Top 7 Research Compliance Issues

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HCCA Desert Southwest Regional Annual Conference
November 15, 2013

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1

Today's Topics/Agenda

1. Review research regulatory risk areas
2. Discuss operational safeguards to manage risks
3. Identify areas for compliance audit plans

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2

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

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3

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

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4 4

Top 7 Issues
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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

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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?

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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?

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7

7

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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?

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8

8

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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

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9

9

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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

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Not an issue yet, but could be…

Starting January 1, 2014, Medicare will require a clinical trial number on claims for items and services provided in clinical research studies that are qualified for coverage under the National Coverage Determination 310.1 or approved as IDE device trials

The number required to be reported is the number identified for the study on **clinicaltrials.gov**

CMS: "Claims submitted without the clinical trial number that were once paid will now be returned for reprocessing/returned to provider for inclusion of the trial number." (Transmittal 2805 – October 30, 2013)

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11

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 to Medicare

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12

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



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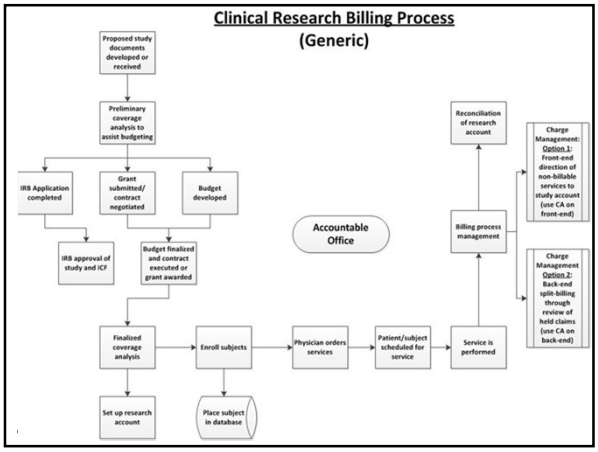

Research Compliance Auditing

- Suggestions for your research compliance auditing plan:
  1. Identification of studies and subjects
  2. Test accuracy of Coverage Analysis or other communication tools
  3. Test accuracy of claims submitted to insurance
  4. After January 1, 2014, application of clinicaltrials.gov number
  5. IRB auditing:
     - What is being reported to the institution
     - Are minutes recording actions appropriately
     - Are informed consents being signed
     - Is annual continuing review occurring



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Questions?

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16