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NEW ENGLAND HEALTHCARE INTERNAL AUDITORS INC.

HFMA/NEHIA 2022 Compliance & Internal Audit Conference

Clinical Research Billing Basics and Auditing for Compliance

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Wednesday, November 30 – Friday, December 2, 2022
Mystic Marriott Hotel, Groton, CT

Clinical Research Billing Basics and Auditing for Compliance

Goals and Objectives

Participants will gain an understanding of:

- Clinical Trial Definitions
- Medicare's Clinical Trial Policy and Associated Billing and Documentation Requirements
- Some Key Clinical Trial Revenue Cycle Processes
- Auditing for Compliance with Regulations and Processes

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Clinical Research Billing Basics
Clinical Trial Definitions

Food & Drug Administration (FDA)- Agency of the United States Department of Health and Human Services responsible for protecting and promoting public health through the regulation and supervision of products such as drugs and medical devices. Ensures adherence to principles of Good Clinical Practice in clinical trials and Human Subject Protection.

Clinical Investigation (Research)- any experiment that involves a test article and one or more human subjects and that either must meet the requirements for prior submission to the FDA or the results of which are intended to be later submitted to, or held for inspection by, the FDA as an application for a research or marketing permit.

Test article- any food additive, color additive, drug, biological product, electronic product, medical device for human use, or any other article subject to regulation under the act or under section 351 and 354-360F of the Public Health Service Act.

Human Subject- an individual who becomes a participant in research, either as a recipient of the test article or as a control. A subject my be either a healthy individual or a patient.

Types of Clinical Trials-

- Observational, Interventional
- Treatment, Prevention, Early Detection/Screening, Supportive Care, Compassionate Use.

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Clinical Research Billing Basics
Clinical Trial Definitions

Sponsor- The organization that initiates a clinical trial and is ultimately responsible for the management of the entire trial, e.g., Pharmaceutical, biotechnology, or medical device companies, governmental agencies, academic medical centers, individual researchers

Institutional Review Board- An independent committee established to review and approve research involving human subjects.

Investigational New Drug Application (IND)- This application is submitted to the FDA and is the means by which a sponsor, e.g., pharmaceutical company, obtains permission to start human clinical trials and to ship an experimental **drug** across state lines (usually to clinical investigators) before a marketing application for the **drug** has been approved. Regulations are primarily at 21 CFR 312.

Investigational Device Exemption Category A- This is an experimental device in which the "absolute risk" of the device type has not been established and the FDA is unsure if the device type is safe and effective.

Investigational Device Exemption Category B- This is considered a non-experimental device in which this device type can be safe and effective because other manufacturers have obtained FDA premarket approval or clearance for that device type.

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Clinical Research Billing Basics
Clinical Trial Billing Regulations

- **Medicare's current Clinical Trial Policy (CTP) as of July 9, 2007**
  www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies/index.html
  - "Effective for items and services furnished on or after September 19, 2000, Medicare covers the **routine costs** of qualifying clinical trials, as such costs are defined below, 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."
    (National Coverage Determination (NCD) 310.1)
- **What is covered by Medicare:**
  - Items and services typically provided absent a clinical trial;
  - Items and services required for provision of an investigational item or service (e.g., administration of a non-covered chemotherapy), clinically appropriate monitoring of effects of item/service, or prevention of complications; and
  - Items and services needed for the reasonable and necessary care arising from provision of an investigational item/service, in particular, for the diagnosis and treatment of complications from participation in the research protocol.
  - If the investigational item itself would be covered outside of the trial, it is still covered within the trial.

Clinical Research Billing Basics
Medicare Clinical Trial Policy

What is **not** covered by Medicare?

- Items and service provided solely to satisfy data collection and analysis needs and are not used in direct management of the patient (e.g., monthly CT scans for a condition usually requiring a scan every three months).

- Items and services customarily provided by research sponsors free of charge for anyone enrolled in the trial.

Clinical Research Billing Basics
Qualifying Clinical Trial (QCT)

The CTP allows Medicare to cover routine costs of a Qualifying Clinical Trial if the following requirements are met:

1. The study must investigate an item or service that Medicare pays for.
2. The study must enroll patients with a diagnosed disease.
3. The study must have therapeutic intent.

AND

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, or VA;
3. Studies being conducted under an IND application reviewed by the FDA;
4. Drug trials that are exempt from having an IND under 21 CFR 312.2 (b)(1); OR
5. Studies done under the Coverage with Evidence Development Process
   https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development

* These studies meet seven desirable characteristics as defined by the CTP, rated to therapeutic intent, trial design, scientific merit, sponsor is a credible organization, and the study is in compliance with federal regulations relating to Human Subjects Protection.

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Clinical Research Billing Basics
Medicare Claims Processing Guidelines

Medicare requires that claims submitted for patients enrolled in clinical trials (inpatients and outpatients) have:

1. ICD-10-CM diagnosis code Z00.6
2. Condition Code 30 (Qualified Clinical Trial reported on the claim to inform Medicare that the service is related to a clinical trial or study
3. Outpatient claims- Modifier Q0 to identity the investigational item or service and Modifier Q1 to identify all lines that contain the routine service with the appropriate CPT/HCPCS code.
4. NIH ClinicalTrials.gov 8-digit National Clinical Trial (NCT) number reported on the claim.
5. Trial name, sponsor, and sponsor-assigned protocol number must be included in the billing provider's medical record (e.g., Informed Consent).

Clinical Research Billing Basics
Medicare Claims Processing Manual, Chapter 32

Medicare Claims Processing Manual (cms.gov)

Type of Study	Hospital Charges (UB-04) Inpatient Claims	Hospital Charges (UB-04) Outpatient Claims	Professional Charges (CMS-1500)
Qualifying Clinical Trial Medicare Clinical Trial Policy • Instructions apply to conventional care, including treatment of complications • Billing provider must include in the medical record the following information: trial name, trial sponsor, and sponsor-assigned protocol number	• ICD-10 diagnosis code Z00.6 as the secondary diagnosis code for trial participation • ICD-10 diagnosis code Z00.6 as the primary diagnosis code for healthy controls only • Condition Code 30 (qualifying clinical trial) reported at the claim level for both trial participants and healthy controls • NCT# • Include Z00.6, Condition Code 30 and NCT# regardless of whether all services on the claim are related to the clinical trial or not	• ICD-10 diagnosis code Z00.6 as the secondary diagnosis code for trial participation • ICD-10 diagnosis code Z00.6 as the primary diagnosis code for healthy controls only • Q1 Modifier- for both participants and healthy controls- apply to each service identified as conventional care only on line items related to the clinical trial • Q0 Modifier- for each service identified as investigational • Condition Code 30 (qualifying clinical trial) reported at the claim level for both trial participants and healthy controls • NCT# • Include Z00.6, Condition Code 30, NCT# regardless of whether all services on the claim are related to the clinical trial or not Note: CMS will return claims as unable to process if Z00.6 and NCT# are not on claim with the Condition Code 30	• ICD-10 diagnosis code Z00.6 as the secondary diagnosis code for trial participation • ICD-10 diagnosis code Z00.6 as the primary diagnosis code for healthy controls only • Q1 Modifier- for both participants and healthy controls- apply to each service identified as conventional care only on line items related to the clinical trial • Q0 Modifier- for each service identified as investigational • NCT# preceded by “CT”

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Clinical Research Billing Basics
Investigational Device Exemptions (IDE)

Category A (Experimental) IDE Study- Medicare covers routine care items and services furnished in an FDA-approved Category A IDE study if CMS (or its designated entity) determines that the Medicare coverage IDE study criteria are met.

Category B (Non-Experimental) IDE Study- Medicare **may** make payment for a Category B IDE device and routine care items and services furnished in an FDA-approved Category B IDE study if CMS (or its designated entity) determines prior to the submission of the first related claim that the Medicare coverage IDE study criteria are met.

Medicare Benefit Policy Manual (cms.gov), Chapter 14

- CMS will post IDE study approvals on the CMS Coverage website. Healthcare providers and Medicare Contractors must check the site prior to submitting claims or making payment.
- https://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies.html

Clinical Research Billing Basics

Affordable Care Act

Impact of the Affordable Care Act on Clinical Trials

Section 2709 applies to all approved clinical trials. An approved clinical trial, as **defined in the statute**, is a **phase I, II, III, or IV** clinical trial that relates to the **prevention, detection or treatment of cancer or other life-threatening diseases** that also satisfies one of three requirements:

1. The trial is **federally funded**;
2. The trial is conducted under an **investigational new drug application**; *or*
3. The trial is **exempt from such an investigational new drug application**.

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Clinical Research Billing Basics

Affordable Care Act

In a provision of the "Act," insurers are prohibited from denying or limiting coverage for routine clinical care for individuals enrolled on a clinical trial **that would otherwise be provided if the individual was not a study participant.** If a group health plan or a health insurance issuer offering group or individual health insurance coverage provides coverage to a qualified individual, then such plan or issuer may not:

1. Deny the individual participation in the clinical trial;
2. Deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and
3. Discriminate against the individual on the basis of the individual's participation in such trial.

Many commercial payers have published Clinical Trial Policies or guidelines to meet the requirements of the "Act", which are often consistent with the CTP.

Clinical Research Billing Basics

Clinical Treatment Act (Consolidated Appropriations Act)

- Effective Jan. 1, 2022, Clinical Treatment Act expanded clinical trial access to Medicaid beneficiaries.

- April 13, 2022, the Center of Medicaid and CHIP Services (CMCS) issued a State Medicaid Director Letter "outlining new Medicaid state plan requirements for assuring coverage of routine patient costs associated with participation in qualifying clinical trials." Requirements consistent with Medicare's CTP. https://www.medicaid.gov/federal-policy-guidance/downloads/smd21005.pdf

https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXXII/Chapter175/Section110L

https://www.dhhs.nh.gov/sites/g/files/ehbemt476/files/documents2/pnclintrial122821.pdf

https://eohhs.ri.gov/sites/g/files/xkgbur226/files/2021-12/signed-to-post-public-notice-clinical-trial-mandatory-coverage.pdf

https://dvha.vermont.gov/forms-manuals/forms/clinical-trials

https://portal.ct.gov/-/media/Departments-and-Agencies/DSS/SPAs/SPA-22-F---Svcs-Covered-in-Clinical-Trials---SPA-Pages---Website-Notice.pdf

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Building a Strong
Clinical Research Billing and Audit Program

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Focal Points

- **Champion the significance**
- Create pillar of institutional oversight
- Find opportunities to support and educate

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Why this is so important

- To avoid ‘double billing’ to participant’s insurance and study fund
- Complexity of clinical service billing process when related to research
- Ensure research bills are allowable and appear in accordance with federal regulations
- Route procedures from patient’s account to study when applicable
- Institution takes fiscal responsibly for viability of research

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Risks of billing non-compliance

- Center for Medicaid and Medicare Services (CMS) and Clinical Trial Policy (CTP) guidelines may result in:
- Audits
- Corporate integrity agreements
- Corporate compliance agreements
- Fines
- Negative publicity
- False claims
- Damage to the institution's and/or principal investigator's reputation
- Potential for OIG/DOJ investigations, potential fines

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Focal Points

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Institutional Support

Clinical Trial Office

- Ensure Coverage Analysis (CA), budget, and contract
- Support Clinical Trial Management System (CTMS) utilization for billing validation

Finance – Patient Billing

- Review and approve charges for patient billing
- Report issues to investigator and compliance

Research Compliance

- Provide ongoing education and oversight
- Perform audits and provide feedback

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Risk Analysis

- Perform research billing risk analysis to determine priorities
  - What types of trials?
    - Inpatient or Outpatient
    - Drugs or devices
    - Interventional or Observational
    - CMS Qualifying or Non-qualifying
- Collaborative effort by Clinical Trial Office and Research Compliance

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Documents required for contracting process

- DRAFT Consent Form from Sponsor
- DRAFT Budget Template from Sponsor
- Draft Clinical Trial Agreement (CTA) or Notice of Grant Award (NOGA)
- Protocol
- FDA-related documentation
- Approval letter(s) or IND/IDE source documentation
- Other pertinent documentation related to the CA
- Funding Sheets
- Investigator's Brochure

Good negotiation of contracts

- Include all required terms and conditions
- Ensure payment for all clinical and administrative services
- Develop payment terms that are able to be operationalized
- Be open, fair-minded, and collaborative

Are all details aligned?

- Document consistency committee/study team review
- Consent form, Billing plan, CA, Contract budget/exhibit

Workflow approval and stop-gap examples:

- IRB application not approved until CA and external contract confirmed by pre-board review
- Hold-up contract execution
- Communicate with Finance - billing system(s): professional and hospital
- Sign off by Department chair/chief if budget insufficient

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Financial Compliance

Internal Study Initiation Meeting
- Upon contract execution
- Prior to starting a study

- Who is responsible for what?
- How will patients be registered?
- What ancillary departments will be involved?
- How will billing procedures be implemented ?
- How will stipends be paid ?

- **Communication is key with Study Staff**

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Shared Oversight

Senior Research Leadership
- Support institutional policies and procedures
- Relay requirements to research community

Clinical Trial Office
- Provide guidance via CA, budget development, contracting
- Answer questions, address issues about billing process

Research Compliance
- Enforce adherence to policies
- Audit and provide feedback

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Focal Points

- Champion the significance
- Create pillar of institutional oversight
- **Find opportunities to support and educate**

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Education touch points

- Contemplation of a clinical trial
  - ✓Confidential Disclosure Agreement (CDA)
  - ✓Non-disclosure Agreement (NDA)
  - ✓Review of viability
    - ➢ Staffing
    - ➢ Subject population
- Clinical Trial Agreement negotiation
  - ✓Coverage analysis
  - ✓Budget development
  - ✓Terms and conditions

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Find all opportunities

CTMS education
- Classroom
- In-person

IRB Submission
- Require alignment of Informed Consent Form (ICF) and contract
- Monitor for trials utilizing hospital clinical services

Study Initiation meeting with PI and study team
- Review CA
- Explain billing process for protocol related ordered clinical
- services
- Discuss who/how/when to bill the sponsor, per contract terms

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Auditing is essential

- Create an audit policy and audit plan
- Schedule regular audits per quarter

Audit activities

- Meet with investigator
- Review charges for a sample of subjects
- Document and report to Research Compliance and investigator

Audit – to enhance education

- Formally audit and provide updates and reporting to administration and management
- Audit charge processing retrospectively, reviewing to CA or billing grid
- Ensure that errors are corrected in a timely manner
  - Processing of insurance refunds or movement of charges from study to insurance within payer filing limit

QUESTIONS

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