



EMR, CTMS and the Clinical Trial Billing Audit

How Tools Can Help You As An Internal Auditor

Cynthia Lawson, BS, CHRC, CPC

Consultant, Kelly Willenberg & Associates

Kelly M. Willenberg, DBA, MBA, BSN, CCRP, CHRC, CHC

Owner, Kelly Willenberg & Associates

HCCA Compliance Institute

March 26-29, 2017

KW

© 2017, Kelly Willenberg, LLC

2

Objectives

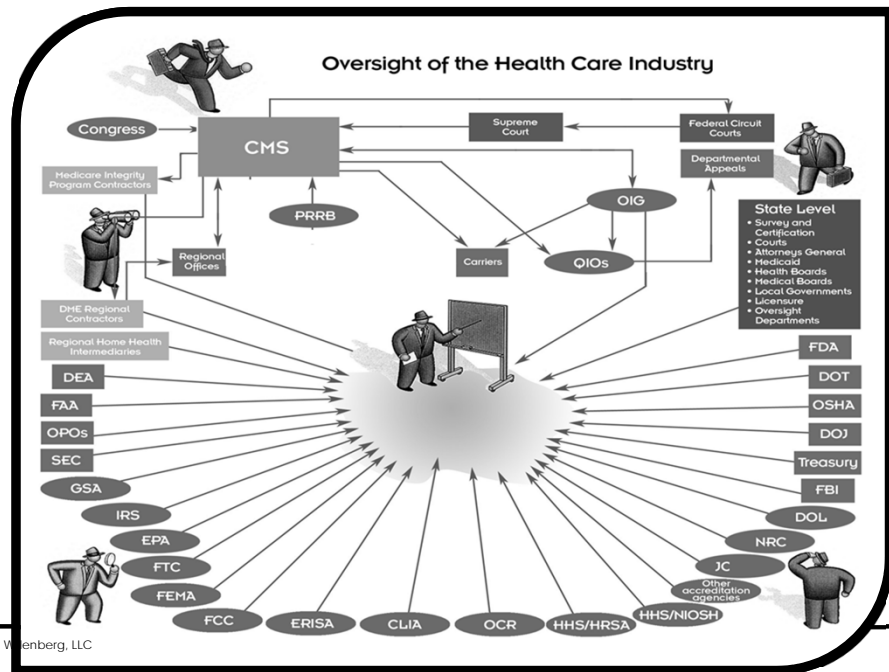
- EMR and billing audits
- CTMS and billing audits
- Clinical trial review and revenue cycle integrity

KW

© 2017, Kelly Willenberg, LLC

3

Healthcare Regulatory Environment



4

Clinical Trial Billing Village

- Principal Investigator
- Clinical Research Coordinator
- IRB process
- Budget negotiators
- Clinical Trial Agreement negotiators
- Project Accounting/Grant administration
- Health Information Management/IT
- Registration/Scheduling/Authorizations/Denials
- Medical center billing and coding
- Physician professional fee billing and coding
- Offsite facilities providing Clinical Trial services
- Managed care contract negotiators
- Others



KW

© 2017, Kelly Willenberg, LLC

Risk Assessments and Audits

What Does Effective Mean?

- Federal Sentencing Guidelines standard –

1. The organization exercises due diligence to prevent and detect inappropriate conduct by the Medicare & Medicaid provider;
2. The organization promotes an organizational culture that encourages ethical conduct and is committed to compliance with the law; and
3. The compliance program is reasonably designed, implemented, and enforced so that the program is generally effective in preventing and detecting improper conduct.

Failure to prevent or detect specific offenses does not necessarily mean that the program is not generally effective in preventing and detecting such conduct.

Federal Sentencing Guidelines amendment effective 11/1/2010 Section 8B2.1(a)

Auditing and Risk Analysis

- An audit begins with risk analysis
 - Identify institutional priorities – could be from special concerns
 - Assess system and user groups for weak links
 - Seek agreement of higher administration
- Select audit elements in relation to risk analysis
 - Prepare and plan for each sub-set of the audit
 - Consider potential sub-sets: complex studies? easy-to-correct studies? biggest billers? a particular document/stage of process? a particular department or investigator?
 - Evidence of flawed system?
- Design audit documents to reflect audit elements

Risk Analysis Can Prevent

- Billing for services that have been provided free by the sponsor
- Billing for services that have been promised free in the Informed Consent
- Billing for services that are for research-purposes only
- Billing for services that are part of a non-qualifying clinical trial (this is a complicated issue)
- Billing for device trials without CMS centralized review and approval
- Billing Medicare Advantage plans for drug studies

Risk Assessment Response

- Responsible parties should identify the procedures for responding and mitigating risk uncovered based on risk assessment
- Consult compliance, counsel, or consultants when addressing assessment/audit findings to determine the proper course of action to mitigate findings
- Establish reasonable and achievable standards for making enhancements and/or supporting change needed to address risk assessment/audit results
- Correct deficiencies, address opportunities, and mitigate the events identified through assessment/auditing

Risk Assessment Response

- Test charge capture, segregation of charges and bill review methods for research related services and regularly select a sample of protocols and participants and trace a sample of bills through the process continuum to identify where (if any) control weaknesses may exist
- Keep an account of lost revenue both on payer side and in research
- Keep an account of residual balances and follow institutional policy
- Ensure your Coverage Analyses are being properly reviewed, approved and utilized
- Ensure healthy communication avenues exist between departments relative to research, avoid siloes
- Review CTMS system for maximum efficacy and ensure integration with billing system if available
- Optimize tracking process from registration forward for clinical trial participants
- Test process for resolving billing inquiries
- Ensure operating procedures include billing compliance responsibilities so it is clear who is responsible.

11

Consequences of Non-Compliance

- Loss of community trust and reputation
- Potential loss of federal grant funding
- Potential loss of participation in Medicare/Medicaid
- Fines and penalties
- Enforcement actions and fines
- Corporate Integrity Agreements
- Lost revenue both on payer side and in research
- Staff time lost on correcting billing errors
- Residual balances

KW

© 2017, Kelly Willenberg, LLC

12

Measuring Success

- How effective are you?
 - Are you asking the right questions?
 - Are you documenting these questions?
 - Are you the sought after subject matter expert within organization?
 - Do you step outside of your comfort zone?
- Internal scorecard for Compliance
- Feedback from external audits
- Number/ amounts of re-payments
- Transparency as an organizational culture

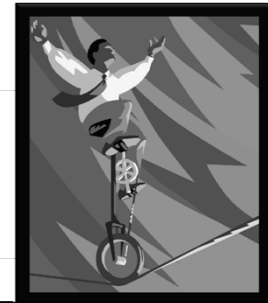
KW

© 2017, Kelly Willenberg, LLC

13

Ignorance is Not Bliss

- For identified risk, exposure or non-compliance, possessing the information puts the institution at risk
- Knowing of non-compliance and not acting to mitigate the event also adds to the risk exposure



KW

© 2017, Kelly Willenberg, LLC

14

Why Auditing is Important

- Properly directed, internal audit programs can help an organization stay focused and uncover educational opportunities
- Clinical trials billing is an area of considerable complexity, uncertainty, and curiosity
- Move beyond collecting findings to providing insight
 - Collect complaints or feedback from audit program "customers"
 - Understand the objectives of the stakeholders who "own" the process being audited
 - Identify and report completed corrective actions
 - Verify improvements and train

KW

© 2017, Kelly Willenberg, LLC

15

An Effective Audit Plan

- Is an educational activity
- Promotes understanding of errors found
- Effectively uses resources
- Raises standards of billing compliance in clinical trials through overall revenue integrity
- Prompts change
- Provides a source of truth in the information
- Reacts to problem areas in clinical trial billing
- Provides sources of information and educational moments
- Ensures that all study accounts are debited for research-related tests and procedures and bill third party payers for routine costs

KW

© 2017, Kelly Willenberg, LLC

16

How to Get Buy-in for Auditing

- Requiring operation teams' self monitor allows greater wider and deeper compliance assurance
 - Stakeholders (CR teams, billing team, IRB, sponsored projects office) working separately cover lots of ground
 - Whenever possible, compare notes to prevent conflict of approaches, to ensure results reach relevant parties
 - Set schedule for collaboration of different primary stakeholders
- Compliance office(r) should also plan for self-monitoring
 - Review billing compliance for completeness
 - Target hottest spots or biggest risk areas

KW

© 2017, Kelly Willenberg, LLC

Audit Types

- Retrospective – after billing
 - Advantages: Simple, documentation is complete, refined sample
 - Disadvantages: Processing findings, may not be timely, billing adjustments may be required
- Prospective – before billing
 - Advantages: Timely, avoid billing adjustments
 - Disadvantages: May hold up billing, sample may be limited
 - More difficult to complete

Audit Timing

- Retrospective – after claim is submitted and reimbursed
 - Advantages: Simple, documentation is complete, refined sample
 - Disadvantages: Processing findings may not be timely, billing adjustments may be required which can lead to alerting the payers of issues
- Prospective – before claim is submitted
 - Advantages: Timeliness, avoids billing adjustments
 - Disadvantages: May hold up billing, sample may be limited

Audit Elements

- Once the elements of an audit are determined, and higher administration has agreed, the percentage of X to audit must be determined.
 - Generally, audit percentage for adequate representation is minimum of 10%
 - Depending upon resources and volume of studies, more or less may be necessary
 - Some audit elements may not be conducive to representation percentage
 - Flawed system element
 - Audit for cause or special concern

Audit Process

- Set up schedule of rotation of audit (by department, by doctor, by highest accrual?)
- Contact study teams and department; provide schedule (and document templates?)
 - Pre-audit meeting: document request, questions answered
 - Audit (Was it routine? For cause? Or started with earlier with issue?)
 - Draft for Discussion Purposed Only with Key Leaders
 - Corrections due date
- Final audit review
- Final audit meeting, with corrective action plan for systemic error
- Follow schedule; follow documents

Areas for Compliance Attention

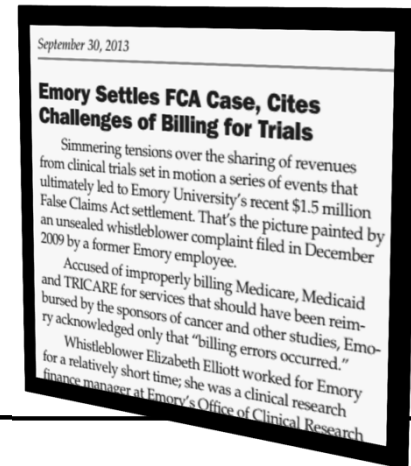
- Software and technology
- Financial operations including billing compliance
- Clinical operations intersect with financial
- Human subject protection
- Coordinating, collaborating and communicating with physicians

Areas of Risk and Why

Area of Risk	Why this is a Risk
Budget development and approval	Lack of consistency
Registration of research subjects	Lack of subject tracking mechanism, billing errors
Charge capture/billing for research related services	No process for tracking or reporting
Document Concordance	Inconsistent documents lead to billing errors
Process for resolving billing inquiries	Follow through not performed

Areas to Watch

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



Suggested Focus Areas

- Medicare Secondary Payer/Other Insurance Coverage
- Documentation of visit with orders
- Hospital Outpatient, Ambulatory Surgery Centers
- Coding of Evaluation and Management Services
- EHR cookie-cutter medical history
- Payments for Evaluation and Management Services
- Evaluation and Management Services during Global
- Test done prior to consent
- Excessive Payments for Diagnostic Tests (Medical Necessity)
- Medicare Billings without research modifiers then research is clearly occurring

Before You Begin Your Audit

- Understand your institution
 - Risk tolerance
- Know your research universe
 - All legal entities involved
- Know how to find all the studies
- Know how to find all the study-related documents
 - Protocol, CTA/budget, Coverage analysis, Informed Consents, research order forms or alerts, summary of sponsor payment
- Know how to find all the study subjects
- Know how to get to all the bills (tech and pro), EOBs, external vendor invoices

The Process Tools

- ALL Claims – BOTH Technical and Professional
- Claims BEFORE the Informed Consent Date and Inclusive up to the Current Date of the Audit
- The EOBs
- Codes, Modifiers, CC's, Drugs, Devices, and NCT#'s on claims
- Medicare Advantage
- Coverage Analysis
- Grant/Budget Reconciliation

What Documents Do I Need?

- Select a sample of two to three research participants for each of the selected clinical trials
- For each clinical trial, collect all versions of:
 - CTA, budget
 - Coverage analysis (CA)
 - Research Protocol, may not be needed if the CA is verified to match the Protocol
 - Informed consent form (ICF) , may not be needed if the CA is verified to match the ICF

The Sample

- Select a sample of 2 to 3 research participants for each of the clinical trials selected for testing
 - For each patient, you need:
 - UB-04 (i.e., CMS 1450), CMS 1500, EOB, any billing activity
 - Revenue accounting from Sponsor
 - On and off study dates and study calendar with visit dates
 - Verification whether the participant is a screen failure
 - Signed informed consent
 - Medical Record

IT Systems Roundup

- Do an accounting of what you have
- IRB system if any
- Grants accounting and financials
- Payroll
- Clinical Trial Management System (CTMS) used for patient and administrative tracking
- Professional billing system
- Facility billing system

Utilize Tools You Currently Have

- Understanding legacy systems and how they can help or hurt
- CTMS
 - Use a CTMS to better enhance your patient management, financial management and billing compliance management
- EMR
 - EPIC, Cerner, Meditech, GE Centricity, Athena, ARIA, MOSAIQ, NextGen, Allscripts and EClinicalWorks, McKesson

31

Consequences of Not Utilizing Tools

- More costly IT and infrastructure bill annually in FTEs or consultants
- Overworked personnel leading to a decrease in organizational productivity
- Inability to solve problems quickly
- Loss of revenue across the spectrum of operations in clinical trials due to inefficient billing of payers and sponsors



KW

© 2017, Kelly Willenberg, LLC

32

Preparing For a Billing Audit

KW

© 2017, Kelly Willenberg, LLC

Findings Leading to an Audit

- Billing for services that have been provided free by the sponsor or promised free or invoiceable
- Billing for services that are for research-purposes only
- Billing for services that are part of a non-qualifying clinical trial (this is a complicated issue)
- Billing for device trials without M/C approval
- Billing Medicare Advantage Plans for drug studies

Further Findings Leading to an Audit

- Physician Errors
 - Lack of a signed proper order for conventional care
 - Inadequate documentation of medical necessity for the item or service
 - Lack of documentation of study participation, as required
- Coding Errors
 - Billing without proper codes, modifiers, IDE # or NCT #
- Waiving/paying/reimbursing subject co-pay or deductible obligations

Which Studies

- Studies with the most risk
 - All services paid for by the sponsor
 - Mixed visits with both research and conventional care
 - Inpatient studies
 - Studies with large number of patients enrolled
 - Studies with numerous visits
 - Studies with drugs/devices where there can be increased number of adverse events
 - Department with a large volume of studies
 - Investigator initiated with off label drugs
 - Problem PI

Which Subjects

- Is there a central database with all subjects registered
- Does the billing system have a flag or an identifier where you can run a report
- Does the coordinator keep a spreadsheet
- Is there a CTMS where all information is stored
- Pull a report from the sponsor's EDC
- Screen failures

The Coverage Analysis (CA)

Systematic review of research related documents to determine the billing status of both the study itself and the items and services provided to the research subjects that are outlined in the research documents over the course of the study

Based on thorough research, supported by industry guidelines which meet the “generally accepted in the medical community” standard and compliant with government regulations

Billing Errors May Start with the Coverage Analysis

This Coverage Analysis is intended as a general guideline for use in determining which items and services are billable to a 3rd Party Payer. All items and services that are billable to a 3rd Party Payer must be supported by medical records.

Protocol Related Items and Services	CPT / HCPCS	Active Monitoring Phase										Comments and Justification
		≤ 60 days prior to	At time of registration	Surgery	Adjuvant Chemotherapy	Radiation Therapy	Observation (6)	Year 1.5	Year 2.5	Year 3.5	Year 4.5	
CBC with Diff. & Platelets	85025	M										NCCN guidelines for Breast Cancer (v2.2015) state that CBC with Diff. & Platelets is generally supported under NCCN Medical records must document medical necessity.
Bilateral Mammogram	77056, 770561	M					M	M	M	M	M	NCCN guidelines for Breast Cancer (v2.2015) state that Bilateral Mammogram is supported during the work-up and surveillance period. Medical records must document medical necessity.
Bilateral MRI of Breasts	77059, A9952, 96374	M										NCCN guidelines for Breast Cancer (v2.2015) state that Bilateral MRI of Breasts is supported during the work-up period. May be used to define extent of cancer or presence of multifocal the ipsilateral breast, or as screening of the contralateral breast at the time of initial diagnosis (category 2B). There is evidence to demonstrate that the use of MRI to facilitate local recurrence or survival. Medical records must document medical necessity.
Biopsy of each suspicious breast lesion	88307, 88305, 19101, 19100, 19081, 19186	M										NCCN guidelines for Breast Cancer (v2.2015) state that Biopsy of each suspicious breast lesion is supported during the work-up for breast cancer. Medical records must document medical necessity.
Optional research blood sample	36415, 36591, 36592, 99000		S									Research purposes only; bill to sponsor

The Coverage Analysis

- Does the Coverage Analysis document credible sources, such as
 - National Guideline Clearinghouse – AHRQ / NIH
 - National Comprehensive Cancer Network
 - American College of Cardiology
 - JAMA, NEJM
 - Attestation of PI

Does the Coverage Analysis

- Use the Protocol as foundation
- Record the services analysis on a billing grid
- Document the QCT analysis
- Cite sources
- CPTs and HCPCS?

Billing Compliance Rules

- Routine Costs Analysis:
 - Items and Services that are
 - Ordinarily provided to beneficiaries and covered by Medicare
 - Typically provided absent a clinical trial (conventional care)
 - Required solely to administer the investigational drug
 - Provided for the clinically appropriate monitoring of the effects of or prevention of complications from the investigational item
 - Needed to deal with the diagnosis or treatment of complications.
- **Does not** include items and services that are:
 - Provided solely to satisfy data collection
 - Provided free of charge.
 - Statutorily excluded or for which there is non-coverage decision.

41

Moving Towards Billing Compliance

- Identify governance & project management team
- Implement formal feasibility process to improve linear process in collaboration with Principal Investigators and impacted areas
- Ensure a complete Coverage Analysis (CA) is in place on all studies with billable items/service
- Always be audit ready!



KW

© 2017, Kelly Willenberg, LLC

42

Identify Potential Risk Areas When Auditing

- Evaluation and management codes
- Medical necessity
- Documentation of referrals
- Designated health services
- Inadequately educated billers
- Insufficient documentation
- Use of incorrect codes or no modifiers
- Coding not supported by the medical record

KW

© 2017, Kelly Willenberg, LLC

How Do Errors Occur?

- Technological errors: A “research flag” (i.e., unique study number, a hold on an encounter or claim, or some other indicator) is not recognized by information systems , not interfaced with all systems or not provided to outside vendors
- Human errors: Multitude of errors can occur
 - Registration or scheduling unaware of research participants
 - Technicians in ancillary service areas are unaware of trial
 - Work queue not handled appropriately

Questions to ask Prior to Starting the Audit

- Protocol, all protocol amendments
- CTA, Budget, Coverage Analysis and ALL amendments
- Informed Consent, all versions
- Confirm anything that was provided by the Sponsor
- Patient records including visit dates
- System access (paper claims if not access available including EOBs)

Obstacles to Auditing

- Clinical trials involve multiple departments that are not communicating
- EMR/Billing systems do not automatically manage research rules
- Lack of coordination and collaboration of the study intelligence
- Inability to distinguish research subjects and research-related services at the time of visit

EMR

Clinical Trial Billing Audits

EMR Functionality

Flagging patient

Bill queue or hold

Medication and Problem Lists

Blinding of drug and other items/services

Break the Glass feature when necessary

Documentation of study events

CMS requirement of EMR medical record documentation

Helps with coding notification for billers

Can assist with direction of charges

Questions to Ask EMR Auditing

- Patient Master Index Level
 - Are study subjects identifiable at the patient level?
 - Is there an easy way to “flag” or “link” a patient to a research study at the patient level?
- Registration
 - Are study subjects identifiable in registration (or scheduling) systems?
 - Is there an easy way for check-in personnel to validate a patient’s status as a research participant?
 - Are all points of entry for your facility equipped to deal with various research patient scenarios?
- Medical Record Documentation and Ordering
 - Are CMS guidelines met?
 - Are JCAHO guidelines met?
 - Are visit names/#’s included in the notes?
 - Are orders entered appropriately?
 - Are notes copy/paste?

Clinical Trial Required Documentation

69.3 - Medical Records Documentation Requirements (Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

The billing provider must include in the beneficiary's medical record the following information: trial name, sponsor, and sponsor-assigned protocol number. This information does not need to be submitted with the claim but must be provided if requested for medical review.

CMS Claims Processing Manual,
Chapter 32

Documentation that during this hospital stay the patient was enrolled in a clinical trial in which patients with the same condition as the measure set were being studied.

- There must be a signed consent form for clinical trial.
- There must be documentation on the signed consent form that during this hospital stay the patient was enrolled in a clinical trial in which patients with the same condition as the measure set were being studied.

Specifications Manual for Joint Commission National Quality Measures (v2013A1)

Tracking Subjects

- CTMS
- Billing Systems
- Bill Hold or Sieve (Work Queue), Report
- The old fashioned way – by paper!

Tracking Subjects By Digging Deeper

- Identify the patient electronically both in the Master Patient Index file (MPI) and by encounter
- Establish methodology for identifying patient when a research encounter is occurring
- Establish ability to order research related items or services that are both routine care and research related

How Do EMR Errors Occur?

- Lack of a “research flag” (i.e., unique study number, a letter on an encounter form, or some other indicator)
- Examples:
 - Research participants are not identified
 - Registration or schedulers are not aware of the research participants
 - Lack of knowledge on EMR can do for research billing
 - Not building EMR customization for research documentation requirements
- Lack of documentation in medical record
- Lack of automation

Clinical Trial Research Order Form

Date of Service: _____ Visit # / Cycle & Day: _____

Research Participant Name: _____ Date of Birth: _____

Research Participant MRN/MRUN: _____ Diagnosis: _____

Title: _____

Location of Ordered Services: (Place X)

PI:	
IRB #:	
Sponsor:	
Protocol Number / Version:	
Project #:	
IND/IDE #:	
ClinicalTrials.gov #:	

Services listed below include all services identified by the research protocol for the clinical trial

KW

Clinical Trial Research Order Form

Services Ordered	Procedures	CPT Code	Bill to Study	Services Ordered	Lab Services	CPT Code
<input type="checkbox"/>	Data Collection only - no protocol stipulated interventions			<input type="checkbox"/>		
<input type="checkbox"/>				<input type="checkbox"/>		

Note: All charges related to services provided for research related injury are to be forwarded to Study Team. Do not bill participant's insurance for research related injuries.

This document serves as an expense invoice if signed below. If you have questions regarding this form or need further assistance, please contact Study Team

Date/Time	Physician / Prescriber Signature	MD ID#
Date/Time	RN Signature/Print: Validation of Correct Transcription	

Date/Time	Read Back: <input type="checkbox"/> VO <input type="checkbox"/> TO
Date/Time	Initials:
Date/Time	12/24 Hour Chart Check RN Print/Initial

KW

55

CTMS

Billing Compliance Audits

KW

© 2017, Kelly Willenberg, LLC

56

Advantages Of A CTMS

- Improves metrics
- Standardizes training
- Easier management of CRC workload
- Easier access to study data
- Provide benchmarking capability
- Assists with calendar build for billing compliance
- Enables a better way to track patient management
- Study financial tracking

KW

© 2017, Kelly Willenberg, LLC

57

Utilize a CTMS During An Audit

- Study Inventory
- Study Calendars
- Patient Inventory
- Patient Visit Tracking
- Budget and Contract Tracking

KW

© 2017, Kelly Willenberg, LLC

58

Clinical Trial Review

Revenue Cycle integrity

KW

© 2017, Kelly Willenberg, LLC

59

Coverage
Analysis
PerformedAudit and
ReviewBudget with
research pricing,
Contract,
Consent Review

Clinical Trial Billing Process

Medicare,
Medicaid, MAP
and Commercial
PayersSubject
Registration and
TrackingCharge Capture,
Segregation,
Research PricingMedical
Documentation
for Medical
Necessity

KW

© 2017, Kelly Willenberg, LLC

60

CLINICAL TRIAL BILLING PROCESS

The Clinical Trial Billing Process Cycle

Coverage Analysis Review "Front End" Cycle



- Review protocol for feasibility
- Do a Qualifying Clinical Trial status
- Perform Coverage Analysis with validation
- Review draft budget, contract and consent
- National Guidelines for disease
- NCD's and LCD's review
- Review draft budget against CA
- Provide consent language based on CA

Document Review "Middle" Cycle



- Ensure Coverage Analysis guides other documents especially the consent language in the expected costs section
- Budget negotiation detailed to coverage analysis level
- Contract language matches financial piece and consent
- Consistency checklist confirming all pieces match in language prior final IRB approval
- Document review ends with final IRB approval and study start up

Patient On Study Review "Back End"



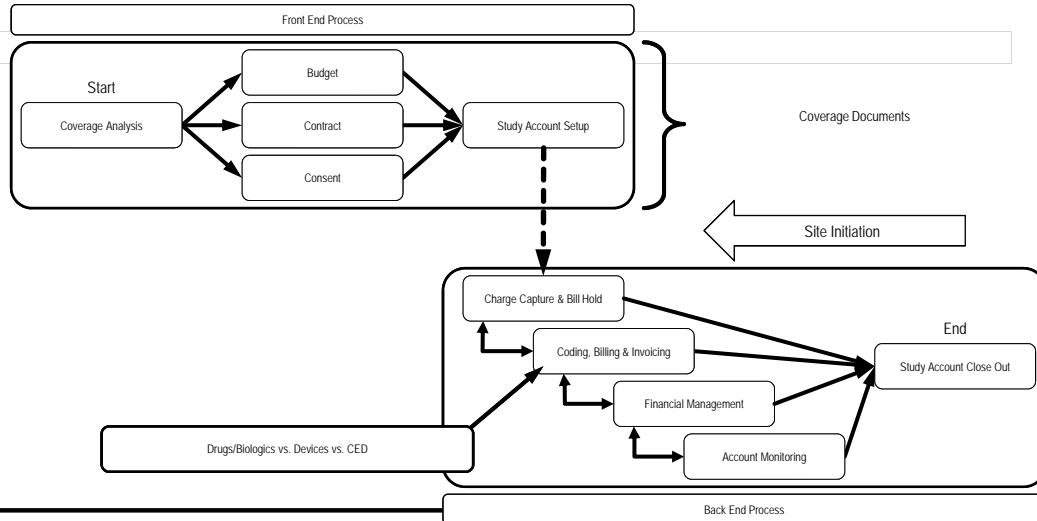
- Patient signs consent understanding financial implications
- Patient Flagged in billing systems
- Identification of Study Specific Visit
- Charge review against Coverage Analysis and medical documentation
- Coding rules applied
- NCT# applied
- Medicare Advantage review for drug clinical trials

KW

© 2017, Kelly Willenberg, LLC

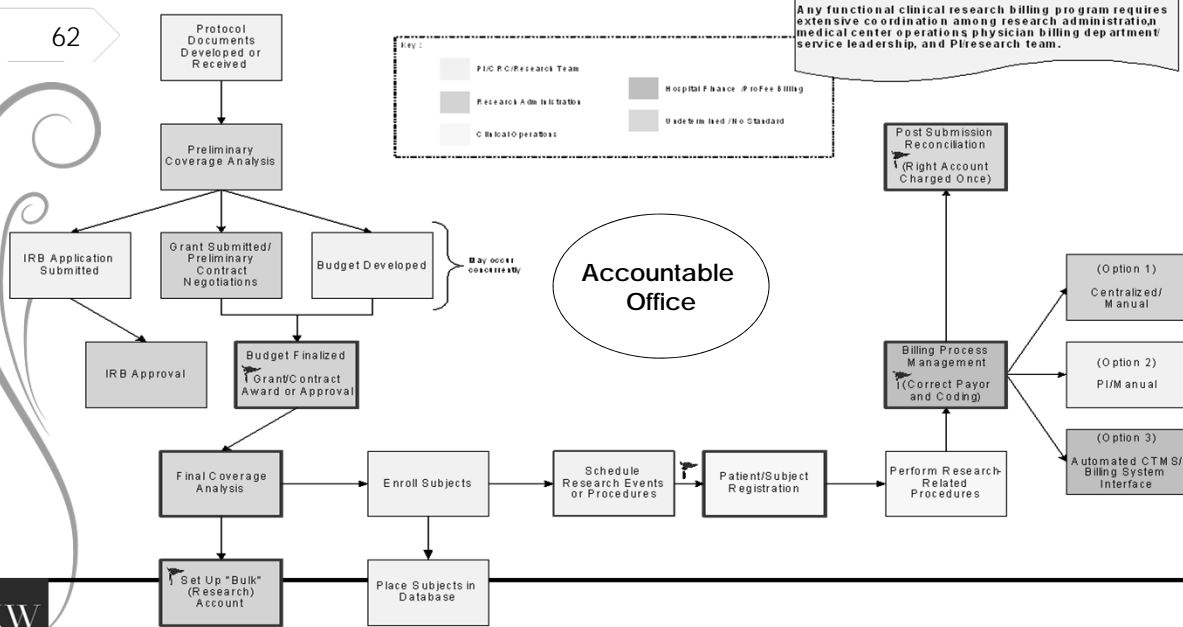
61

The Clinical Trial Revenue Continuum



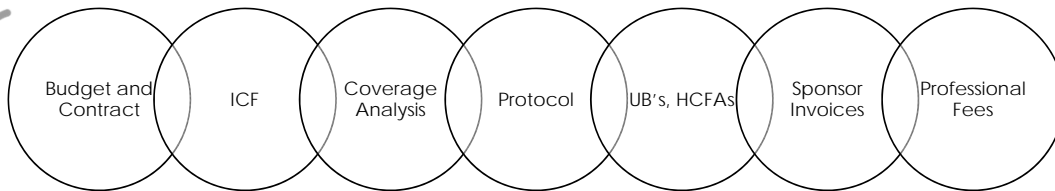
Clinical Research Billing Process Flow

62



63

Fragmented Billing Information



KW

© 2017, Kelly Willenberg, LLC

64

Hypothetical Scenario

	Total # of Claims Reviewed	# of Claims Billed To Correct Payer	# of Claims Billed to Incorrect Payer	Total Dollars in Overpayments	Claim Error Rate %
Medicare & Medicare Advantage	200	97	103	\$256,345.00	52%

KW

© 2017, Kelly Willenberg, LLC

Operational Questions

- Master Patient Index Level
 - Encounter level vs MPI
- Registration and Scheduling
 - Are all points of entry for your facility equipped to deal with various research patient scenarios?
- Charge Capture
 - Who is entering charges?
 - Know you bill "scrub" system
 - Who is working the "queue"

Revenue Cycle Impact

- Verify items charged to a payer on UB or 1500 agree with allowable items per the MCA
- Verify coverage analysis
 - Follow first patient through to look for missing items/services or coding
- Verify that bills match the revenue that was paid
 - Look for denials
 - Look for partial payments on remittances
- Calculate excess charges and then calculate excess reimbursement

Medicare & Clinical Trials: Coding Concepts

- Clinical Trial Number – NCT# from www.clinicaltrials.gov
- Revenue Codes - Devices, Supplies, and Drugs
 - 0624 - Investigational Device
 - 0278 - Medical/Surgical Supplies: Other implants
 - 0256 - Investigational Drugs
- Condition Codes
 - 30 - Qualified clinical trial
 - 53 - Initial placement of a medical device provided as part of a clinical trial or a free sample
 - Diagnosis Code
 - ICD 10 - Z00.6 - Encounter for examination for normal comparison and control in clinical research program
- HCPCS Modifiers
 - Q0 - Investigational clinical service
 - Q1 - Routine clinical service

Must have Medical Record Documentation:
Trial name, trial sponsor & protocol number (assigned by sponsor)

Routine Costs vs. Research

- Routine Costs
 - Ordinarily provided to beneficiaries and covered by Medicare
 - Typically provided absent a clinical trial (conventional care)
 - Provision of the investigational drug
 - Provided for the clinically appropriate monitoring of the effects of or prevention of complications from the investigational item
 - Diagnosis or treatment of complications
- Routine Costs do not include items and services that are:
 - Provided solely to satisfy data collection
 - Provided free of charge
 - Statutorily excluded or for which there is non-coverage decision

Look at the Claims

■ Charge Segregation

- Verify that the patient received the services per the clinical trial protocol
- With the Coverage Analysis as your guide, review orders and medical documentation
 - Verify that the charges for each item or service associated with conventional care were posted to the patient account
 - Verify that the charges for each item or service, including incidentals, considered "research related" were posted to the research account

Check Bills for Appropriate Coding

- Diagnosis Code: Z00.6
- NCT #
- Condition Codes: 30 for QCT, 53 for devices provided at discount or free
- Modifiers:
 - The Centers for Medicare & Medicaid Services (CMS) has discontinued the QA (FDA Investigational Device Exemption), QR (Item or Service Provided in a Medicare Specified Study), and QV (Item or Service Provided as Routine Care in a Medicare Qualifying Clinical Trial) HCPCS modifiers as of December 31, 2007.
 - Effective for dates of service on and after January 1, 2008, CMS has created the following two new modifiers that will be used solely to differentiate between routine and investigational clinical services:
 - Q0 - Investigational clinical service provided in a clinical research study that is in an approved clinical research study.
 - Q1 - Routine clinical service provided in a clinical research study that is in an approved clinical research study.

The Rules on Modifiers

- Depends on the type of claim
- Know when to use the IDE# and how to get it correctly on the claim
- Inpatient: No
 - Use Z00.6 (i.e., Examination of a participant in a clinical trial)
 - Condition Code 30 only. This indicates that you are working with a "qualified clinical trial." When this condition code is reported on a claim, it generally means the service is part of a CMS related clinical trial, demonstration or study
- Outpatient: Yes - Q1
 - Routine clinical service provided in a clinical research study that is in an approved clinical research study
 - Use it to identify routine services provided in the trial/study
- Outpatient: Yes - Q0
 - Investigational clinical item or service provided in a clinical research study that is in an approved clinical research study
 - Use it to designate the item or service under investigation in the trial/study

What Else Should I Review?

- For conventional care procedures that are payable by Medicare but performed outside the normal allowable time limit, refer to the ICF to determine if they should be billed to a research participant's payor
- Verify items charged to a payer on UB-04 & 1500 agree with allowable items per the MCA
- Verify that bills match the revenue that was paid.
 - Look for denials and write offs
 - Look for partial payments on remittances.
- Calculate excess charges and calculate excess reimbursement received.

73

The Final Step

- ▶ Look at the study accounts
- ▶ Confirm signed ICF is in medical record
- ▶ Confirm summary of protocol is in medical record

KW

© 2017, Kelly Willenberg, LLC

74

The Clinical Trial Billing Plan and What to Avoid

- Billing for services paid for by the sponsor
- Split billing great
- Hospital bill and physician billing inconsistency
- Lack of reconciliation with sponsor payments
- Study teams not aware of denials or write offs
- No post-study analysis
- No communication, coordination and collaboration

KW

© 2017, Kelly Willenberg, LLC

75

Case Study

Clinical Trial Process Review - When is There Cause to Audit

KW

© 2017, Kelly Willenberg, LLC

76

Hospital Case Study to Analyze Hospital's Internal Process Review



KW

© 2017, Kelly Willenberg, LLC

Potential Risk Areas

- Identification of Evaluation and management codes related to research studies
- Insufficient medical necessity documentation for routine costs
- Documentation of referrals
- Use of incorrect codes or no modifiers, over-coding or under-coding

PLEASE PRINT OR TYPE
PLEASE PRINT OR TYPE

HEALTH INSURANCE CLAIM FORM

PATIENT AND INSURER INFORMATION

MEDICAL INFORMATION

PLEASE PRINT OR TYPE

PLEASE PRINT OR TYPE

Case Study Sample

- Prioritize which studies are at risk for billing compliance
- Determine number of active patients on high risk studies
- Select 10%-15% of total number of patients on 10% of high risk studies
- Review all study regulatory and financial documents to determine benchmark of starting point

79

Community Hospital with 200 Open Studies Open

- Oncology, neuro and cardiology largest areas of research
- No centralized office for billing compliance
- No staff identified to ensure that coding is being handled appropriately
- A report out of billing system shows limited Z00.6 on any claims although it is believed that about 800 patients are either on study with interventions, in follow up, or in registry studies

KW

© 2017, Kelly Willenberg, LLC

80

Review Active List to Prioritize Studies

- Verify items against consents that were promised at no charge
- Review coverage analysis against all other documents for consistency
- Validate study calendar against visits
- Review claims for proper coding
- Analyze reimbursement to determine if payback is warranted

KW

© 2017, Kelly Willenberg, LLC

The Audit

- Talk to the people involved in the process
- Review protocol and schedule of events
- Review Coverage Analysis including Qualifying Status
 - If there is not a Coverage Analysis available, create one based on protocol, CTA/Budget and Informed Consent
 - If there is a Coverage Analysis, how robust is the documentation to support billing?
- Review Medical Records to ensure proper documentation for items and services determined to be “conventional care” or research only
- Verify subject received services that were billed and posted to the correct account – research or third party payer

The Audit

- Verify claims that were submitted to Medicare or Medicare Advantage were properly coded with research codes and modifiers including the clinicaltrials.gov number
- Verify claims for drug studies were redirected to Medicare for Medicare Advantage subjects
- Verify that there is corresponding professional fee claim for every technical fee claim where appropriate
- Verify that ancillary charges for an item or service that should be billed to a sponsor are posted to the appropriate study account
 - Example – sedation for MRI in pediatric study or BUN/Cr for a contrast-enhanced CT or pathology for a Bone Marrow Biopsy

The Audit

- Look for denials or partial payments
 - There may be Local Coverage Determinations that were not accounted for when the study was started
 - Also important in drug studies
- Look at study accounts in relation to the budgets and reconciliation
 - Check for high residuals
- Confirm that a signed copy of the ICF is in the Medical Records and in the pharmacy records if study drug is being used

Findings from Review

- Billing had occurred for services paid for by the sponsor, promised at no costs or listed as an invoiceable with some patients getting the service for free
- Split billing not done for Medicare Advantage Patients on drug trials
- Lack of consistency between hospital bill and physician bill
- Lack of reconciliation with sponsor payments
- Study teams not aware of denials
- Lack of any type of post-study analysis
- Lack of medical necessity in medical records

Lessons From the Audit

- There must be structure
 - Coverage Analysis for all studies regardless of sponsor MUST be completed, available and updated as studies are amended
 - Study-related documents should be stored in such a way that they are immediately retrievable
 - There must be a way to easily identify research subjects
 - Patient level flags
 - Visit level flags
 - Subject registration with different plan codes
 - CTMS and EMR
 - Monitoring and Auditing need to be ongoing processes
 - Errors can be difficult to eradicate

Billing Compliance

- Financial and compliance risks must be considered
- Quality measures must be taken and reviewed by institution
- Understand that clinical trial billing is complex and must be a priority



Summary

- To successfully conduct a Clinical Trial Billing audit, prior planning is essential
- Understand that the process can be long and it is not possible to do overnight
- Auditors must know all the billing rules in addition to the institutional policies
- The audit results can be used to enhance process improvement efforts

Verify Improvements and Train

Training Objectives To Target Weaknesses

Training

- Develop a research compliance curriculum for
 - Investigators
 - Coordinators
 - Billing personnel
 - Coverage analysts
 - Financial analysts
 - Coding team
- Develop standard policies and procedures and train as they are amended

QUESTIONS?

Kelly M Willenberg

864-473-7209

<http://kellywillenberg.com>

kelly@kellywillenberg.com

Cynthia Lawson

208-321-4638

<http://kellywillenberg.com>

cynthia@kellywillenberg.com

KELLY WILLENBERG
& ASSOCIATES
RESEARCH. COMPLIANCE. CONSULTING.