

Training for Clinical Research



Gary W. Eiland, Co-Chair
Health Industry Group
Vinson & Elkins LLP

Samuel J. Tilden, MD, JD, LLM
Deputy Provost and
Research Compliance Officer
University of Alabama at Birmingham

Carolyn Whitmire, MBA
Research Compliance Manager
University of Alabama at Birmingham

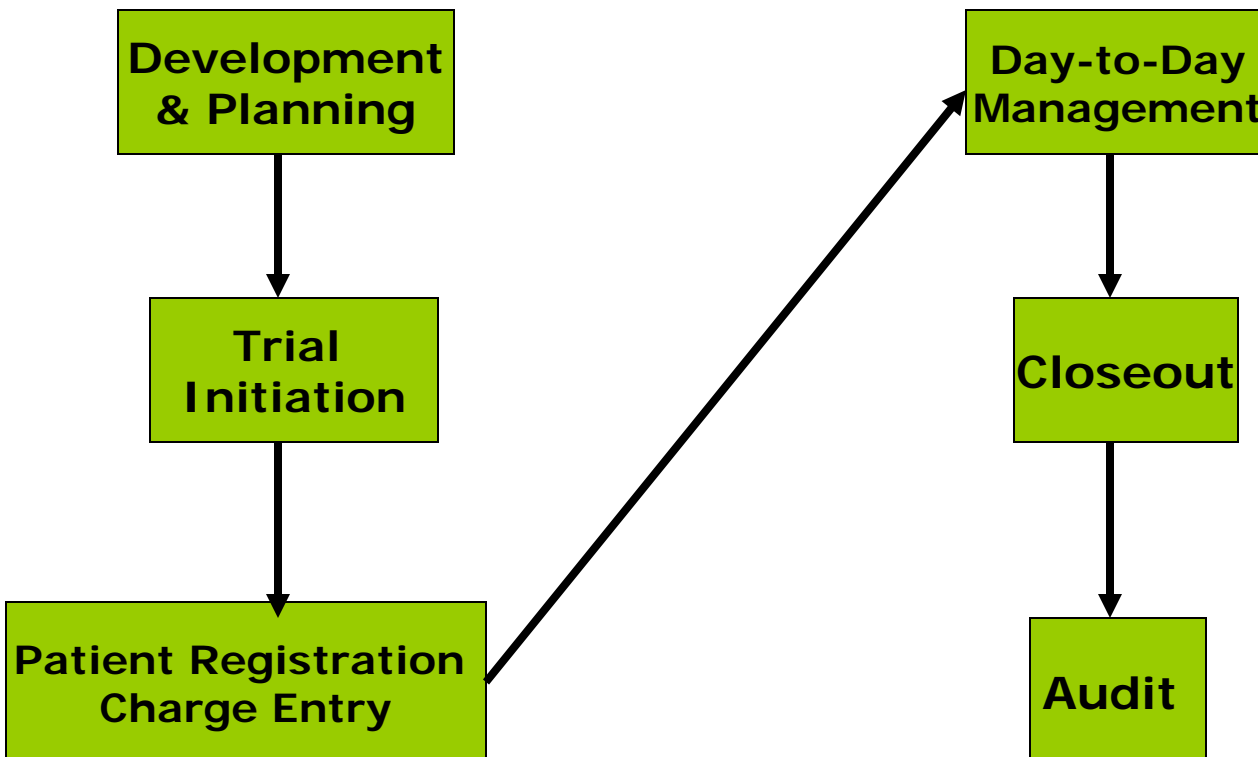
Disclaimer

This presentation reflects the opinions of Dr. Tilden and Ms. Whitmire and does not necessarily reflect the views of the University of Alabama at Birmingham. In addition, the examples set forth in this presentation are purely hypothetical.

Training for Clinical Research

- Part I: Basic Overview of a Clinical Trial for Billing
- Part II: Billing for Device Trials
- Part III: Medicare National Coverage Decision
- Part IV: Steps in a Successful Clinical Trial Billing Process
- Part V: Lessons from False Claims Act Cases

Part I: Basic Overview of a Clinical Trial for Billing



Different Clinical Trial Perspectives

Relationships – investigator, sponsor

Agreements – awards, budgets, CDA's,
CTA's

Regulatory approvals: FDA, IRB, COI, etc.

Scientific – conduct, analysis, reporting

Financial – is study feasible

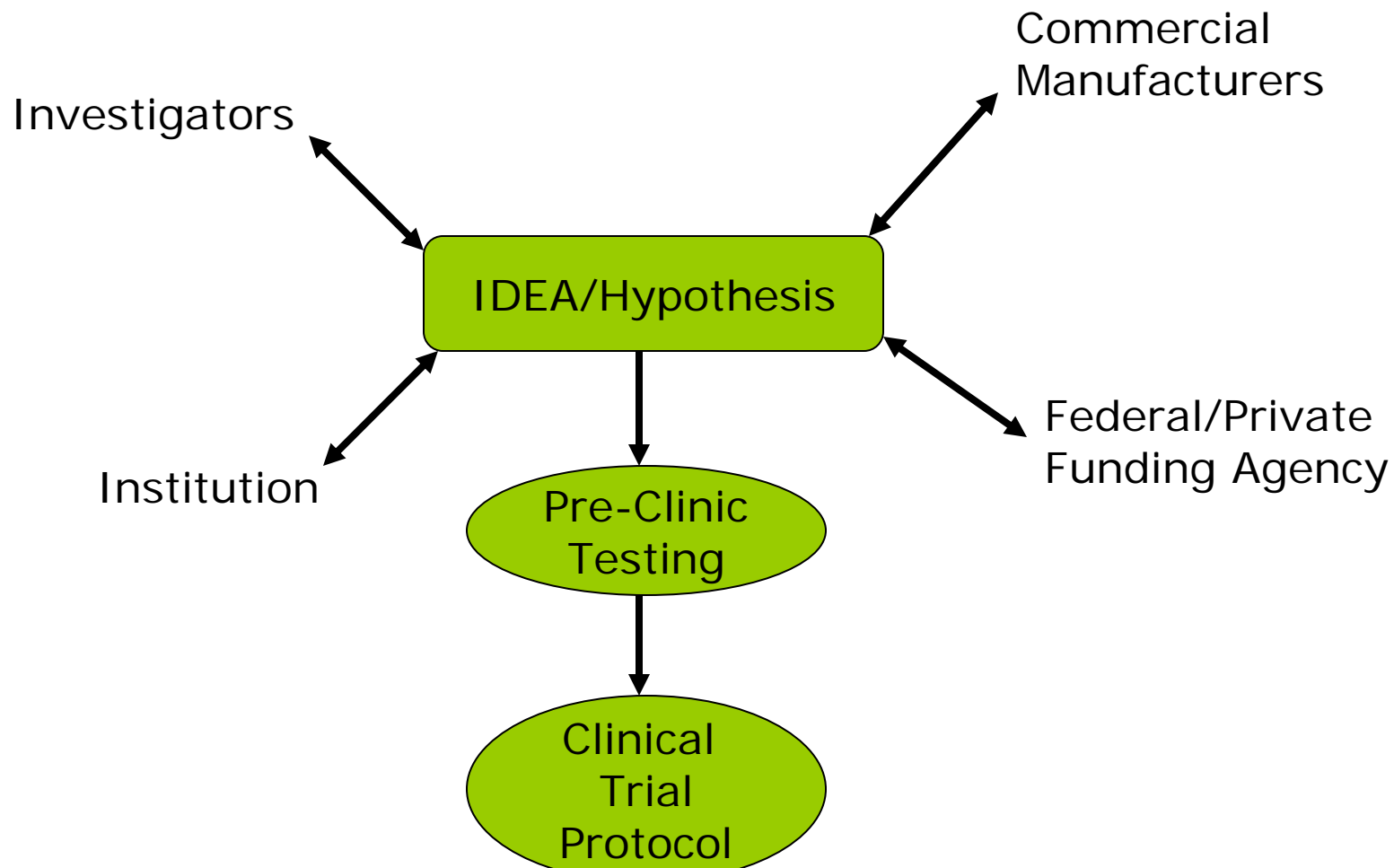
Definitions

Clinical investigation – 21 CFR §§
50.3(c), 56.102(c), 312.3(b), 812.3(h)

NIH GPS – clinical research, clinical
trials

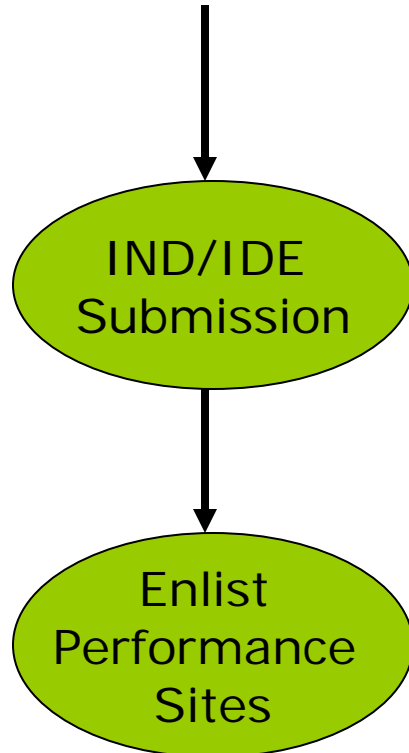
CMS, DoD Clinical Trial Policies

Clinical Trial Process I



Clinical Trial Process II

Clinical Trial Protocol



Clinical Trial Process III

Sponsor Contacts Investigator

→ **CDA**

Research Protocol
Investigator's Brochure
Clinical Trial Agreement

Institutional
Negotiation

Institutional
Reviews

Investigator
Feasibility
Study

Clinical Trial
Agreement Signed

IRB, COIC, etc.
Approvals

+ Balance

Grant Awards/Clinical Trial Agreements

Contractual in nature

Spells out terms and conditions for performance of research project

Includes consideration for performance

Elements in Clinical Trial Agreement

- Performance criteria
- Term of Agreement
- Termination provisions
- Financial consideration/payment schedule
- Data ownership
- Confidentiality
- Publication
- Patents/intellectual property
- Reporting of data
- Compliance with applicable law

Elements in Clinical Trial Agreement

1. Monitoring of study
2. Cost of investigational item
3. Publicity
4. Status of Parties – IC
5. Indemnification
6. Insurance
7. Modifications to Agreement
8. Notices
9. Survival

Criteria for IRB Approvals

Eight requirements for IRB approval (7+1)

(1) Risks to subjects are minimized: by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risks, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes. [45 CFR 46.111 (1); 21 CFR 56.111 (a) (1)]

(4) Informed consent will be sought from each prospective subject...in accordance with and to the extent required by [45 CFR 46.116, 21 CFR 50.27]

Elements of Informed Consent

Eight basic elements

- Statement that study involves research
- Foreseeable risks and discomforts
- Benefits reasonably to be expected
- Confidentiality
- Voluntary participation

Six additional elements

- Presence of unforeseeable risks
- Circumstances for termination
- Additional costs to subjects for participation

Financial Conflicts of Interests

May bias research

- Design
- Conduct
- Reporting
- Analysis
- 21 CFR Part 54 (FDA)
- 42 CFR Part 50 (NIH)

DA Financial Disclosure Requirements Between Sponsor & Investigators

Absence of Financial Interests

Compensation affected by the outcome of study

Significant payments of other sorts (>\$25K)

Proprietary interests in test products

Significant equity interests (>\$50K)

Significant Payments to Other Sorts

Payments made by the sponsor of a covered study to the investigator or institution to support activities of the investigator that have a monetary value of more than \$25K, exclusive of the costs of conducting the clinical study or other clinical studies (e.g. grant to fund ongoing research, compensation in the form of equipment or retainers for ongoing consultation or honoraria) during the time the clinical investigator is carrying out the study and for 1 year following completion of study.

Example

Investigator A agrees to conduct study for sponsor S:

S agrees to pay \$9000 per patient

A negotiates with Medical Center to pay \$4000 for all study labs and radiology services

If A enrolls 10 subjects, how much surplus is involved?

Is surplus a significant payment of other sorts?

Investigator Feasibility Study

Investigator Perspective

Develop comprehensive cost plan and budget

Detail visits and services

Negotiate best possible budget

Up front payments

Gain/(Loss)

Institutional Feasibility Study

Service Provider Perspective

Will the service provider be reimbursed?

Who will purchase supplies, i.e. devices? Are they billable/reimbursable?

Is there any potential for a non-covered service? If so, ABN process may be initiated. Is this reflected in the consent form?

How will or should the patient be identified at registration?

Does billing office have information for generating claims?

Are there any specific coding requirements for the claims?



End of Part I



Questions/comments

Part II - Billing for Device Trials

Coverage of Medical Devices

Device Classifications

Notification Requirements

Category B Device Trials

Category A Device Trials

Common Pitfalls

Coverage of Medical Devices

Nov 1, 1995. Medicare coverage was expanded to certain medical devices being studied as part of a Food and Drug Administration (FDA) approved clinical trial. Under this new policy, the FDA and CMS established a more precise mechanism for classifying devices in clinical trials, making it possible for some of these devices to be **eligible** for Medicare coverage.

Section 731(b) MMA Act of 2003, expands ability of CMS to cover costs in device trials by authorizing coverage of "routine costs" in certain category A device trials, effective January 1, 2005.

Device Classifications

Category A

- Innovative devices for which the absolute risk has not been established; initial questions of safety and effectiveness have not been resolved.
- CMS may cover routine costs (effective January 1, 2005), however the device costs remain **excluded** from coverage.

□ Category B

- Newer generations of proven technologies; evolutionary changes in proven technologies
- CMS views as potentially reasonable and necessary, and therefore, **eligible** for coverage and payment.

Notification Requirements

In order to submit claims for costs in any device trial, providers **must** notify the fiscal intermediary prior to enrolling patients.

- Must submit
 - IDE Device cover form
 - Signed copy of FDA approval letter
 - Copy of the sponsor's protocol
 - Copy of the IRB approved consent form along with the IRB approval letter

Coverage Requirements

The following criteria will be applied when making coverage determinations on FDA approved IDE category B devices:

Device must be used within context of an FDA-approved clinical trial

Device must be used according to the clinical trial's patient protocol

Established national policy or local policy for similar FDA-approved devices

Policy/position papers or recommendations made by pertinent national and/or local specialty societies

Medically necessary and reasonable for the particular patient

Furnished in a setting appropriate to the patient's medical needs and condition.

Category B Device Trials

Coding and Reimbursement

Professional claims should include the QA modifier (investigational device) and the investigational device exemption (IDE) number assigned by the FDA.

Hospital claims should include the IDE and any charges associated with the device should be included in revenue code 24.

Reimbursement for a device is limited to Medicare reimbursement for a comparable approved device.

Deductible and coinsurance apply

Attending for an IDE means that the provider attests that the device was approved at the time the service was rendered.

Category A Device Trials

Fiscal Intermediary shall determine if the Category A device as used in the trial is:

- Intended for the diagnosis, monitoring or treatment of an immediately life-threatening disease or condition
- Immediately life threatening requirement = “a stage of a disease in which there is reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment.”

Use NCD rules for defining routine costs

Category A Device Trials

Coding and Reimbursement

Professional claims should include the QV modifier (investigational device), ICD-9 diagnosis code V70.7 and the investigational device exemption (IDE) number assigned by the FDA.

Hospital inpatient claims

- IDE number
- Condition code 30
- ICD-9 diagnosis code V70.7
- Revenue code 624
- Outpatient claims should also include QV modifier

Deductible and coinsurance apply

Question

How will Medicare reduce the DRG payment for a hospital admission to implant a category A device so that payment for the device is excluded?

Common Pitfalls in Billing for Device Trials

Incorrect coding for the procedure

Incorrect split bills

Failure to include the 624 revenue code

Failure to obtain FI/Carrier approval
before enrollment and billing

End of Part II



Questions/comments

Part III – Medicare National Coverage Decision



Medicare Coverage Policy

General principles

- Medicare payment is contingent on a determination that a service or item
 - Meets a benefit category
 - Is not specifically excluded from coverage, and
 - Is “reasonable and necessary” for the diagnosis or treatment of injury

Medicare Coverage Policy

“Reasonable and necessary”

- What constitutes reasonable and necessary changes over time based on Medicare coverage determinations that are made by CMS and the agency’s administrative contractors
- Such coverage determinations are made on both a national and a local level
 - NCDs and LCDs are posed at www.cms.hhs.gov/CoverageGenInfo/

National Coverage Decision (NCD)

History

June 7, 2000. Presidential executive order issued to CMS to “explicitly authorize [Medicare] payment for routine costs... and costs due to medical complications associated with participation in clinical trials.”

Sep. 19, 2000. CMS National Coverage Decision (NCD) for Clinical Trials became effective. Medicare covers:

1. the routine costs of qualifying clinical trials, and
2. reasonable and necessary costs to treat complications of any clinical trial

NCD - Routine Costs Defined

All items and services that are otherwise generally available to Medicare beneficiaries that are provided in either the experimental or control arms of a clinical trial.

Routine Costs Include

Those typically provided
absent a clinical trial
(conventional care)

Those required solely for
the provision of the
investigational item or
service

- e.g. administration of non-covered chemotherapeutic agent

- Those required solely for the clinically appropriate monitoring of
 - Effects of investigational item, or
 - Prevention of complications
- Those needed for reasonable and necessary care arising from provision of investigational item or service
 - In particular, for diagnosis and treatment of complications

Routine Costs **DO NOT** Include

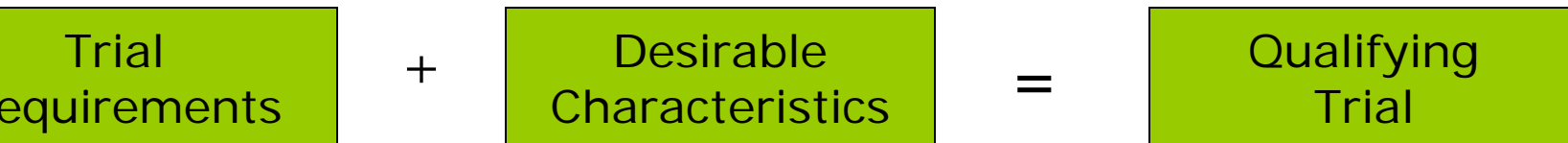
Items and Services Not Generally Available

- Those lacking a Medicare benefit category
- Those which are statutorily excluded
- Those that fall under a national non-coverage policy

Items/Services Not Covered

- Investigational item or services itself
- Those provided solely to satisfy data analysis and collection needs and are not used in direct clinical management of the patient
- Those customarily provided free of charge by the sponsor to any participant

NCD What is qualifying trial?



NCD - Qualifying Clinical Trials

Trial Requirements

- Must evaluate a Medicare benefit
- Have a therapeutic intent
- Enroll patients with diagnosed disease
- Trials for diagnostic interventions may enroll healthy volunteers as control group

Desirable Characteristics

1. Principal purpose is to improve health outcomes
2. Well supported by scientific and medical information
3. Doesn't unjustifiably duplicate existing studies
4. Appropriate design to answer question
5. Sponsored by credible organization
6. Complies with Federal regulations relating to protection of human subjects.
7. Standards of scientific integrity apply to all aspects

NCD - Qualifying Clinical Trials

“Therapeutic intent” – Hot topic

- Undefined by CMS
- Office of Human Research Protection (OHRP) definition is limiting
- Look to protocol objectives
- Develop policy / protocol regarding documenting therapeutic intent decision
- Contractor has the ultimate call

IND - Qualifying Clinical Trials

“Desirable” characteristics

- Open issues

- Complies with federal regulations regarding human subjects
- All aspects of trial are conducted in accordance with standards of scientific integrity

NCD – Qualifying Clinical Trials

Deemed Trials

- Trials funded by NIH, CDC, AHRQ, CMS, DOD and VA
- Trials supported by centers or cooperative groups funded by above
- Trials performed under investigational new drug (IND) application reviewed by the FDA
- IND exempt drug trials under 21 CFR 312.2(b)(1)
- Meets other “qualifying” criteria (e.g., Medicare benefit, diagnosed beneficiary and therapeutic intent)

NCD - Proposed Qualification Process

- Trials not deemed must be certified by the Principal investigators that the criteria have been met and the trial should be enrolled in national registry before coverage initiated
- AHRQ will convene a multi-agency panel to develop criteria reflecting the desirable characteristics promulgated
- In interim, only those trials have trial requirements and are deemed to meet criteria are afforded coverage under the NCD
- Notification to CMS still required
- There is no CMS process in place – none under discussion

NCD – Notification Requirements

Sponsors must identify themselves via e-mail to Clinicaltrials@cms.hhs.gov

Trial sponsor's name and contact info

Info on the drug under study (name, route of administration etc)

Disease being investigated

Expected enrollment and length of trial

Misrepresentation of Trial As Qualifying

- Medicare coverage of routine costs denied
- Medicare trial enrollees would not be liable for the costs
- Billing providers would be liable for the costs where appropriate
- Billing providers and PI's subject to fraud investigation

NCD

Billing and Coding Requirements

■ Professional Claims

- QV procedure code modifier for each line item representing routine costs
- Diagnosis code V70.7 (only for healthy control group volunteers)

■ Hospital (Technical) Claims

- Diagnosis code V70.7 as secondary or tertiary diagnosis
- Condition Code 30
- Outpatient claims should also the QV modifier
- G codes allow hospitals to report services furnished in outpatient departments

NCD

Documentation Requirements

Billing provider must include in the beneficiary's medical record:

- The trial name,
- Sponsor's name, and
- Sponsor assigned protocol number

If medical review initiated, then a copy of the signed informed consent must be readily supplied upon request

Copy of items and services billed as routine costs in clinical trial

Clinical Trials

Other coverage / payment issues

- Clinical trials outside of the NCD
 - NCD does not supersede coverage under LCDs or final rules on Category A and Category B devices
- Financial support from other sources
 - No payment for items / services furnished by other third-party payors
- Informed consent – financial disclosure
 - Should clearly enumerate any out-of-pocket costs that enrollees may incur while participating in the trial

Clinical Trials

Open issues


- Research related injuries
- Medicare Part D and the NCD
- How does the OIG feel about CMS clarifications?
- How much documentation is required for “therapeutic intent”?

End of Part III



Questions/comments

Part IV – Steps in a
Successful Clinical Trial
Billing Process



Key Steps in Clinical Trials Monitoring

Identify clinical trials for review

Data collection

Compile actual claims generated by service providers

Billing analysis

Communicate results of the review

Identify Clinical Trials for Review

Gather database of clinical trials

- What trials exist with potential for billing errors?

Choose selection criteria

- Investigators
- Trials
- Patients

Data Collection

Participant names, medical record numbers, visit dates and service rendered

Budget identifying what services should have been paid by the study sponsor

Consent form (cost section/injury clause)

Visit schematic/protocol

Clinical trial agreement (CTA)

Financial statements for the study account

Claims data

Hospital (intermediary)

- UB-92
- Itemized statements
- Procedure codes
- DRG
- Actual payments
- Denied charges
- Diagnosis codes

Clinic (carrier)

- Provider
- Modifiers
- CPT codes
- Service description

Billing Analysis

Compare budget to actual claims data

- Were services billed correctly to the study sponsor?
- For services billed to insurance, were appropriate modifiers/diagnosis codes included?
- Was insurance payment denied for any services identified as standard care?

Other source documents

- Procedure notes, case report forms, research charts

Communication and Follow-up

Communicate results of reviews back to Principal Investigator/Coordinator, billing office, coding office, budget analyst, etc.

Determine corrective action plan for errors

Feedback loop to ensure errors are corrected in a timely manner

Lessons Learned: Keys to a Successful Clinical Trial Billing Process

Prospective coverage analysis

- Develop billing grid
- Coordinate informed consent language with billing grid

Identify study patient

Process for communication to billing and coding offices

Clinical trial billing reviews

Prospective Coverage Analysis

Occurs prior to initiation of clinical trial

Three component review

- Research protocol/events
- Sponsor agreement & budget
- Informed consent document

Analysis of 3rd party billing rules

Accurately identifies on a visit by visit basis all items and services provided along with the correct disposition of charges (i.e. billing grid)

Conducting a Coverage Analysis

Start with visits/items matrix

- Visits – use protocol schema
- Identify all clinical billable items
 - Description of item on the grid from chargemaster/activity list from billing provider
- CPT code/charge code
- Location of services (inpatient, outpatient)
- Correct disposition of charges (who will pay?)
 - Determine standard care services
- If paid by the study, what rate?
- Coding requirements

Conducting a Coverage Analysis

Analyze services identified as standard care with third-party billing policies

- ❑ National coverage decision (qualifying trial)
 - ❑ Local Medical Review Policies
- ❑ Device trial billing rules
- ❑ Tricare clinical trial policy
- ❑ Medicaid, if applicable
- ❑ Private payors (e.g. Blue Cross)

Challenges of Implementing a Coverage Analysis Process

Efficiently and effectively incorporating it into organizational review processes

Identifying appropriate staff

- Specialized training

Investigators may view this as yet another hurdle

- Marketing the process to the investigators as a benefit
- Assistance with contract negotiations
- Assistance in identifying potential liability of the physician and the organization

Identify Study Patients and Communicate with Billing offices

Evaluate your billing process/system

Registration

- Plan codes
- Pre-bill edits

Order entry

Charge entry

- Specialized charge tickets

Back-end process

- Billing grids used for notification

End of Part IV



Questions/comments

Part V- Lessons from False Claims Act Cases

NIH Grants and Medicare

Self-Disclosure

Selected Government Investigations
and Settlements

OIG Draft CPG

OIG draft compliance guidance for recipients of PHS research awards

- First guidance designed specifically for segment of federal grant community, not focused exclusively on Medicare / Medicaid issues
- Primarily concentrates on the “allowability” of costs and “whether awardees should be subjected to a disallowance action or, in appropriate circumstances, an investigation for criminal or civil fraud”

OIG Draft CPG

Basic compliance elements

Development / distribution of written standards of conduct

Designation of a compliance officer / committee with sufficient funding, resources, and staff

Regular education and training of all employees

Effective lines of communication including an anonymous hotline

Internal audits to monitor compliance; identify problem areas

Policies / procedures for investigating noncompliance

The enforcement of appropriate disciplinary action against employees / contractors for violations

***NEW* – Clear definition of roles / responsibilities within the institution's organization and ensuring the effective assignment of oversight responsibilities**

OIG Draft CPG

the 8th element

■ **Roles and responsibilities**

- Includes administration or department personnel with oversight responsibility as well as PIs and other personnel engaged in research
- Clearly delineated, communicated and accessible
- Included in the institution's written policies / procedures and its formal training and education program

Govt. Wide Initiative Based on OIG Guidance

OIG and Committee on Science (COS), National Science and Technology Council (NSTC)

- Agree to expand efforts to provide voluntary compliance guidance to recipients of federal research awards

COS Research Business Models Subcommittee

- Will establish inter-agency initiative to develop guidance for recipients receiving funding from all federal agencies
- Guidance to expand on OIG's "Draft Compliance Program Guidance for Recipients of PHS Research Awards"

OIG Draft CPG

Identified risk areas

- **Reporting financial support from other sources in grant application process**
 - Institutions must properly report financial support from all sources
 - Critical for awarding agency to understand the commitment of resources by grantee to particular project
 - Required part of PHS Form 398 application for funding and related certification on face page of application

OIG Draft CPG

Identified risk areas, cont.

- **Reporting financial support from other sources during term of grant**
 - ▣ Failure to accurately report support may result in the charging of both award funds and Medicare and other health care insurers for performing the same service

Synchronizing with Medicare Rules

“A problem related to the failure to accurately and completely report support from other financial sources is the charging of both award funds and Medicare and other health insurers for performing the same service.

This is clearly improper and has subjected institutions to fraud investigations.”

OIG Draft CPG

Identified risk areas, cont.

- **Reporting financial support from other sources**
 - *Settlements*
 - Weill Medical College of Cornell University
 - University of Alabama at Birmingham

OIG Draft CPG

Identified risk areas, cont.

- **Properly allocating charges/costs to award projects**
 - ▣ Accounting systems should properly separate funding from each source and costs allocated to each grant or project
 - ▣ Cost principles are set forth in federal guidelines

Federal Guidelines

Cost principles are set out in various documents and incorporated in 45 C.F.R. 74.27 and 92.22, including:

- **OMB Circular A-21** – Cost Principles for Educational Institutions
- **OMB Circular A-87** – Cost Principles for State and Local Governments and Indian Tribal Governments
- **OMB Circular A-122** – Cost Principles for Non-Profit Institutions
- **OASC-3** – A Guide for Hospitals – Cost Principles and Procedures for Establishing Indirect Cost and Patient Care Rates for Grants and Contracts

Federal Guidelines

45 C.F.R. 74, Appendix E – Principles for Determining Costs Applicable to Research and Development under Grants and Contracts with Hospitals

48 C.F.R. Subpart 31.2 (Federal Acquisition Regulation) – Contracts with Commercial Organizations

OMB Circular A-110

- Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations (45 C.F.R. Part 74)

OMB Circular A-133: Single Audits

NIH Grants Policy Statement

Other: Agency Grant Policy Manuals

Cost Transfers

When a clerical or bookkeeping error occurs

- A cost transfer should occur within 90 days of when the error was discovered
- A cost transfer should be accompanied with documentation that fully explains how the error occurred and a certification of correctness for the new charge

Cost transfers to make up shortfalls are inappropriate

Cost Transfers

Institutions need to be vigilant about “clearly fraudulent practices,” such as:

- PIs on different projects trading award funds among themselves
- Transferring costs from overspent to underspent award accounts to maximize federal reimbursement or avoid refunding unused grant proceeds

Not mere accounting problem

- Drawing away limited federal research funds from intended use
- Subverting agency’s ability to distribute funds to projects most in need of support

OIG Draft CPG

Identified risk areas, cont.

- **Properly allocating charges to award projects**

- ***Settlements***

- Weill Medical College of Cornell University
- Harvard/Beth Israel Deaconess Medical Center
- Johns Hopkins University
- Northwestern University
- Thomas Jefferson University
- New York University

OIG Draft CPG

Identified risk areas, cont.

■ **Time and effort reporting**

- Need to be vigilant that researchers:
 - Do not bill for more effort than is possible
 - Bill only for expended effort – not budgeted effort
 - Account properly for teaching, research, and clinical work
 - For example, it would be improper to report to NIH that 70% of a researcher's time would be spent on an award when 50% of the researcher's time would be spent on clinical responsibilities

OIG Draft CPG

Identified risk areas, cont.

- Time and effort reporting, cont.
 - Relationship between research effort reporting and Medicare time studies and time allocations
 - Objectives
 - Research: allocate individual physician effort and salary related costs to specific grants
 - Medicare: identify portion of aggregate physician compensation costs to be claimed as allowable "Part A" teaching and administrative service costs
 - Procedures
 - Research: "effort" report measures total effort over relevant time period
 - Medicare: two week per quarter "snapshot" of physician activities
 - Compliance issues
 - Unrealistic to expect 100% consistency
 - Examine material difference

OIG Draft CPG

Identified risk areas, cont.

- **Time and effort reporting**

- ***Settlements***

- University of Alabama at Birmingham
 - Johns Hopkins University
 - Northwestern University
 - Thomas Jefferson University

OIG Work Plan FY 2006

Risk Areas

Level of commitment by investigators

- Whether major research universities have committed more than 100% of the PIs effort when applying for NIH grants and if so, whether the resulting grant awards were inflated

Subrecipient costs and monitoring

- Compliance with applicable federal regulations regarding the monitoring of subrecipient costs

University administrative / clerical salaries

- Whether administrative and clerical salaries are being appropriately charged to federally-sponsored grants as direct or indirect costs

Cost transfers

- Allowability of cost transfers including supporting documentation and certification by grantee officials regarding the correctness of the new charges

Self-Disclosure

What should be reported?

■ According to the OIG

“The existence or amount of a monetary loss to PHS or other federal programs is not solely determinative of whether the conduct should be investigated and reported to governmental authorities.”

“In fact, there may be instances where there is no readily identifiable monetary loss, but corrective actions are still necessary to protect the integrity of the program.”

Self-Disclosure

Reporting — Timing issues

■ The NIH on prompt reporting

“Recipients shall immediately notify the HHS awarding agency of developments that have a significant impact on the award-supported activities.”

“This notification shall include a statement of the action taken or contemplated, and any assistance needed to resolve the situation.”

Self-Disclosure

Reporting — Timing issues

■ **The OIG on prompt voluntary reporting**

Demonstrates the institution's *“good faith and willingness to work with governmental authorities to correct and remedy the problem.”*

“... may be considered a mitigating factor by the responsible law enforcement or regulatory office including the OIG.”

“When reporting to the government, the institution should provide all information relevant to the alleged violation”

Self-Disclosure

Reporting — Timing issues

- **Disclosure within 60 days after —**
 - Determining credible evidence of a violation
 - Identifying an overpayment
- **Disclosure within 30 days of —**
 - The time the violation was initially detected
 - May limit risk to double damages under the FCA
- **Immediate disclosure**
 - Clear violations of criminal law; significant adverse effect on quality; evidence of a “systemic failure to comply”

Investigations / Settlements

University of California (Oct. 1995)

■ Allegations

- University made false statements in NIH grant applications
- Applications relied on inaccurate scientific studies – failed to cite retractions of some of the findings of a previously published university study

- University and ORI determined that failure to cite retractions did not constitute scientific misconduct

Investigations / Settlements

University of California, cont.

- Court granted summary judgment for defendants
 - Accurate citations to allegedly inaccurate articles did not violate FCA
 - Failure to discuss retraction did not constitute a false statement
 - **Disagreements over scientific methodology do not give rise to FCA liability**
 - Inability to replicate results is normal part of the scientific process
 - Case presents a legitimate scientific dispute, not a case of fraud

"The legal process is not suited to resolving scientific

"disputes over scientific methodology."

Investigations / Settlements

Mercy Hospital of Pittsburgh (Feb. 2002)

■ Allegations

- Director of clinical trials filed FCA charges arguing that application seeking designation as a center in a multi-site trial was false and misleading

■ Court granted summary judgment for defendants

- Application to be designated as a clinical center for a multi-site trial is not considered a claim for payment, thus such a false application may not support a FCA action
- Submission of application was just the first step in a process that *MIGHT* lead to payment of federal funds
 - Hospital not selected as a site

Investigations / Settlements

Rush University Med Ctr (\$1 M, Dec. 2005)

■ Allegations

- Improperly billed Medicare for physician and hospital outpatient cancer research services as routine care costs under the NCD
- Violations attributed to absence of *“synchronization of the Medicare rules, the compensation arrangements with the sponsors, and the financial discussion in the informed consent”*

■ Among the first settlements related solely to the NCD on clinical trials

Investigations / Settlements

Rush, cont.

- **Voluntary self-disclosure to DOJ**
- **Corrective action**
 - Establish Research & Clinical Trials Admin. Office
 - Centralized office responsible for coordinating documents and information from all departments so as to develop single standardized billing guidance
 - Require clinical trials to receive a coverage analysis
 - Refund Medicare overpayments *plus* 50% penalty
 - 2 year Certification of Compliance Agmt (CCA)

Investigations / Settlements

U. of Alabama at Birmingham (\$3.39 M, Apr. 2005)

■ Allegations

□ **Falsely billed Medicare for:**

- Researcher's time spent on patient care when no patients had been seen
- Clinical research trials that were also billed to the sponsor of the research grants

- Overstated percentage of effort devoted to the grants and falsely reported T/E of employees who did not work on the grants

- Whistleblowers = Compliance officer; academic physician

Investigations / Settlements

Weill Medical College of Cornell (\$4.3 M, June 2005)

■ Allegations

- Charged NIH grant for full salaries of:
 - Inpatient nurses who didn't provide services under the grant
 - Employees who did not dedicate 100% effort to the grant
- Failed to account for outpatient costs charged to grant
- Double-billed Medicaid for services charged to grant
- Allowed physician-investigator and his division to monopolize grant funds and to dominate the research

Whistleblower = Asst. professor of pediatric medicine

Investigations / Settlements

Northwestern University (\$5.5 M,
Feb. 2003)

■ Allegations

- Overstated time spent by researchers on federally-sponsored projects
- Knowingly failed to comply with researcher percentage of effort requirements
- Inappropriately treated physician salary earned from an independent entity as part of the institutional based salary paid by the University

Whistleblower = former employee, Office of
Research and Sponsored Programs

Investigations / Settlements

Johns Hopkins University (\$2.6 M,
Mar. 2004)

■ Allegations

- Overstated percentage of effort; falsely reported T/E of employees who did not work on grants
- Failed to maintain adequate compliance mechanisms to reconcile proposed effort commitments with actual effort
- Applied erroneous fringe benefit rates to grants

Whistleblower = office supervisor

Investigations / Settlements

Dartmouth College

- **OIG audit findings** (Sept. 2005)
 - Overcharged \$37,780 for PI's salary for effort unrelated to the NIH grant
 - Lacked adequate procedures for identifying
 - Actual activities
 - Adjusting for changes to planned activities
 - Accurately computing labor distribution percentages

Investigations / Settlements

Dartmouth audit, cont.

- Lacked internal controls to ensure proper account of grant funds
- Internal control weakness related to:
 - Inadequate procedures to properly account for grant application activity
 - Non-compliance with HHS conditions for approval of proposed changes to its payroll distribution system
 - Inadequate procedures for monitoring \$716,522 in sub-recipient costs

Investigations / Settlements

Dartmouth audit, cont.

- Dartmouth agreed with the proposed adjustment of \$1,512 related to miscalculation of the PI's salary in excess of the NIH ceiling for a two month period
- Dartmouth did not concur with the other recommendations of the Report

Investigations / Settlements

East Carolina University

- **OIG audit findings** (Aug. 2004)
 - Interim audit of costs claimed for reimbursement over a 4-year period under a National Library of Medicine (NLM) contract
 - Of the \$4 M claimed by ECU, only \$1.7 M found allowable
 - \$565,820 recommended for financial adjustment
 - \$1.8 M set aside for adjudication by NLM due to inadequate documentation by ECU

Investigations / Settlements

ECU Audit, cont.

■ **Inappropriate charges included:**

- Salaries, wages, and fringe benefits for:
 - Employees who had been instructed to falsely certify that they were devoting effort to the NLM grant even though they were not working on the project
 - Clerical and administrative personnel whose duties did not apply directly to the project
- Equipment that was not used for the project
- Payments to firms with business relationships with former Co-PI even though services were not rendered or were unrelated to the project

Investigations / Settlements

ECU Audit, cont.

■ Inadequate controls

□ Examples

- T/E reports based on inconsistent methods
 - Some employees reported based on a percentage of time and effort
 - Others reported hours supposedly worked
 - Some employees did not report at all
- No procedures in place to compare T/E reported for each employee to approved funding levels for the contract

Investigations / Settlements

ECU Audit, cont.

- **Inadequate controls, cont.**

- No requirement for the timely submission of employee efforts to the contract administrator
- Neither ECU's grants administration office nor its manager of effort reporting fully understood the procedures required to correctly report and compute the costs of employees' paid leave
- No procedure to reconcile the reported time and effort to ECU's actual payroll distribution

Investigations / Settlements

ECU Audit, cont.

- **OIG asserts ECU lacked adequate internal and management controls**
 - *“The University had not implemented an effort reporting system adequate to comply with the requirements of OMB Circular A-21 and document the actual efforts of covered employees. Instead, the University relied upon an incomplete, inconsistent system that was subject to frequent errors and could easily be manipulated.”*
 - *“The University’s control environment was not adequate to prevent charges for equipment and other costs that provided no documented benefit to the NLM contract.”*

Investigations / Settlements

Harvard / Beth Israel Deaconess Med Ctr (\$2.4 M, June 2004)

■ Allegations

- Harvard/BIDMC improperly billed 4 NIH grants \$1.9 M over 5-yr period

■ Examples of inappropriate activity

- Salaries inappropriately paid for researchers who:
 - Did not work on the grants
 - Did not meet citizenship requirements (not eligible)
 - Failed to meet 75% effort requirement

Investigations / Settlements

Harvard / BIDMC, cont.

- Inappropriate activity, cont.
 - PI salary expenses charged to grants in excess of budgeted amounts
 - Additional expenses incurred
 - For research animals used for unrelated projects
 - Supply and equipment expenses incurred for projects unrelated to the grants

Investigations / Settlements

University of Minnesota (\$32 M, Nov. 1998)

■ Allegations

□ **Inflated billings on 29 federal grants**

- Charged salaries for employees who did not work on the grants and for supplies not used for the grants

□ **Illegally profited from selling unlicensed drug**

- Failed to report income from the drug to NIH
- Tested drug on patients w/o informed consent

Whistleblower = Microbiology professor

Investigations / Settlements

Thomas Jefferson University (\$2.6 M, May 2000)

- **Allegations connected with 2 PHS grants**

- Falsified and fabricated data that was used to obtain additional federal grant monies
- Failed to tell government that PI listed in reports had resigned from TJU and left the country
- Improperly charged salaries to the grants

Whistleblower = former post-doc fellow

Investigations / Settlements

Mayo Foundation (\$6.5 M, May 2005)

■ Allegations

- Improperly transferred costs from overspent grants and internal Mayo cost centers to underspent grants
- Inappropriately charged the government for costs unrelated to research sponsored by the grant
- "Mayo had an accounting system unable to monitor and manage charges made to federal grant awards in the manner required by federal law"

Whistleblower = former accounting associate

Investigations / Settlements

Yale University

■ **OIG audit findings** (Aug. 2004)

- Yale improperly billed \$193,779 in subaward costs under a U. of Mass Med School grant from NIH
 - The majority of the improper costs involved cost transfers for researcher labor and salaries
 - OIG found evidence that cost transfers were used to “spend down the subgrant funds” to cover a shortfall
 - PI failed to provide the 25% level of effort proposed in the subaward grant application and Yale did not obtain prior approval from UMMS for “the significant reduction in effort”

Investigations / Settlements

Yale audit, cont.

- **OIG recommendations**
 - Verify cost transfers are adequately explained and documented
 - Improve procedures for direct charging of costs and comply with procedures for confirming effort reports
 - Ensure that levels of effort are satisfied
- Yale acknowledged \$78,965 in disallowances but disagreed with the remaining \$114,814

Investigations / Settlements

Yale University Subpoenas (June 2006)

- 3 federal agencies seeking documents relating to the management of research grants
 - ▣ Dept. of Health and Human Services (DHHS)
 - ▣ Dept. of Defense
 - ▣ National Science Foundation (NSF)
- Over 90% of federal grants awarded to Yale come from these 3 agencies
- Consulting group brought in last year to help efforts to upgrade accounting procedures and ensure compliance with federal regulations

Investigations / Settlements

University of Chicago

■ **OIG audit findings** (June 2006)

- Although written policies and procedures and controls relating to cost transfers were adequate, staff did not always follow procedures and cost transfers were not always documented and authorized as required
 - One transfer lacked required documentation to explain reason for error
 - Four late transfers made without properly authorizing required form for oversight and approval

■ **OIG recommendations**

- University reemphasize cost transfer policies and procedures with Comptroller's and dept.

The End



Questions/Comments