

A pair of surgical forceps is shown holding a stack of US dollar bills. The forceps are positioned diagonally across the frame, with the handles at the top left and the jaws at the bottom right. The bills are held between the jaws, and the top bill is a \$50 bill. The background is a soft, out-of-focus blue and white.

**Deloitte
& Touche**

The Second Annual
Medical Research Summit

**BILLING AND
RESEARCH:
A Practical Approach
Toward Compliance**

by Sandy Piersol & Kim St. Amant

Session Objectives

Learn more about...

- Techniques to untangle the web of regulatory compliance issues around clinical research
- Practical ways to apply what you have learned at this Summit to mitigate risk and add value to your research enterprise
- Research billing compliance (case study illustrations)

Untangling the web of regulatory compliance issues

- All of the OIGs compliance guidance documents are organized around risk areas – areas of vulnerability
- Identifying and understanding where the enterprise is vulnerable is the best starting point for figuring out what steps are needed to prevent problems
- This risk assessment process is precisely how generic compliance program principles can be fashioned into practical applications

Risk Assessment Framework

FORMULA:

$$\begin{array}{r} \text{Risk Areas} \\ - \text{Controls} \\ \hline = \text{Assessment of Risk} \end{array}$$

Risk Assessment Approach

- Step 1: Identify risk areas
- Step 2: Prioritize high risk areas
- Step 3: Assess risk
- Step 4: Analyze findings and solutions
- Step 5: Operationalize corrective actions

Repeat As Necessary

Risk Assessment Approach

Step 1: Identify Risk Areas

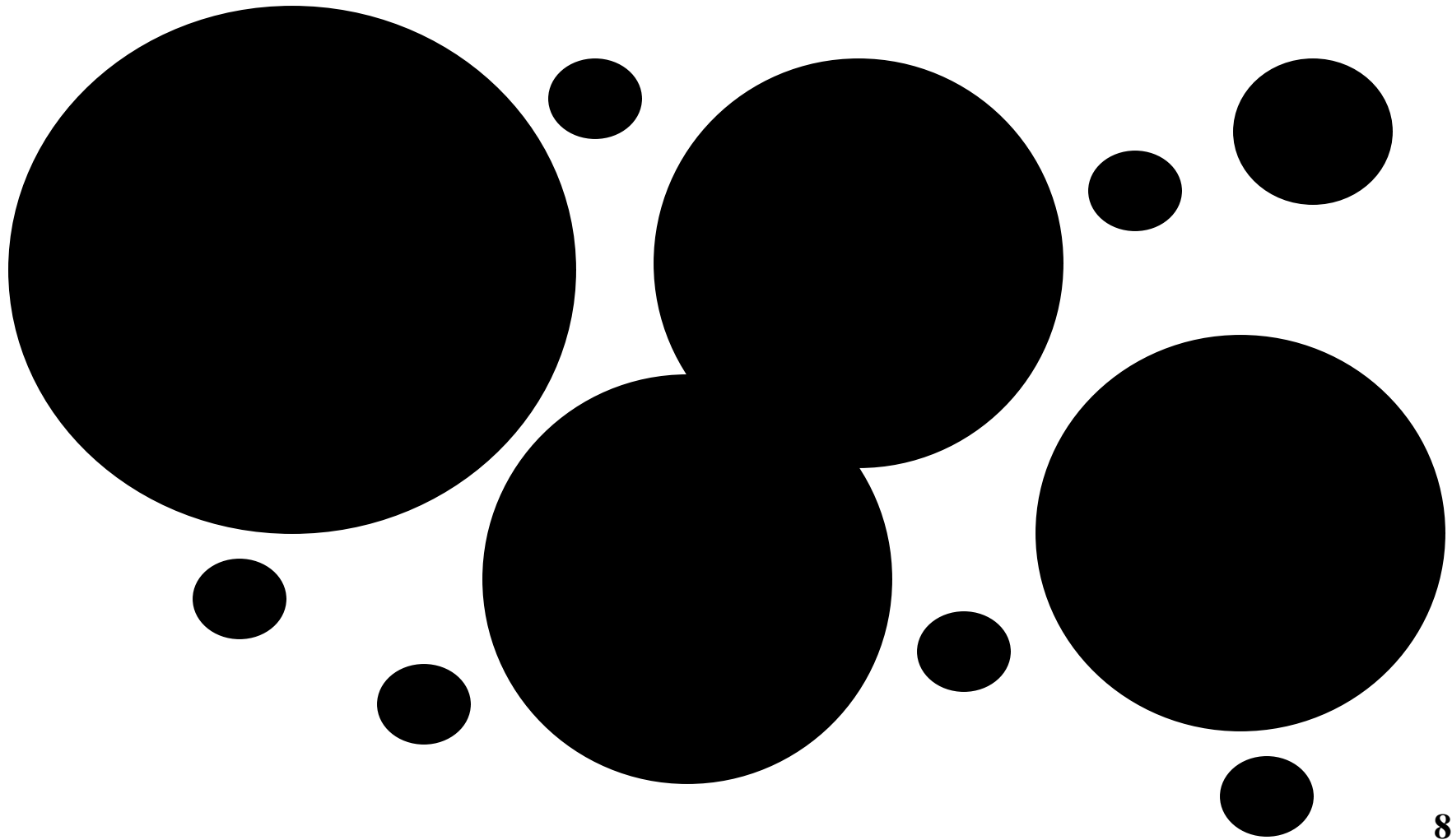
- What risk areas have special relevance to your research portfolio?
- Where is the research enterprise vulnerable?
- Risks areas are not static
 - New laws and regulations (or interpretations)
 - New lines of business
 - New ways of doing things
 - New staff

Risk Assessment Approach

Step 1: Identify Risk Areas

- Sources for Identifying Risk Areas
 - OIG documents: compliance program guidance, special fraud alerts, advisory opinions, audit reports, inspection reports, annual work plans and semiannual reports
 - Analysis of applicable laws, regulations and interpretations
 - Relevant lawsuits, qui tam cases, settlement agreements
 - Stated enforcement priorities
 - Conferences, industry newsletters, word of mouth

Compliance Risk in Clinical Research



Risk Assessment Approach

Step 2: Prioritize High Risk Areas

- Unless resources are unlimited, it is essential to start with the risk areas that are most likely to give rise to “liability” \$\$\$
 - Strategy: Emphasize attention upon higher risk areas and devote less effort to lower risk areas

Risk Assessment Approach

Step 3: Assess Risk

- Determine “current state” of compliance
 - Are we in compliance? Yes-No-Maybe
 - If Yes, why?.....Got Lucky or Was it by Design
 - If No, why not?....Redesign Control

Risk Assessment Approach

Step 4: Analyze Findings and Solutions

- Seek to understand the cause and extent of the problems identified
 - Evaluate the need for further investigation
 - Not every “rumor” requires investigation
- Identify plausible solutions and timeframe for corrective action

Risk Assessment Approach

Step 5: Operationalize Corrective Actions

- Prioritize corrective actions and assign accountability
- Operationalize corrective actions through
 - Policies and procedures
 - Training
 - Monitoring and Auditing
- Strategy: Compliance controls should be part of the basic infrastructure (controls should be “built-in” versus “added-on”)

Research Billing Compliance

Case Study Illustration

Note: case study materials are not included in conference binder

Research Billing Compliance Defined

Research Billing Compliance

- Billing patients or third party payors for products and services provided to patients enrolled in clinical trials in accordance with applicable laws and regulations including:
 - Federal health care program requirements e.g., Medicare Part A, B &C
 - National and Local Coverage Policies
 - Final National Coverage Determination (NCD), Medicare Coverage Policy – Clinical Trials (Sept. 19, 2000)
 - Coding guidelines established by the cooperating parties for the *International Classification of Diseases, 9th revision, 6th edition, Clinical Modification* (“ICD-9-CM”): AHA, AHIMA, CMS and the National Center for Health Statistics
 - Procedural coding guidelines developed and maintained by the AMA and published in *CPT Assistant*.

Research Billing Compliance

Step 1: Identify Risk Areas

Risk areas relating to the costs of clinical research and experimental drug trials specific to hospitals:

- Billing Medicare (or the patient) for items or services that are otherwise reimbursable (or free) to the hospital through federal or private grant funds – *a.k.a.* “*double billing*”
- Billing Medicare for experimental drugs, devices or procedures
- Charging for an investigation drug in a clinical trial under an investigational new drug application without approval of the FDA
- Waiving Medicare copayments and deductible obligations for study participants
- Receiving remuneration from research sponsors that could be viewed by Medicare as kickbacks
- Coding and billing for noncovered items or services as a covered benefit by an insurer
- Billing for items and services solely to satisfy data collection needs
- Billing for items and services provided solely to determine trial eligibility
- Inadequate medical record documentation for items or services billed
- Upcoding of billable services
- Use of Advance Beneficiary Notices (ABNs)
- Other typical compliance risks applicable to federal health care programs e.g., credit balances, MSP, etc.

Research Billing Compliance

Step 2: Prioritize High Risk Areas

- Identify studies with billing compliance risk
 - Federally funded studies
 - Medicare beneficiary enrollment
 - Protocols with billable items or services
 - Cost/payment provisions per informed consent form
 - Funding provisions per study agreement
- Next, determine which risk areas have special relevance and attempt to rank them low to high

Research Billing Compliance

Step 3: Assess Risk

- “Current State” Assessment Techniques
 - Interview key personnel (e.g., PI, Coordinators, HIM, Patient Accounting, Reimbursement Specialist, Budget/Finance)
 - Check for complaints/correspondence
 - Review policies and procedures
 - Test medical records and billing information
 - Data mining
 - Look for data trends or patterns

Step 4: Analyze Findings and Solutions

- What caused the problem?
 - Breakdown in internal controls
 - Lack of policies and procedures
 - Lack of training and education
- How can the problem be fixed?
 - Implement system controls
 - Revise/implement policies and procedures
 - Clarify personnel responsibilities
 - Improve communication and reporting
 - Provide training and education
 - Internal auditing

Step 5: Operationalize Corrective Actions

- Build in compliance controls (front to back)
 - Budgeting process controls
 - Formalize billing protocol development policies and procedures
 - Design monitoring controls
 - Ongoing training and communication to increase awareness
 - Close-out audits

Adding Value Through Compliance

- Optimizing the research revenue stream
 - How much does the research enterprise contribute to the organization?
 - How much research is the organization funding?
 - Which areas are Winners? Losers?
 - Are you capturing appropriate reimbursement for all “billable” services? Are you leaving any dollars on the table?
 - Do you have billing protocol controls in place? Is the billing protocol comprehensive?

Summary

- Whether your compliance program is new or well established, it is important to periodically evaluate if ethical and regulatory standards are adequately addressed
- Risk assessment is not a one-time event, ongoing identification and monitoring of risk areas is mission critical
- Don't underestimate the importance of increasing awareness of risk areas
- Best practices may not exist, the right solutions depends on several factors
- The recent expansion of Medicare coverage of clinical trials does not eliminate the risk of inappropriate billing
- Revitalize the research revenue stream through compliance

Questions & Answers

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