TOP 7 RESEARCH COMPLIANCE ISSUES

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Today’s Topics/Agenda

1. Review top research regulatory risk areas
2. Discuss operational safeguards to manage risks
3. Looking on the horizon

Enforcement/Actions

• What agencies are concerned with research compliance and what are the issues? (just a selection!)
  • Human Subject Protection
    • OHRP
    • FDA
    • NIH
  • Clinical Research Billing
    • CMS
    • OIG
    • DOJ
    • State AG
  • Federal Grants
    • NIH
    • OIG
    • DOJ
Top 7 Issues
(not presented in order of importance)

1. Movement of clinical research into the community setting
   - For many years, clinical research has been the domain of academic medical centers...not any more.
   - Some estimates peg 40% of clinical research is performed at a community hospital or in independent physician practices

Top 7 Issues
(not presented in order of importance)

2. Not knowing the studies conducted at your institution – and not knowing who the patients are
   - It seems like a simple thing, but it can be quite complicated!
   - Who knows? The physician.
   - Consider developing a process to be informed of the patient's enrollment at the time of signing informed consent
     • CTMS, secure email, or fax notification

Top 7 Issues
(not presented in order of importance)

3. Not knowing who got paid for what
   - Items and services paid for by the sponsor cannot be billed to insurance
   - Who are the parties to the clinical trial agreement?
   - Who took the money? What is the money for?
   - Is the hospital receiving money that must be paid to a physician?
Top 7 Issues
(not presented in order of importance)

4. Stark Law issues lurking in the confusion of documents
   - Is the hospital taking money which must be paid to a physician? (For example, professional fees for radiology services)
   - A financial relationship between a hospital and a physician who refers Medicare patients to the hospital must meet a Stark exception (and Anti-kickback Statute compliance must also be considered)
   - Is there a negotiated rate for the physician’s charges?

5. Abiding by the financial discussion in the research informed consent
   - Anything promised free in the research informed consent cannot be billed to insurance
   - The informed consent must be written at a 6th to 8th grade reading level – it is interpreted from the perspective of the patient
   - What is being promised free in the informed consent? Is there a system to manage this information?

6. Not having a process to review research-related claims before sending to third-party payors
   - Services which cannot be billed to insurance must have their charges directed to the study
     - There must be a process to:
       - A. Bring all the information together about the study to know which services can be billed to insurance and which can’t (“Coverage Analysis”)
       - B. Review claims against the Coverage Analysis
   - The information in a Coverage Analysis should be coordinated between the hospital and the physician
Top 7 Issues
(not presented in order of importance)

7. Auditing your IRB
   - Do you know who your IRB is?
   - An institution can outsource the IRB function, but it cannot outsource the liability
   - Compliance audits should occur for both internal IRBs and external IRBs
   - Write into your contract with an external IRB the ability to conduct compliance audits

Summary of Clinical Research Billing Risks

1. Billing for services that are already paid by the sponsor (double billing)
2. Billing for services promised free in the informed consent
3. Billing for services that are for research-purposes only
4. Billing for services that are part of a non-qualifying clinical trial
5. Billing Medicare Advantage Plan when claim should be directed to Medicare Administrative Contractor ("MAC")
6. Not putting appropriate codes/identifiers on claims

Operational Solutions for Clinical Research Billing

1. Intake process for research
2. Coordinate documents
3. Develop Coverage Analysis
4. Identify research subjects
5. Hold research subject’s claims
6. Review claims against Coverage Analysis
Clinical Trial Number (August 9, 2013)

- August 9, 2013 CMS Transmittal (Change Request 8401):
  - Changes to Claims Processing Manual, Chapter 32
  - “Effective for claims with dates of service on or after January 1, 2014, it is **mandatory** to report a clinical trial number on claims for items/services provided in clinical trials/studies registries, or under CED” (emphasis in original)

Clinical Trial Number (January 6, 2014)

- January 6, 2014 MLN SE1344:
  - “Since the release of CR 8401, the Centers for Medicare & Medicaid Services (CMS) has learned that some physicians, providers, and suppliers do not have the capability at this time to submit the clinical trial identifier number associated with trial-related claims. This article presents those physicians, providers, and suppliers with an alternative means of satisfying the CR 8401 requirements until January 1, 2015. At that time, such providers must fully comply with CR 8401.”
Clinical Trial Number (January 6, 2014)

- January 6, 2014 MLN SE1344:
  - “Beginning January 1, 2014, and continuing no later than through December 31, 2014, those above-mentioned physicians, providers, and suppliers **may instead report an 8-digit, generic number of 99999999** using the instructions in CR 8401. This will allow trial-related claims to process appropriately if they are prepared according to instructions in CR 8401.” (emphasis added)

Clinical Trial Number (January 6, 2014)

- January 6, 2014 MLN SE1344:
  - “Keep in mind that trial-related claims will be returned if they do not contain either the actual clinical trial identifier number or the 8-digit generic number 99999999 – you may not leave those indicated fields blank.” (emphasis added)
  - “Beginning January 1, 2015, without further notice, CR 8401 shall be fully implemented.”

Clinical Trial Number (January 6, 2014)

- January 6, 2014 MLN SE1344:
  - “For clarification, the clinical trial identifier number is required for all items/services provided in relation to participation in a clinical trial, clinical study, or registry that may result from coverage with evidence development (CED), the Medicare Clinical Trial Policy, or a CMS-approved investigational device exemption (IDE) study.” (emphasis added)
Questions?