliance

- Current environment
  - Large penalties and settlements for improper Medicare billing
  - Continues to be a priority issue for compliance and legal departments within academic medical centers (AMC) and teaching hospitals
  - Regulations and guidance from the Centers for Medicare and Medicaid Services (CMS) can be complex, unclear and/or counter-intuitive
  - Health care reform legislation requires changes for commercial payers
  - Increased funding for CMS fraud and abuse control

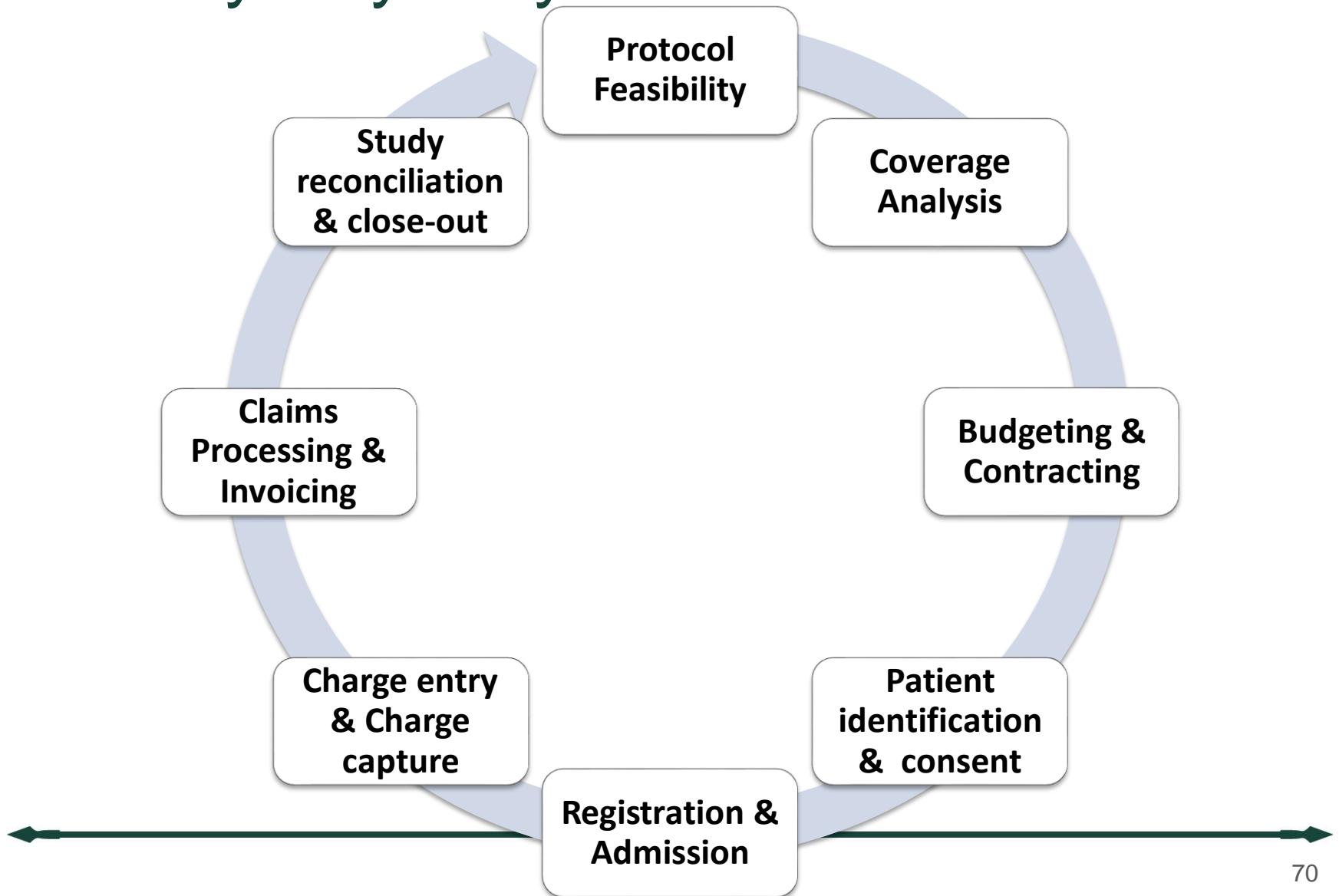
# Refresher: Primary Risk Areas

- Billing for items/services that are:
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  - Promised for free in the informed consent
  - Not supported by required documentation
    - Proper order, documentation of medical necessity, NCT#, modifiers, etc.

# Managing Billing Risk Early On

- Pre Budget Preparation
  - Understand the Study; Feasibility Assessment
  - Compare & contrast to ensure all procedures/events are included in these documents:
    - Informed Consent Form (ICF)
    - Schedule of Events (within Protocol)
    - Sponsor's Budget Line Items
    - Funding agreement
- Building the Budget and Billing Grid
  - Conduct prospective Medicare coverage analysis
  - Consider mandatory fees, per patient fees, admin time
  - Payment Schedule—based on CRF completion, milestones
  - Study Duration—include inflation factor
  - Invoiceable Fees
  - Finalize the Billing Compliance Plan

# Identify Key Players in Process



## Qualification

- Assessment of the study for determining the appropriateness for seeking reimbursement for routine costs. Four elements are required to qualify.

## Coding

- Review of relevant clinical trial documents to ensure that all patient care costs are identified and included in the billing grid with Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) codes as applicable. Clinical team must review the codes as these dictate services to be performed.

## Coverage Analysis

- Review of billing rules and coverage determinations to identify limitations on coverage for billable events. Includes providing citations for documentation. If coverage determinations are not present, clinical guidelines will be used.

## Billing Intent

- Identification of the responsible party to cover the cost (e.g. Sponsor, patient/payer, or department). May also include items that are non-billable (e.g. investigational item provided for free).

# Refresher: Billing Compliance Plan

- The billing compliance plan is a **hybrid** between a budget and billing grid
- provides documentation of billing decisions, including an assessment of the routine care costs that are billable to insurance
- Used as a communication tool for charge segregation
- Used throughout study's lifecycle

# Example Supporting Documentation

- Example 1:
  - Complete Blood Count (CBC) (**local**) CPT 85025
    - Routine Care; items and services that are for the prevention, detection and treatment of complications. Coverage supported by NCD 310.1 and 190.15. Blood counts are used to evaluate and diagnose diseases relating to abnormalities of the blood or bone marrow. These include primary disorders such as anemia, leukemia, polycythemia, thrombocytosis and thrombocytopenia. Per drug labeling for DRUG123 "Complete blood counts should be performed as needed to monitor response and toxicity, but at a minimum, prior to each cycle."

# Example Supporting Documentation

- Example 2:
  - Drug 123; CPT J9025
    - Per LCD L28576, Section C.5 DRUG123, 1 mg is covered for the following indications: Myelodysplastic Syndrome (238.72-238.76), Acute myelogenous leukemia (205.00-205.02), Chronic Myeloid leukemia (205.10, 205.12). Protocol and PI preference for administration method is subcutaneous.

# Billing Compliance Plan (BCP) Hands on Exercise



# Post Award



# Budgeting vs. Billing

- Pre-Award: Budgeting
  - Developing budget grid
  - Identifying study staff
  - Obtaining CMS approvals  
*(if applicable)*
  - Negotiating rates internally
  - Negotiating with Sponsor
  - Creating charge codes for research services
- Post-Award: Billing
  - Tracking subject enrollment
  - Research registrations
  - Reviewing subject bills
  - Processing charge corrections
  - Allocating time/effort for personnel
  - Manage research account(s)
  - Invoicing sponsor & track payments

# Billable Events FAQs

Q: How do I know whether the study needs a MCA?

A: If a billable event may be generated in the patient care billing system, then a MCA is required.

Q: How do I know which budget category an item falls under?

A: For outpatient items/services, billable events will be associated with CPT/HCPCS code(s). Contact the CRBC office for inpatient studies.

Q: How do I look up and find the billing codes?

A: The CRBC Office can assist with coding the study protocol. We have software the coding staff uses.

## Billable Events FAQs (continued)

Q: My study is not negotiable. It is a proposal to NIH. Does this make a difference?

A: Federal studies inherently carry greater compliance risks for double billing. Federal agencies also have specific policies regarding clinical research and patient care costs. Performing a coverage analysis during proposal development will allow the study team to determine the associated patient care costs according to applicable rules. This allows the study team to budget appropriately and reduce the risk of incurring a cost overrun during the project period, regardless of the funding source. If MSU will be the prime for a multi-site clinical research proposal, please contact the CRBC office for guidance. Additional Sponsor responsibilities and costs will be applicable.

# PRELIMINARY BASIC INFORMATION ON CLAIMS PROCESSING

- Most third party payors follow Medicare rules and guidelines regarding clinical trials
- All third-party payors use the same claim forms:
  - Hospital Inpatient & Outpatient
  - CMS 1450 (UB-04)
  - Physician
  - CMS 1500 (HCFA 1500)

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# Medicare Research Modifiers: Q0

- “Investigational clinical services are defined as those items and services that are being investigated as an objective within the study. Investigational clinical services may include items or services that are approved, unapproved, or otherwise covered (or not covered) under Medicare.”



# Medicare Research Modifiers: Q1

- “Routine clinical services are defined as those items and services that are covered for Medicare beneficiaries outside of the clinical research study; are used for the direct patient management within the study; and, do not meet the definition of investigational clinical services. Routine clinical services may include items or services required solely for the provision of the investigational clinical services (e.g., administration of a chemotherapeutic agent); clinically appropriate monitoring, whether or not required by the investigational clinical service (e.g., blood tests to measure tumor markers); and items or services required for the prevention, diagnosis, or treatment of research related adverse events (e.g., blood levels of various parameters to measure kidney function).”

# Payer Claims and Submission

## Example - Payer Documentation Requirements

“The individual’s medical record must reflect the medical necessity for the care provided. These medical records may include, but are not limited to: records from health care professional’s office, hospital, nursing home, home health agencies, therapies, and test reports.”


- “Additional documentation requirements include:

- Trial name, trial sponsor, ClinicalTrials.gov identifier number and sponsor-assigned protocol number

- The specific routine items and services provided to the individual (Time and Event or approved study budget)

- Copy of the signed and dated study-specific Informed Consent Form

- The specific FDA-approved prescription pharmaceutical(s) or biologic(s) being used in combination with a clinical trial that are and are not supplied by the clinical trial sponsor”

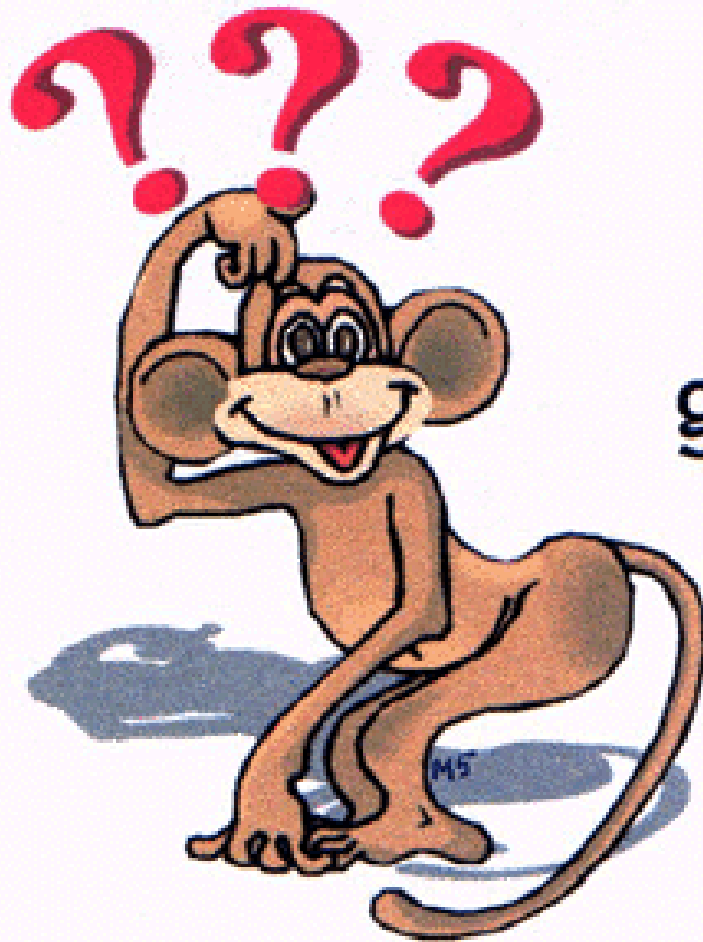


# Post Approval Monitoring



# Post Approval Monitoring

- TEACH - Develop a program to office input and help with compliance as they are being billed rather than as after-the-fact auditing or paybacks
- Collaborative effort- partner with clinical sites to ensure compliance
- Bill Hold and Review



Questions  
are  
guaranteed in  
life;  
Answers  
aren't.