Cleveland Clinic

Meeting the Challenge of Compliant Clinical Research Billing

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Objectives

- Review current regulatory climate
- Budget development
- Coverage analysis
- Charge reconciliation / 3rd party billing
- Lessons learned

Current Regulatory Climate

- Medicare Fraud Strike Force
  - President Obama fiscal plan for 2010
  - $1.5 billion dedicated to effort
  - RAC audits
    - Identify “improper” Medicare payments
    - Pilot: over $900 million overpayments returned 2005-2008
- Looking for:
  - Double billing
  - Up coding
  - Unbundling
  - Routine waiver of co-pays

Regulatory Climate – Significant Audits / Settlements

Spectranetics (2010)
Illegal import / False Claims
$5 million

Johns Hopkins Univ
Effort Certification
$2.7 million

Palm Beach Imaging (2008)
Anti-kickback
$7 million

Public Demand for Improved Control

Scripps Memorial Hospital (2001)
False Claims
$29 million

University of Minnesota
Misuse federal funds
$32 million

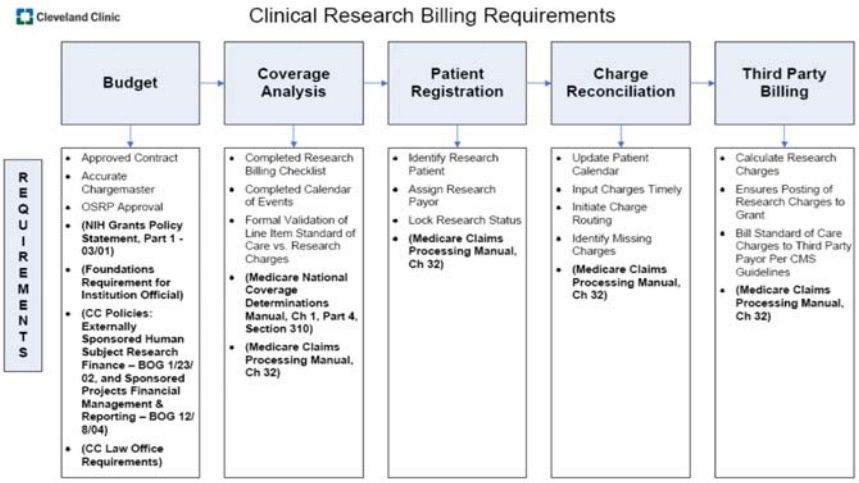
New York University Medical Center
Inflated research grant costs
$15.5 million

U of Alabama (2005)
Effort Cert & Double Billing
$3.4 million

Cornell Medical (2005)
Effort / Salary
$4.4 million

Northwestern University
Committed Time/Effort
$5 million

Regulatory Climate – What Everyone Must Do



Budget Development: First Steps

- Obtain <u>final</u> version protocol
- Obtain clarifications from sponsor
- Review basis of protocol with principal investigator and/or study team
- Assess needs and key components required for the implementation of the protocol

Budget Development : Major Components

Three major components to a study budget:

- Start up costs
  - Non-subject charges
  - Standard across Institution
- Per-subject costs
  - Budget for one single, completed subject
    - Personnel costs
    - Patient care costs
    - Ancillary costs
- Variable costs
  - Event that may or may not occur during the study

Budget Development: Start Up Costs

- Institutions generally have an established start up fees
  - Personnel time in reviewing protocol, IRB submission preparation; Investigator meetings; initial study training; preliminary patient screening
  - Budget development and contract negotiation
- Other potential start up costs:
  - IRB fee
  - Pharmacy
  - Laboratory
  - Radiology
- Generally range from $2,500-$10,000

Budget Development: Personnel

- Generally, the most under estimated cost of a trial
- Largest, single category of expense
- Think of it more than the hourly rate by "X" estimated hours. Think about:
  - Hourly wages
  - Reduction for time off/vacation
  - Training time
  - Data entry time
  - Preparation time

Budget Development: Patient Care Costs

14.1. Appendix 1: Schedule of Assessments

Procedure	Pre-Screen[1]	Screen	Baseline (Randomization)	Up-Titration[2]		Maintenance			Down-Titration		Follow Up	Early Withdrawal
	P	S	R	T	End T	MV[3]	M3 (12 wks)	M6 (24 wks)	DT1	End DT[4]	FU	EW
Signed Informed Consent	X											
Inclusion and exclusion criteria	X	X	X[5]									
Medical History	X	X										
Complete Phys Exam[6]		X			X			X				X
Chest X-Ray		X[5]										
ECG (Standard 12-Lead)		X	X[5]					X				X
Urine Pregnancy Test		X										
Vital Signs (BP/HR)	X[5]	X	X	X	X	X	X	X	X	X	X	X
FPG/ HbA1c/insulin/c-peptide		X[7]	X				X	X				X[10]
New Onset Diabetes								X				X
Fasting lipid panel[8] /inflammatory markers	X[5]	X[9]	X				X	X				X[10]
Concomitant Medications	X	X	X	X	X	X	X	X	X	X		X
Hematology and Clin Chem, Urinalysis (Safety)		X	X				X	X			X[11]	X
AEs/ Serious AEs		X	X	X	X	X	X	X	X	X	X	X
Assessment of Tolerability			X	X	X							
Study Medication Compliance				X	X		X	X	X	X		X

- Review the visit and the potential billable items (i.e., patient care & personnel)
- Compare the schedule of visits with the description of the visits in the body of the protocol
- Assure that all billable items are reflected in the budget accurately

Budget Development: Ancillary Costs

Ancillary Charges

- Radiology
- Laboratory
- Pulmonary
- Cardiology
- Pathology
- Audiology

Budget Development: Variable Costs

- Services that are not specifically listed in the protocol. Such as:
  - Re-consenting and the cost involved
  - IRB submission of amendments
  - Excessive, non-merited monitoring visits
  - Printing costs for electronic medical records
  - Teleconference attendance
  - Screen failures
  - Close out visit requirements (i.e., additional data queries, submissions)

Budget Development: Variable Costs

- Study delays
- Unscheduled visits
- Completion of CRFs and tech cost if electronic
- AE/SAE care
- Early termination
  - Don't forget costs of notifying and education of study subjects
- Phone call follow up
- Long term follow up

Budget Development: Dealing with Variable Costs

- Invoice, invoice, invoice!
- Keep in mind these are site specific
- Note in budget template as footnote OR outline in contract
- Make sure Variable Costs that are in the budget are realistic to be invoiced

Budget Development: Comparing Actual Budget to Sponsor Suggested Budget

- After the actual budget has been developed, compare actual budget to sponsor suggested budget
- Assure that the sponsor suggested budget:
  - Includes all of the components of your budget (i.e., all data points, visits, phone calls, tests, procedures)
  - Covers your actual cost for patient care and personnel
  - Invoiced items – are they in line with the actual budget?
  - Includes start up, pharmacy, lab, radiology fees where applicable
  - Include fringe for personnel
  - Include institutional indirect charges

Budget Development: Payment Terms

Timing Is Everything!

- What triggers a payment?
- Expectation of the first payment
  - After 1st patient enrolled or randomized
  - What happens if no patients are enrolled?
  - Costs are incurred with no reimbursement
- Always ask for a reasonable initial payment
  - One patient up front
  - No patients enrolled, site will refund payment after all costs paid- recruitment efforts, meetings, etc
  - Start up costs – invoiced upon executed contract

Budget Development: Tips for "Profitable" Budgets

- Allot enough coverage for personnel time
- Appropriately utilize the charge master charges
- Make sure you are allotting for the fringe and indirect costs in your negotiations
- Appropriately budget for all ancillary & variable fees
- Establish realistic invoice terms
- Review your payment terms – these terms can always be renegotiated and should make sure it is covering the study

Harmonization of Documentations

- Contract/Budget/Payment Terms
- IC/IRB
  - Cannot bill for items that are put forth in the IC as "free"
  - Educate physician staff not to say "everything" is covered by the research project / sponsor
- Patient Billing Schedule

Coverage Analysis

- A uniform method of analyzing the items and services provided in a clinical trial to determine if the item or service can be appropriately billed to Medicare and other insurances.
- Clinical research often takes place in conjunction with the routine clinical care of patients. It is very important to ensure routine/standard of care services and non-routine/research services are billed to the appropriate payer and in compliance with applicable statutory requirements.

Coverage Analysis

An accurate and complete coverage analysis:

1. Provides patients with an accurate accounting of their financial liability before they enroll.
2. Protects your institution from violations of the False Claims Act and other regulations.
3. Protects patients from billing errors and unexpected balances not covered by their insurance.
4. Provides an accurate assessment of the costs to your institution to participate in a clinical trial.

Coverage Analysis - Steps

- Gather relevant documents - protocol, ICF, contract, budget, FDA letters and/or IND/IDE #s
  - Review the entire protocol, not just the schedule of events
- Determine if the trial is investigating a device, drug or a service.
- Apply appropriate Medicare criteria for coverage - determine if coverage provisions are applicable to the health conditions (disease) of the subjects enrolled
  - National Coverage Decision (NCD)
  - Investigational Device Regulations (Category A & B)

Coverage Analysis – Steps (cont.)

- Complete the Coverage Analysis Worksheet
  - Assess for “qualifying trial” characteristics
- Develop a Coverage Analysis Billing Grid
  - Analyze the coverage of each patient care item and service
  - Utilize websites:

  CMS coverage database:
  http://www.cms.hhs.gov/mcd/overview.asp

  MediRegs (check if your organization has subscription)

  Medicare Administrative Contractor (MAC) sites
- Document if each item and service is covered (SOC r/t research) or non-covered (research).

Risks of Ignoring Coverage & Clinical Research Billing Rules

- Billing for services that are already paid for by the sponsor (double billing)
- Billing for services promised free in the informed consent
- Billing for services that are for research-purposes only and not medically necessary (Medicare fraud)
- Billing for services that are part of a non-qualifying clinical trial
- Billing for services in a device trial in which no intermediary or carrier has approved billing under Category A and Category B device rules

A Few Final Comments on Medicare…

- Medicare generally does not reimburse for purely experimental medical care, even if there is no other source of payment
- If a service / item is provided or reimbursed by another payor (including industry-sponsored, federally sponsored clinical trials and / or by private insurance), Medicare cannot be billed
- If a service is promised free in the informed consent, it cannot be billed to Medicare

Charge Reconciliation

Medicare Claims Processing Manual – Ch 32

- "The billing provider must include the beneficiary's following information: trial name, sponsor, sponsor-assigned protocol number…must be provided if requested."
- "Note: The QV/Q1 modifier is line item specific."

Charge Reconciliation

- Done between patient billing schedule events and billing system
- Match patient, service codes and DOS
- Add appropriate charge type modifiers ("ID tag") → flow through billing system
  - Non-covered (research) charge routed to grant
  - Covered (SOC r/t research) charge routed to billing office
- Patient billing schedule event updated as BILLING REVIEWED

Third Party Billing

- Outpatient services
  - Billing office receives charges with internal identifier for Medicare patients
  - SOC r/t research
  - Internal modifier stripped and Q1 applied
- Inpatient services
  - Episode put on “hold” when notified that research patient
  - At discharge, services reviewed and research (non-covered) services identified →billed to research activity
  - Rest of charges go to billing, diagnosis code v70.7 and condition code 30 placed on claim

Lessons Learned

- Need process refinement
  - Labor intensive
  - Lack internal controls
  - Collect data
- Roles & responsibilities
  - Registration / patient billing schedule errors
  - Ongoing educational needs
- Patient bill format
  - Confusing
  - Manage expectations in IC process

Remediation – Process Refinement

- Assess software solutions for improvements in usability
  - No system integration between IRB software, research admin databases, EMR (scheduling), and billing
  - CTMS software is very robust – more than we need / confusing to a lot of users
  - Need increased efficiency and dynamic nature of CTMS sofrware → use of excel spreadsheets as temporary measure

Remediation – Process Refinement

- Lack of internal controls
  - Create “locks” so that key data cannot be changed
  - Monitor and use audit trails
    - Patient billing schedule
    - Patient registration status as “research”
    - Financial services manipulation of internal research coding
- Collect and utilize data
  - Define source of majority of process errors
  - Takes personnel, time, effort

Remediation – Collect Data

Issues	Total Issues
Missing Charge	9
Pt. Complaint on Billing Items	37
Research Billed to SOC	56
SOC Billed To Research	7
Wrong Activity Billed	16
(Select)	5
Total	130

Root Cause	Total Issues	
ADT/R Appointment Not Created	3	
Charge Misclassified on Calendar	1	
Charges Billed Correctly	11	
Inpatient Error	0	
Item Not Listed In Calendar	5	
No Research Registration	4	
Post Charge Modification	0	
Pre-CROP process not followed	8	
Pt misinterpretation of statement	3	
Registration error	14	
Wrong Modifier Applied	0	
Total	49	49

Institutes	Total per Institute
Anesthesia	4
Cole Eye Institute	1
Dermatology & Plastic Surgery	0
Digestive Disease	19
Education	0
Endocrinology & Metabolism	19
GCRC	2
Glickman Urological & Kidney	12
Head & Neck	0
Heart & Vascular	24
Imaging	1
Neurological	24
OB/GYN & Women's Health	2
Orthopaedic & Rheumatologic	7
Pathology & Laboratory Medicine	0
Pediatrics & Children's Hospital	2
Quality & Patient Safety	0
Rehabilitation	0
Respiratory	13
Surgery	0
Taussig Cancer Center	0
Wellness	0
Total	130

Issue Status		
Total	130	
Active	51	
Closed/Resolved	79	130

Remediation – Collect Data

Type of Root Cause(s)

Records for Institutes	Institutes	ADT/R Appointment Not Created	Charge Misclassified on Calendar	Charges Billed Correctly	Inpatient Error	Item Not Listed In Calendar	No Research Registration	Post Charge Modification	Pre-CROP process not followed	Pt misinterpretation of statement	Registration error	Wrong Modifier Applied
4	Anesthesia	1							2			
1	Cole Eye Institute											
0	Dermatology & Plastic Surgery											
19	Digestive Disease			8			1			1		
0	Education											
19	Endocrinology & Metabolism					1			1		1	
2	GCRC								2			
12	Glickman Urological & Kidney									1		
0	Head & Neck											
24	Heart & Vascular	2		3		1			1	1	2	
1	Imaging											
24	Neurological		1				3		2		9	
2	OB/GYN & Women's Health											
7	Orthopaedic & Rheumatologic										1	
0	Pathology & Laboratory Medicine											
2	Pediatrics & Children's Hospital					1						
0	Quality & Patient Safety											
0	Rehabilitation											
13	Respiratory					2					1	
0	Surgery											
0	Taussig Cancer Center											
0	Wellness											
0	**Total Root Causes**	49										
130												

Remediation - Roles and Responsibilities

- Found expectations varied between participating groups
- Critical to have written roles and responsibilities
- Explore and understand the skill set as well as the interest of individuals in certain roles prior to assigning responsibility
- Central versus institute responsibility

Remediation - Staff Education

- Must have a central core of experts that are available for ongoing education
- Provision of consistent, current, & correct content
- All levels of personnel; not only clinical research support staff, but physicians
  - Mandatory investigator training 2009

Remediation - SOPs

- Detailed guidance of what is minimally required
- Annual review and sign-off of understanding
- Establish policy to support processes
- Consequences for disregard of policy

Monitoring Compliance

Lead PI must certify that the trial meets Medicare qualifying criteria (Nat'l Coverage Determination Manual)

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Central Review of Research Billing Checklist

- High level review of coverage – identify potential LCDs on procedures
- Verify "deemed status" or "qualifying" for Medicare coverage
- Attestation page – document rationale!

Monitoring Compliance (cont.)

Central Review of Study Billing Schedule

- High level review of patient billing schedule to assure routine/SOC and research services are delineated
- Study billing schedule matches protocol study visits
- CDM / CPT codes utilized
- Technical and professional charges both included when needed

Monitoring – Study Audit (for cause)

- Research Billing
- Coverage and Medical Necessity
- Pt billing schedule
- Budget
- Current IRB approval
- Informed Consent Form
- Grants Management system
- Billing Review
- Departmental processes

Questions / Discussion