Auditing Clinical Trial Billing: A Real-World Approach

HCCA Compliance Institute
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Disclaimer

- No legal advice is provided.
- Please seek legal representation to have your questions clarified or discussed.

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Objectives

- Conduct hands on review of clinical trials related claims and relate the review to the clinical trial billing rules
- Understand how to apply the coverage analysis in a clinical trial billing audit
- Review claims submitted on clinical trials that were denied and understand why

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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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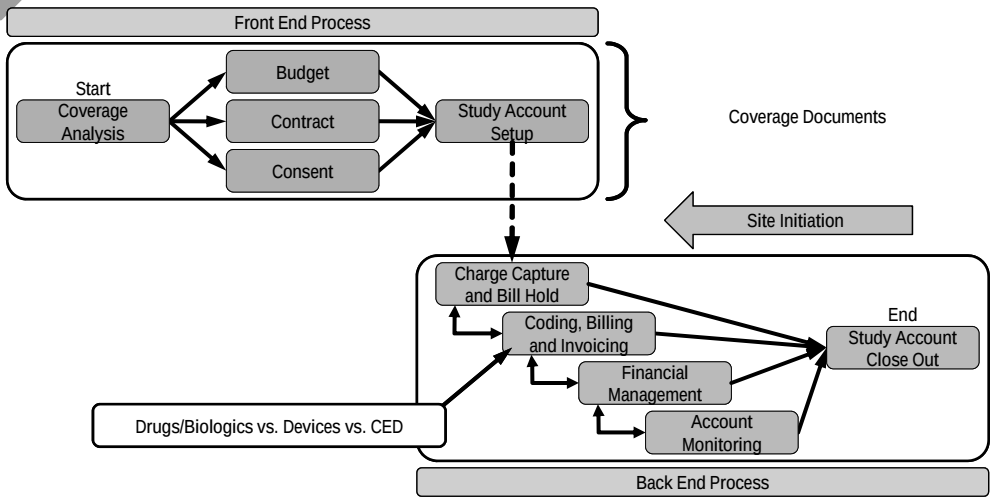
Clinical trial revenue continuum



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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

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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? 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).			
Does the study have therapeutic intent stated in the study objective(s) or aim(s) and is consistent with Institutional policy?			
Does the study enroll patients with diagnosed diseases?			
Is the study a deemed trial? (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)			
Is the study a qualifying clinical trial? **(All questions must be answered "Yes" to qualify)**			

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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
  - Promised by the sponsor (contract) / budget
  - Promised by the consent form
- Apply the Medicare-specified **research modifications** as applicable
- Follow all other **(many)** Medicare rules, for example:
  - **Medicare Advantage patients** in qualifying non-IDE studies routine charges revert to Traditional Medicare
  - National Coverage Determinations **(NCDs)**
  - Medicare Administrative Contractor Local Coverage Determinations **(LCDs)**
  - **Non-covered benefits**

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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

September 30, 2013

Emory Settles FCA Case, Cites Challenges of Billing for Trials

Simmering tensions over the sharing of revenues from clinical trials set in motion a series of events that ultimately led to Emory University's recent $1.5 million False Claims Act settlement. That's the picture painted by an unsealed whistleblower complaint filed in December 2009 by a former Emory employee.

Accused of improperly billing Medicare, Medicaid and TRICARE for services that should have been reimbursed by the sponsors of cancer and other studies, Emory acknowledged only that "billing errors occurred."

Whistleblower Elizabeth Elliott worked for Emory for a relatively short time; she was a clinical research finance manager at Emory's Office of Clinical Research

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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 as possible
- **Correct** process errors or gaps
- **Educate** users as applicable
- Conduct **follow-up review** to assure sufficient remediation
- Document **quality assurance** diligence

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Charge segregation exercise

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Common audit 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; **"Off the books"** research activities
- 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
- **Patient reimbursements** held or not paid

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Audit scope and planning

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Areas to understand prior to audit testing

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- 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?

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Before audit can be planned, identify standards

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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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Three types of clinical trial billing audits

1. Process / Internal Control
2. Study Level (Document Concordance & Coverage Analysis Validation)
3. Patient Level (Claims)

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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

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Audit scope: preliminaries

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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**?

Interviewees and assistants

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

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Audit scope: one or all of the following, 1

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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**?

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Audit scope: one or all of the following, 2

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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**?

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Audit scope: one or all of the following, 3

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Payer selection

- Audit **Medicare/Medicaid** only or include **commercial** payers?
- If commercials 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?

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Audit scope: one or all of the following, 4

Denials

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

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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?

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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

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Document Concordance Auditing

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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)

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

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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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Billing grid/sponsor budget review

Exercise

What's missing/incorrect?

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

Green = billing grid; Blue = sponsor budget

Procedure/Event	CPT/HCPCS Codes	Billing Designation
MRI BRAIN STEM W/O & W/DYE	70553	S
CBC	85025, 85027	S
Chemo Admin	96413	S
Chemo Study Drug	J9999	S

Procedure/Event	CPT/HCPCS Codes	Amount Paid
MRI BRAIN STEM W/O & W/DYE	70553	1131
CBC	85025, 85027	27
Venipuncture	36415	9
Chemo Admin	96413	429
Chemo Study Drug	J9999	0

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Insurance claims review & exercises

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Summary: Medicare requirements – drug trials

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Claim Type	Coding Requirements	Location on Claim

Technical UB-04 (CMS1450)	- Z00.6 – Secondary Diagnosis
	- Modifier Q0 & Q1 as needed (Outpatient Only)
	  - Q0 – Investigational Clinical Service (Drug)
	  - Q1 – Routine Costs
	- Condition Code 30 "Qualifying Clinical Trial"
	- Rev Code 256 – Drug Trial
	- NCT # (www.clinicaltrials.gov)
		- Field 66
		- Field 44
		- Field 18 - 28
		- Field 42
		- Field 39; D4 & Value Code = 8 digit NCT#

Professional CMS1500	- Z00.6 – Secondary Diagnosis
	- Modifier Q0 & Q1 as needed
	  - Q0 – Investigational Clinical Service
	  - Q1 – Routine Costs
	- NCT # (www.clinicaltrials.gov)
		- 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)	- Z00.6 – Secondary Diagnosis
	- Modifier Q0 & Q1 (Outpatient Only)
	  - 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
	  - 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
		- 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	- Z00.6 – Secondary Diagnosis
	- Modifier Q0 & Q1 as needed
	  - Q0 – Investigational Clinical Service (Procedure)
	  - Q1 – Routine Costs
	- NCT # (www.clinicaltrials.gov)
	
	- IDE Number
		- 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

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

Billing grid/claim Exercise

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What's missing/incorrect?

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

Green = billing grid; Blue = Facility Claim

Procedure/Event	CPT/HCPCS Codes	Billing Designation
MRI BRAIN STEM W/O & W/DYE	70553	S
Venipuncture	36415	S
CBC	85025, 85027	S
Chemo Admin	96413	S
Chemo Study Drug	J9999	S

Procedure/Event	CPT/HCPCS Codes	Amount Paid
MRI BRAIN STEM W/O & W/DYE	70553	3500
CBC	85025, 85027	65
Port Draw	36591	190
Chemo Admin	96413	750
Chemo Study Drug	J9999	0

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Claims review exercise drug study

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Denials review exercise

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Invoicing review

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Example: invoiceable items

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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*

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Data collection & error rates

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Data collection during a claims review audit

General

- Subject identifier
- Payer Type – Primary, Secondary and Tertiary
- Visit #, DOS

Claim Information

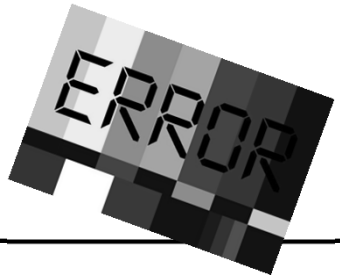
- Claim type
- Encounter Number
- Claim Number
- Item / Service Description
- CPT/HCPCS Codes
- Coding: NCT#, Modifiers, Dx code, IDE#, CC 30 , CC53

Documentation requirements

Amount billed and amount paid

Overpayments / Underpayments

- Calculate overpayments
- Calculate underpayments
- Calculate error rates



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CMS error rate data – A/B MACs

Improper Payment Rate Scores/Rankings:

- **1 0.0% - 3.9% (Oh Yeah!)**
- **2 4.0% - 7.9% (Getting Better)**
- **3 8.0% - 11.9% (Tighten Up)**
- **4 12.0% - 15.9% (Processes?)**
- **5 16.0% and above (Uh-OH!)**

Focused monitoring and corrective actions help organizations get to an acceptable ranking

Source:

- https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/CERT/MedicareFFSJurisdictionErrorRateContributionData.html

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Error rate calculations - examples

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Payment Error Rate

- Total dollars paid in error / total dollars paid
  - EX: $195,000 / $500,000 = **39% payment error rate**

Claim Error Rate

- Total # of claims billed to the incorrect payer / Total # of claims reviewed
  - EX: 90 / 500 = **18% claim error rate**

Line Item Error Rate

- Total # of line items billed to incorrect payer / Total # of line items reviewed
  - EX: 975 / 5000 = **20% line item error rate**

Coding Error Rate

- Total # of claims billed to correct payer, incorrect coding / Total # of claims reviewed. Coding errors count as 1 error per claim.
  - EX: 200 / 500 = **40% coding error rate**

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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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