



Internal Investigations & Clinical Research

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Research compliance issues that may give rise to an internal investigation

- Clinical trials billing**
- Research grant accounting**
- Time & effort tracking**
- Scientific misconduct**
- HIPAA privacy issues**
- Conducting research without IRB approval**
- Lack of informed consent**
- YNI**

What is an internal investigation?

No formal definition....

An organized approach for finding facts and identifying:

- Whether a problem exists
- The root cause of the problem

Methodology should be clearly set out (but flexible)

An internal investigation should have an end, with a report on facts identified, conclusions (or inability to reach a conclusion) and recommendations

Why do an internal investigation?

- If you don't, you may have an external investigation!

- If an issue is raised to managers, the issue should be examined

- not investigating may lead to liability under:

- corporate theories of knowledge or

- “acting in ignorance of the truth” standard under the False Claims Act

- Most issues can be reviewed and dealt with informally, but even informal reviews should be documented and results recorded

- Internal investigations are seen as a formalized review of a potential issue in which the methodology of reviewing the issue is documented meticulously and consistently balanced against the liability exposure for the organization

- Issues may present themselves for which it may be best to have an independent person or firm conduct the investigation

- Organizations should consider whether the internal investigation should be protected by the attorney-client privilege

Basic features of an internal investigation

Interviews

- Avoid group interviews if a problem is suspected
- Set out a plan of who should be interviewed (but be flexible)
- Encourage interviewee to supplement interview if facts are later remembered

Review of documents

- What is the paper trail?
- Minutes, notes, memos, policies
- Emails are forever!

Audits

- Craft samples appropriately

Report

Research Compliance Issues Investigations: Focusing on Clinical Trials Billing

Nature of the risk for improper billing during clinical trials is large:

- Culture of research has historically been one of “decentralization”
- Many areas touching research in the same organization have never worked with each other
- Clinical trials billing usually touches virtually every area of a provider – knowledge of what is or is not happening is often widespread

Research Compliance Issues Investigations: Focusing on Clinical Trials Billing

If a provider embarks on a clinical trials billing compliance initiative, should it look at past practices and conduct an internal investigation of the past?

A provider must weigh the nature of potential overpayments, whistleblower risks and *knowledge* the provider may obtain when establishing compliance structures

A reality in clinical trials billing: developing the tools to bill correctly on a going-forward basis for an active trial will identify how a provider should have done it in the past

If overpayments are identified, the overpayments must be returned. An internal investigation can establish that the provider has done its due diligence in identifying whether the overpayment is limited to what is returned or it runs deeper

Research Compliance Issues Investigations: Focusing on Clinical Trials Billing

Who should be interviewed?

- Consider....
 - Clinical trials contracting personnel
 - Grants office
 - Patient finance (billing)
 - A clinical investigator from each department sampled
 - Research coordinators
 - Department administrator for each department sampled
 - IRB chair
 - Registration

Research Compliance Issues Investigations: **Focusing on Clinical Trials Billing**

Clinical trials billing audits:

- Initially select a sample of studies from the highest volume departments
 - “highest volume” may be based on number of enrollees or number of studies
 - “high risk” areas by specialty: cancer, cardiology, ortho
 - “high risk” areas by type of study: Phase I trials & investigator-initiated trials

- Review and identify the billing posture for each item and service in the protocol by using:
 - The protocol
 - The executed contract or the notice of grant award
 - The IRB-approved informed consent
 - Relevant FDA correspondence

Research Compliance Issues Investigations: Focusing on Clinical Trials Billing

Clinical trials billing audits:

- Once a generic coverage review has been developed for a specific study, then patient billing records for the study should be audited against what should or should not have been billed**

- Does more than one patient per study need to be audited?**

- A provider should audit all services during the trial for the sampled patient, in whatever provider setting the services were performed and the organization controls (e.g., hospital inpatient, hospital outpatient, employed-physician practice)**

- A clinical trial is usually unique in its billing implications because in each trial the protocol, the contract/grant and the informed consent will interact differently**

Research Compliance Issues Investigations: Focusing on Clinical Trials Billing

What to do with the results?

- Did policies direct consistent activities?
- Were departments “doing their own thing”?
- Did an inaccurate claim result in a denial and therefore no overpayment was received?
- Was a claim inaccurate and paid but no overpayment received?
- Does a bill hold need to be placed on specific trials or departments to ensure inaccurate claims are not generated?

Research Compliance Issues Investigations: **Focusing on Clinical Trials Billing**

If an overpayment is identified....

- Determine how the overpayment will be returned (e.g., directly to the Medicare contractor or through a disclosure to the OIG or DOJ)
- Consider statute of limitations implications
- Consider a formal voluntary disclosure (especially if it may take a long time to determine the full results of audits but initial results identify an overpayment problem that is certain)