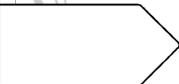




Payer Issues, Denials and
Process for Clinical Trials:
How to Audit for Lost Revenue!

HCCA Compliance Institute – April, 2018



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Kelly Willenberg & Associates, LLC



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Disclaimer

- 
- No legal advice is provided.
 - Please seek legal representation to have your questions clarified or discussed.
 - The information, thoughts and opinions provided here are not legal advice: consult your institution's legal, compliance and other appropriate leaders and, at their discretion, your local Medicare Administrative Contractor (MAC), for any specific billing questions or issues



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Objectives

- ▶ Review claims submitted on trials that were denied and understand why
- ▶ Discuss clinical trial billing audit tools, best practices and processes
- ▶ Understand the risk for your hospital and how it impacts revenue

Speakers



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Kelly Willenberg is the owner of Kelly Willenberg, LLC. Kelly has extensive knowledge in clinical trials management and research compliance, including all aspects of clinical trial billing compliance. She has over 30 years of clinical research experience and billing compliance. She has a Bachelor's Degree in Nursing, a Masters and a Doctorate in Business Administration. She is an experienced oncology nurse with the majority of her experience in oncology, pediatrics, school nursing and cardiac rehab. Kelly worked for over twelve years at Vanderbilt University Medical Center. She established the enterprise wide billing compliance program at Vanderbilt and served as the first Director of Billing Compliance in 2002. She also served as the Director of the Clinical Trials Office for the Cancer Center managing a Community Oncology Research Program (CCOP and an affiliate network throughout the southeast while at Vanderbilt and was an active member of the nursing committees in the cooperative groups). cooperative groups).

Kelly is a frequent presenter and speaker at the Oncology Nursing Society, Academy of Health Care Administrators, American Society of Clinical Oncology, Association of HealthCare Internal Auditors, MAGI, The Society of Clinical Research Associates, Association of Clinical Research Professionals, ExL Events, HCCA, and other professional organizations. She assisted in writing the Research Compliance Professional's Handbook for Healthcare Compliance Association (HCCA). She served as an editor for the 3rd Edition of the Manual for Clinical Trials Nurses for ONS. She has a bi-monthly column in Compliance Today titled "Research Reflections". She is a Certified Clinical Research Professional (CCRP), Certified as a Healthcare Research Compliance Professional (CHRC) and Certified in Healthcare Compliance (CHC).

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Speakers



Wendy Portier, MSN, RN, CHC, CHRC, CCM
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Wendy Portier has over 25 years of experience in health and managed care including: Health Care Compliance, Research Compliance, Consulting, Clinical Research, Critical Care Nursing, Quality, Utilization Management, Case Management and Disease Management. Having worked on the provider, researcher, payer and sponsor sides, Wendy has a unique perspective and extensive knowledge regarding clinical research compliance. Her specific research compliance experience includes: implementing process improvements, leading government inspections & responses, auditing, monitoring, implementing compliance programs and improving the research billing revenue cycle – from coverage analysis & budgets, authorizations, claims review to denials & appeals management.

Wendy obtained a Bachelor of Science in Nursing from Nicholls State University and a Master of Science in Nursing in Clinical Research Management from Duke University. She also completed a Health Care Corporate Compliance - Post Graduate Certificate Program at George Washington University in Washington, DC and holds several health care related certifications. Wendy has lectured locally, nationally and internationally on various topics related to clinical research, health care auditing and health care compliance.

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Polling Question – Who do we have in the audience?

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Why are Clinical Trials Important?

- ▶ Key research tool for advancing medical knowledge and patient care
 - ▶ Clinical trials show us what works and what does not work
- ▶ Clinical trials answer 2 important questions:
 1. Does the new treatment work in humans?
 2. Is the new treatment safe?
- ▶ New treatments must pass many tests before they get to the public at large
- ▶ Examples:
 - ▶ Asthma treatment
 - ▶ Hormone therapy
 - ▶ High-dose chemotherapy & bone marrow transplant
- ▶ Help healthcare decision makers direct resources to and treatments that work best



Identifying essentials of research
billing compliance assurance

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Clinical Trial Billing Compliance - Synchronous Work Flow is Key

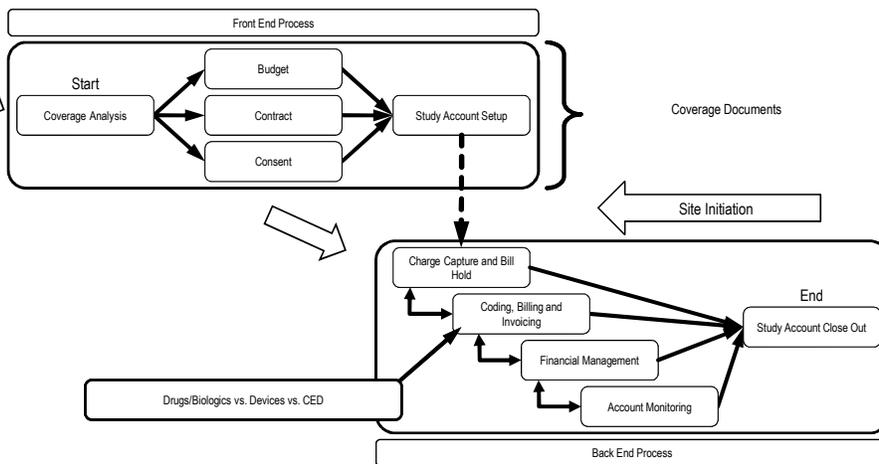
- Vetting & Feasibility Analysis
- Coverage Analysis & Billing Plan
- Budgeting, Pricing & Contracting
- IRB Approval
- Enrollment & Informed Consent
- Identification, Registration, Scheduling & Tracking
- Authorization & Documentation for Medical Necessity
- Charge Capture
- Charge Segregation
- Claims Submission

Compliant Billing

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Clinical trial revenue continuum



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What Does It Take to Get Clinical Trial Billing Compliance Right?

- ▶ A broad understanding of many fragmented, disconnected processes and systems
- ▶ An appreciate of many events that take place before and after billing
- ▶ Correctly debiting a study account and billing a third party (insurance, patient, etc.)
- ▶ Four main reasons for incorrect billing:
 1. Technological error
 2. Human error
 3. Training
 4. Awareness

The most basic basics!

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Clinical trial billing compliance: Primary rules*, 1

“Clinical Trials Policy”: National Coverage Determination 310.1

- Defines **qualifying clinical trials** and types of **routine services**

Investigational Device Guidelines

- Defines **device and routine service billing** requirements

**Other laws, regulations, rules also are relevant but are largely captured by 310.1 and claims requirements*

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Clinical trial billing compliance: Primary rules*, 2

Medicare claims processing rules

- Research-specific and non-research-specific: **all relevant rules to be met**
- Federal payers follow Medicare; Medicaid may have specific alterations

False Claims Act protects federal taxpayers from overpayment for services provided:

- **Overpayments** result from false claims made by federal service providers
- In health care billing, an overpayment occurs when a federal insurer pays for a **clinical service that was not allowable**
- Rules stipulate requirements for reporting and correcting overpayments

**Other laws, regulations, rules also are relevant but are largely captured by 310.1 and claims requirements*

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NCD 310.1: What is a Qualifying Clinical Trial?

Qualifying Clinical Trial Analysis			
Requirement	Yes	No	Comment
Does the investigational item or service fall into a Medicare benefit category? <small>Note: The subject or purpose of the trial must be the evaluation of an item or service that falls within a benefit category and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).</small>			<input type="text"/>
Does the study have therapeutic intent stated in the study objective(s) or aim(s) and is consistent with Institutional policy?			<input type="text"/>
Does the study enroll patients with diagnosed diseases?			<input type="text"/>
Is the study a deemed trial? <small>(Study funded by NIH, CDC, AHRQ, CMS, DOD, or the VA or supported by cooperative groups funded by NIH, CDC, AHRQ, CMS, DOD, or the VA or Provided under BLA / BB IND / IND # or IND Exempt as verified by the FDA or IRB)</small>			<input type="text"/>
Is the study a qualifying clinical trial? (All questions must be answered "Yes" to qualify)			<input type="text"/>

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NCD 310.1: What are Routine Costs?

- ▶ “Items or services that are typically provided absent a clinical trial (e.g., 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), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and”
- ▶ “Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service--in particular, for the diagnosis or treatment of complications.”

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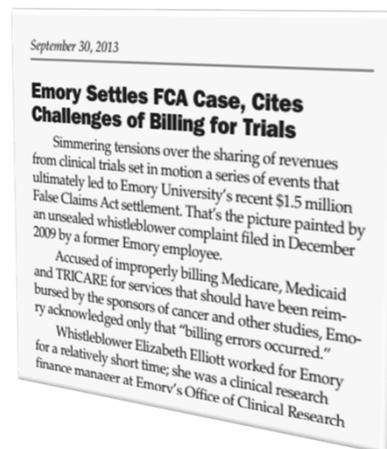
Research billing compliance assurance

Although there are many nuances, in a nutshell:

- **Do not bill patient/insurance** for services that are:
 - Not medically necessary
 - Otherwise not allowable / non-covered services / statutorily excluded
 - Promised by the sponsor (contract) / budget
 - Provided solely to satisfy data collection
 - Promised by the consent form
- Apply the Medicare-specified **research modifications** as applicable
- Follow all other Medicare rules

Areas to watch in research billing and finance

- Inadequate financial accounting
- **Research subjects not identified**
- **Document non-concordance:** Protocol, Coverage Analysis, Budget, Contract, ICF
- **Charge capture/billing** for research related services and routine costs, study drugs and devices
- No monitoring of billing inquiries
- Poor budget process, lack of proper accounting and invoicing to Sponsors
- Claims lack proper **research coding:** dx, modifiers, CCs, and NCT # on claim
- **Charge segregation** occurring between research and payer or Medicare and Medicare Advantage
- Communication on **denials management** not thorough or lack of attention to detail



Research billing audit goals

Although there are many nuances, and scope depends upon specific institutional goals, in a nutshell:

- Identify system or human **error in research billing**
- Make **repayments** if overpayments are found, following required timelines
- Identify **underpayments** and invoice/bill as possible
- **Correct** process errors or gaps
- **Educate** users as applicable
- Conduct **follow-up review** to assure sufficient remediation
- Document **quality assurance** diligence

Audit scope and planning

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Before audit can be planned, identify standards

1. Audits are designed to track and evaluate existing processes and their results
2. In order to identify **audit scope**, need to have evaluated the potential failure of existing process(es) to provide intended results: **risk assessment** of entire process
3. In order to evaluate existing processes, need to compare to **minimum necessary to achieve compliance** assurance: regulations, other external requirements, and organizational policies

What does clinical research billing compliance assurance require?

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Types of clinical trial billing audits

- Process / Internal Control
- Study Level (Document Concordance & Coverage Analysis Validation, Invoicing)
- Patient Level (Claims, Denials, Invoicing)

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Audit scope: preliminaries

Stakeholders and auditors, internal and external

- ▶ Depends upon the **content scope**
- ▶ **Skill set** to be parallel to content: e.g., denials review requires person with denials experience
- ▶ Do **internal audit or compliance departments** have authority?
- ▶ Is Office of General Counsel to be consulted?
- ▶ Decision to go external may be related to risk assessment results



Audit scope: preliminaries, 1

Time span

- ▶ Are you auditing a **process improvement**?
- ▶ Do you want to see **before and after** or just after?
- ▶ Are you performing it **for cause** and need a specific time point?

Sample size

- ▶ Determining **significant sample**
- ▶ Unless reviewing a process only, number of **studies**?
- ▶ If conducting billing review, number of **patients**, number of **claims**?

Audit scope: preliminaries, 2

Interviewees, assistants and notifications

- ▶ Depends upon the content scope
- ▶ Will involve those according to assigned operational tasks
- ▶ **Leadership channels** to be considered

Audit scope: one or all of the following, 1

Coverage analysis

- ▶ Is the **coverage analysis concordant** with study documents? (protocol, ICF, budget, contract, coverage analysis)
- ▶ Does the study **qualify** for billing?
- ▶ Do the justifications support billing the subject's insurance?
- ▶ Were all costs included?

Document concordance

- ▶ Are all study **documents concordant**? (protocol, ICF, budget, contract, coverage analysis)
- ▶ Do study documents contain **clear language**?

Audit scope: one or all of the following, 2

Subject identification

- ▶ Are the **subjects identified** “flagged” in the systems?
- ▶ Was the “flag” applied timely?

Claims review

- ▶ Did the claim go to the **appropriate payer**? (Medicare, Medicare Advantage, Sponsor, Commercial Insurance, etc.)
- ▶ Does the claim contain **correct coding**? (Z00.6, Q1, Q0, CC30, IDE#, Rev Code 256/624, NCT#, etc.)
- ▶ Does the medical record **documentation support medical necessity**?

Audit scope: one or all of the following, 3

Payer selection

- ▶ Audit **Medicare/Medicaid** only or include **commercial** payers?
- ▶ If commercial payers to be included, do you want
 - ▶ A different **sample size**?
 - ▶ A **subset** of them?

Invoicing

- ▶ Did invoicing occur?
- ▶ Was invoicing **timely**?
- ▶ Was the **proper amount billed**?
- ▶ Was **overhead** included?

Audit scope: one or all of the following, 4

Denials

- ▶ Are research related **denials identified**?
- ▶ **What causes** research related denials?
- ▶ **Who manages** research denials?

Areas to understand prior to audit testing

- ▶ Operations
 - ▶ Charge segregation
 - ▶ Registration
 - ▶ Charge Capture
 - ▶ Billing
- ▶ Financial Management
 - ▶ Budgeting, Pricing, Contracting
 - ▶ Accounts Receivable
 - ▶ Professional Fees
- ▶ Compliance Management
 - ▶ Investigations & Monitoring
 - ▶ Training
- ▶ Personnel
 - ▶ Roles & Responsibilities
 - ▶ Communication

What areas at your organizations do you understand fully?

Summary: how to audit a clinical trial, 1

- ▶ Take the **standard steps**:
 - ▶ Risk assessment
 - ▶ **Objectives**: what are we trying to achieve?
 - ▶ **Scope**: what and who are to be included in the audit?
 - ▶ **Approval(s)** required: Identify necessary authorities, advisors, stakeholders
- ▶ Create an **audit plan**
 - ▶ What is the objective of each step?
 - ▶ Does the step tie to the overall audit objective?

Summary: how to audit a clinical trial, 2

- ▶ Conduct **sample selection**
- ▶ Request and **review documents**
 - ▶ Study Level – protocol / study documents, ICF, CTA, budget, CA, IND/IDE
 - ▶ Patient Level – UBs/1500s, EOBs, study accounts, subject calendars, EMR
- ▶ Perform **interviews and testing**
 - ▶ Documentation
 - ▶ Work papers
 - ▶ Data collection
- ▶ Write a report



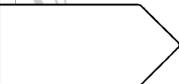
Four audit planning exercises:

Bill hold and subject identification

Invoiceable items

Research billing audit

Claims and denials review



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Audit planning: bill hold and subject identification Exercise

You have implemented a “bill hold” triggered by CRCs entering the subject’s name into a database upon informed consent

The hold is critical to ensure all billable items/services are reviewed and directed appropriately to payers/sponsors, but you have **limited resources**

- ▶ How would you **approach** with audit?
- ▶ What activities/areas would you **include** in the audit?
- ▶ What activities/areas would you **not include** in the audit?
- ▶ What is the **objective** of your audit?
- ▶ How would you choose your **sample**?

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Audit planning: invoiceable items

Exercise

The organization includes many invoiceable items in all budgets and just implemented a new invoicing process

You need to determine if **invoicing and receivables** improved after implementing the new invoicing system on 1/1/2016

- ▶ How would you **approach** this audit?
- ▶ What **time period** would you choose to audit?
- ▶ How would you choose your **sample**?
- ▶ Who would you **interview** for this audit?
- ▶ What **systems** would you need **access** to perform the audit?
- ▶ Considering the organization includes many invoiceable items in budgets, what **recommendations** would you give regarding invoiceable items in general?

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Audit planning and testing: research billing audit

Exercise

You determine a “soup to nuts” research billing audit is desirable

Place the following activities in the correct **audit planning order** and indicate why you placed one item before another

- ▶ Review claims
- ▶ Perform document concordance
- ▶ Review subject “flagging”
- ▶ Select the sample: studies and subject to review
- ▶ Determine audit scope and objectives and plan the audit
- ▶ Conduct interviews
- ▶ Request documents (ICF, protocols, budgets, contracts, coverage analysis)
- ▶ Determine if the coverage analysis is correct
- ▶ Identify the “source of truth” for the claims review
- ▶ Determine error calculation

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Audit planning: claims and denials review, 1

Exercise

The organization has received several patient complaints about denials related to clinical-trial procedures in a device study

You need to determine if research-related payer claims are billed to the **appropriate payer**

- ▶ How would you **approach** this review?
- ▶ What may **cause** a denial?
- ▶ What **documents** would you need to perform the review?

Document Concordance Auditing

Term alert: document concordance

We use “document concordance” to refer to a key and complex practical requirement in research billing: the consistency and accuracy of all study-initiation and continuation documents relevant to billing for protocol-specified clinical services

*Without concordance,
accurate billing is impossible
(– or accidental)*

Example: document concordance and content review

Compare **key documents**

- Contract
- Budgets (Internal and External)
- Informed Consent Form (ICF)
- Coverage Analysis
- Protocol

Are there any **discrepancies** between the documents?

Were there any discrepancies on the Coverage Analysis?

Did the budget contain **invoiceable items**?

Were there any additional **regulatory issues** identified?

- Did the contract or ICF contain language that violate the Medicare Secondary Payer Rule?
- Did the ICF contain Medicare Advantage language for drug trials?

Sample checklist

IRB #: 12-00000 PI Name: MD		Study Name: XYZ Study Consistency Checklist Date:		
Issue	Agreement / Budget Date	ICF Version/Date:	Protocol	Reviewer
A. Confidentiality Describe how data or information will be shared between INSTITUTION, or sites and the research sponsor.	N/A	YES	YES	XXX
B. Benefits of Taking Part in the Study Describe benefits of participating for the subject and/or others in the context of therapeutic intent.				XXX
C. Research vs. Conventional Care The procedures that will be performed during the course of the trial that are considered to be part of the subjects' conventional care and that would be performed anyway notwithstanding the research study are differentiated from the procedures that will be performed during the course of the study that are for research purposes only.	N/A	YES	N/A	XXX
D. Additional Costs Subjects will be required to bear additional costs beyond those associated with their conventional care as a result of participating in the study.	N/A	N/A	N/A	XXX
E. Subject Compensation Subjects will be compensated for agreeing to participate in the trial.	N/A	N/A	N/A	XXX
F. Research Related Injury Identify the individual or entity responsible for the costs of any research-related injuries to subjects.	N/A	N/A	N/A	XXX
G. Future Use Of Data Are subjects asked or expected to donate data, materials, samples etc. to databases or tissue repositories and if the sponsor receive any future rights to the data or materials collected in the course of the study?	N/A	YES	YES	XXX
H. Study is registered at clinicaltrials.gov and statement is in the ICF (Input Registration Number)				XXX
I. Medicare Advantage statement included in the ICF				XXX

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Insurance Claims Review & Exercises

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Billing grid/sponsor budget review

Exercise

What's missing/incorrect?

S = Sponsor Paid
M = Medicare/ 3rd Party Payer

Blue = billing grid; orange = sponsor budget

Procedure/Event	CPT/HCPCS Codes	Billing Designation
CT Scan Abd/Pelvis w/ Contrast incl RECIST	74177, Q9967	S
CMP	80053	S
Chemo Admin	96413	M
Chemo Study Drug	J9999	S
Procedure/Event	CPT/HCPCS Codes	Amount Paid
CT Scan Abd/Pelvis w/ Contrast	74177	\$3000.00
Port Draw	36591	\$50.00
CMP	80053	\$30.00
Chemo Admin	96413	Routine

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Summary: Medicare requirements – drug trials

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Claim Type	Coding Requirements	Location on Claim
Technical UB-04 (CMS1450)	<ul style="list-style-type: none"> - Z00.6 – Secondary Diagnosis - Modifier Q0 & Q1 as needed (Outpatient Only) <ul style="list-style-type: none"> - Q0 – Investigational Clinical Service (Drug) - Q1 – Routine Costs - Condition Code 30 “Qualifying Clinical Trial” - Rev Code 256 – Drug Trial - NCT # (www.clinicaltrials.gov) 	<ul style="list-style-type: none"> - Field 66 - Field 44 - Field 18 - 28 - Field 42 - Field 39; D4 & Value Code = 8 digit NCT#
Professional CMS1500	<ul style="list-style-type: none"> - Z00.6 – Secondary Diagnosis - Modifier Q0 & Q1 as needed <ul style="list-style-type: none"> - Q0 – Investigational Clinical Service - Q1 – Routine Costs - NCT # (www.clinicaltrials.gov) 	<ul style="list-style-type: none"> - Field 21 - Field 24.D – Modifier - Field 19 (Use CT pre-fix on paper claim only)

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Summary: Medicare requirements – device trials

Claim Type	Coding Requirements	Location on Claim
Technical UB-04 (CMS1450)	<ul style="list-style-type: none"> - Z00.6 – Secondary Diagnosis - Modifier Q0 & Q1 (Outpatient Only) <ul style="list-style-type: none"> - Q0 – Investigational Clinical Service (Procedure) - Q1 – Routine Costs - Condition Code 30 "Qualifying Clinical Trial" - Condition Code 53 – Free Devices (Outpatient only) - NCT # (www.clinicaltrials.gov) - Value Code FD (Free Device as part of a trial, Outpatient Only) - Rev Code 0624 – Device Trial <ul style="list-style-type: none"> - Device charge – list as non-covered (token) charge if device is provided at no cost - Rev Code 278 – Medical/Surgical Supplies: Other Implants - IDE Number - Category B IDE device HCPCS code, as applicable - Generally, Category A not reported on institutional claim. Follow Medicare's specific instructions for the trial 	<ul style="list-style-type: none"> - Field 66 - Field 44 - Field 18 - 28 - Field 18 - 28 - Field 39; D4 & Value Code = 8 digit NCT# - Field 39; Credit amount for device - Field 42 - Field 47 & 48 - Field 42 - Field 43 - Field 44
Professional CMS1500	<ul style="list-style-type: none"> - Z00.6 – Secondary Diagnosis - Modifier Q0 & Q1 as needed <ul style="list-style-type: none"> - Q0 – Investigational Clinical Service (Procedure) - Q1 – Routine Costs - NCT # (www.clinicaltrials.gov) - IDE Number 	<ul style="list-style-type: none"> - Field 21 - Field 24.D – Modifier - Field 19; Use CT pre-fix on paper claim only - Field 23

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Medicare Q&A 2014

Mandatory Reporting of NCT# Identifier on Medicare Claims*

Medicare coverage of clinical trials, prospective studies, and registries			
	CTP	IDE	CED
CMS approval required	No – must qualify under NCD 310.1	Yes –each specific study approved by FDA before 1/1/2015, requires MAC approval; for each specific study approved by FDA after 1/1/2015, requires CMS approval	Yes – requires CMS approval for each specific study
Public notification	No – provider determines qualification	Each specific study approved by FDA after 1/1/2015 appears on CMS IDE Website	Each specific study approved by CMS appears on CMS IDE Website
Routine services (Q1)	Covered if otherwise coverable by Medicare in qualified study	Covered if study is approved by CMS and otherwise coverable by Medicare	Covered if study is approved by CMS and otherwise coverable by Medicare
Investigational item/service (Q0)	Covered if otherwise coverable by Medicare in qualified study	Covered if study is Category B, and approved by CMS	Covered if study is approved by CMS

*<https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Downloads/Mandatory-Clinical-Trial-Identifier-Number-QsAs.pdf>

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Billing grid/claim

Exercise

What's missing/incorrect?

S = Sponsor Paid
M = Medicare/ 3rd Party Payer

Blue = billing grid; orange = payer claim

Procedure/Event	CPT/HCPCS Codes	Billing Designation
CT Scan Abd/Pelvis w/ Contrast incl RECIST	74177	S
CMP	80053	S
Chemo Admin	96413	M
Chemo Study Drug	J9999	S
Charge Description	CPT/HCPCS Code	Charge Amount
CT Scan Abd/Pelvis w/ Contrast	74177	\$5000.00
CT Contrast	Q9967	\$150.00
Port Draw	36591	\$200.00
CMP	80053	\$100.00
Chemo Admin	96413	\$500.00

Invoicing Review & Exercises

Example: invoiceable items, 1

Review contracts, budgets, coverage analysis for invoiceable items

Identify activities that are invoiceable

- ▶ Conduct a **process audit**
- ▶ Conduct **internal control testing**
- ▶ For example:
 - ▶ External **vendor invoices** – PEAR* groups
 - ▶ Items/services performed for specific cases
 - ▶ Was **overhead** included?



** Pathology, Emergency, Anesthesia, Radiology*

Example: invoiceable items, 2



The budget indicates payment upon invoice for certain activities and items/services, such as:

- ▶ Serious Adverse Event (SAE) reporting
- ▶ Re-consent of subjects
- ▶ Items/services conducted for research purpose only

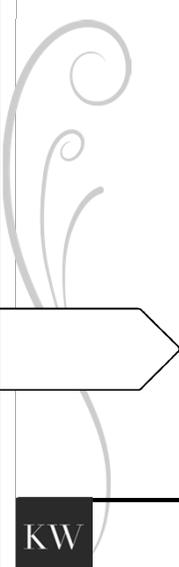
How do you know when:

- ▶ An SAE occurs?
- ▶ Subjects are re-consented?
- ▶ A CT scan is conducted for study purposes only?

Example: lost revenue and billing risks

1. Collect **key documents** – contract, budget, coverage analysis, informed consent form and protocol
2. Perform a “**document concordance**” review
3. Establish the “**source of truth**” for the audit
4. Audit the **coverage analysis**
5. Use the original coverage analysis versus revised coverage analysis
6. Identify **invoiceables**
7. Determine how subjects are identified in systems
8. Gain **system access** needed to perform the audit
9. Follow orders / **claims** / invoices through the systems and review for correct billing/payer, coding, etc.
10. Review **denials**
11. Calculate **error rates** / overpayments / underpayments

Invoicing exercise



Insurance Denials

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General Causes for Denials: Pre & Post Service

- ▶ Not a covered benefit
- ▶ Not enough information
- ▶ Not medically necessary
- ▶ Lack of pre-authorization
- ▶ Complete disconnect between hospital and physician billing
- ▶ Documentation by physicians inadequate in some instances
- ▶ Coverage Determinations:
 - ▶ LCD prohibits payment
 - ▶ Ordered test with certain ICD-9 / ICD-10 codes and there is an LCD that prohibits payment
- ▶ Coding:
 - ▶ Government codes on commercial payer claims
 - ▶ Z00.6 not in secondary position so it is removed from the claim by coders
 - ▶ Lack of NCT# when there is a Z00.6 and a condition code 30
 - ▶ Improper coding for commercial payers

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Medicare Denials

- ▶ The Medicare beneficiaries enrolled in the trial would not be held liable (i.e., would be held harmless from collection) for the costs consistent with provision of §1879, 1842(l) or 1834(j)(4) of the Act, as applicable.
- ▶ Where appropriate, the billing providers would be held liable for the cost and fraud investigations of the billing providers and the trial's PI may be pursued. (NCD 310.1)
- ▶ Advanced Beneficiary Notices (ABNs)

Common findings

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Auditing clinical trial billing and finance: common findings, 1

- ▶ Non-employed physician group **not notified of clinical trial / subject**
- ▶ **Under** budgeting
- ▶ **Lack of fund** accounting
- ▶ **Excessive residual** balances and no residual funds policy
- ▶ **Claims submission errors**
 - ▶ Misdirection of charges – **double billing**
 - ▶ **Denials**
 - ▶ For example: pre-authorization, investigational article
 - ▶ **Coding errors** and mismatches
 - ▶ IDE, NCT numbers on claim no CC or Q-modifiers
 - ▶ IV administration with no study drug on claim
 - ▶ **No follow-up** on denials: write-offs

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Auditing clinical trial billing and finance: common findings, 2

- ▶ **Charges not posted** in billing systems
- ▶ Billing of professional (pro) and technical (tech) **charges not coordinated**. For example, pro charge is billed:
 - ▶ to insurance and tech charge is billed to sponsor/research
 - ▶ to Medicare and tech charge is billing to Medicare Advantage
 - ▶ with clinical trial coding but the tech charge lacks coding
- ▶ **“Off the books”** research activities
- ▶ **Patient reimbursements** held or not paid

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Wrapping up

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Not to be a broken record, but...

- ▶ Audit **planning effort** cannot be underestimated!
- ▶ Scope and objectives follows responsible **risk assessment**
- ▶ Thorough knowledge of billing regulations and rules, as well as institutional policies, is crucial
- ▶ **Matching** audit to **auditors** and interviewees is key to planning
- ▶ Did we mention that audit planning is really important?

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Contact us

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