Tactical Framework for a Clinical Trials Billing Audit

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Presentation Objectives

- Elements of an Effective Audit Program
- Issues & Challenges that Can Trigger a Clinical Trials Billing Audit
- Summary of Approach for Conducting a Clinical trial Billing Audit
  - Before you get started
  - Study level
  - Patient level
- Strategic Options for Reducing Risk and Minimizing Audit Findings
Elements of an Effective Audit Program
Audit Programs
Importance of Having an Effective Program

- Properly directed, internal audit programs can help an organization stay focused and uncover new improvement opportunities.

- Clinical Trials Billing is an area of considerable complexity, uncertainty, and curiosity.

- Move beyond counting findings to providing insights.
  - Collect complaints or feedback from audit program “customers” (auditee, program manager, management, operations personnel)
  - Understand the objectives of the stakeholders who “own” the process being audited
  - Identify and report completed corrective actions
  - Install competent auditors to review the business process being targeted
  - Communicate
  - Verify claimed improvements
  - Provide visual as well as written descriptions of issues
  - Do it right the first time
  - Document issues encountered so that it runs better the next time
Audit Programs
Effective Programs are Key for Managing Risk

- Clinical Trials Billing overlaps multiple segments of the business and is complex to monitor.
  - The risks created by research are complex and difficult to assess due to its overlap.
  - An ERM framework when applied to research, and CT Billing in particular, is beneficial to an institution because it is a comprehensive model to monitor research compliance as cross functional, flexible and not static.

CT Billing (if left unchecked) can adversely impact nearly every function and operation in a hospital. Effective CT Billing requires understanding of the unique regulatory requirements it demands as well as an understanding of how it impacts the normal operation of the business it is built upon.
Audit Programs
Effective Programs are Key for Managing Risk

- The risks and potential pitfalls in CT Billing are inherent and almost impossible to fully eradicate.
- Managing the risks that will be identified through the audit process is crucial to any organization that seeks a thriving research program.

Risk Response:
- Responsible parties should identify the procedures for responding and mitigating risk uncovered based on risk assessment/audits.
- Consult compliance, counsel, or consultants when addressing assessment/audit findings to determine the proper course of action to mitigate findings.
- Establish reasonable and achievable standards for making enhancements and/or supporting change needed to address risk assessment/audit results.
- Correct deficiencies, address opportunities, and mitigate the events identified through assessment/auditing.

For identified risk, exposure or non-compliance, possessing the information puts the institution at risk. Knowing of non-compliance and not acting to mitigate the event also adds to the risk exposure.
Issues & Challenges That Can Trigger a Clinical Trials Billing Audit
Getting It Right
What Does it Take?

- Billing is a discrete event.
- **But, getting it right demands an appreciation for the numerous other “events” that take place before and after billing.**
  - Few persons in an organization have adequate authority or a thorough awareness of the full process continuum. Examples include:
    - Budget preparation and negotiation:
      - Who pays for adverse events?
      - What is the language related to subject injury?
    - Informed consent language:
      - Are there items promised free of charge?
    - Protocol approval:
      - Who pays for additional tests if required by the IRB?
    - Patient registration:
      - Are research visits identified separately from regular visits?
    - Are research charges removed from bills to 3rd party payors?
The likelihood of correctly following through on both debiting a study account and billing some other third-party (insurance, patient, Medicare, etc.) depends on considerable investments in operations, financial management, and compliance oversight.

- In the absence of suitable IT systems, *investments* means deploying enough *people to own the process*.
- In most organizations the variety of stakeholder leads to a situation where many of them have varied, often misaligned priorities, time, or interest in seeing the process through.
Getting It Right
What Does it Take?

When clinical activities performed strictly for research purposes get inadvertently billed to the patient or insurer (rather than a grant/study account) there are usually four main reasons why.

1. **Technological errors**: A “research flag” (i.e., unique study number, a letter on an encounter form, or some other indicator) was not recognized by information systems.

2. **Human errors**: A study number was never placed on the encounter form and/or no one performing charge capture was informed.
   - Check-in personnel are unaware of research participants.
   - Technicians in ancillary service areas are unaware.
   - PI and person negotiating CTA are not in communication. Leads to PI thinking something is billable to payor but it may be for item negotiated for payment from sponsor leading to inadvertent double dip.
Getting It Right
What Does it Take?

Most common reasons for failure (continued):

3. **Training**: Inadequate explanation of expectations, use of forms, work flow.
   - Policies not updated
   - Policies exist without accompanying SOP
   - Training not regularly updated

4. **Awareness**: Because research related care can take place in so many care settings (and, often concurrently with routine services), ensuring that those at every point of entry in your facility know what to do is unlikely in the absence of a coordinated strategy. Must know the following:
   - Who is the patient (research patient or not)?
   - What is the name of their study?
   - What episode of care, per the protocol, are they receiving?
   - In an emergency, how do you ensure that EMTs and ED docs know a patient’s research status?
Clinical Trial Billing
Synchronous Work Flow is Key

- From the standpoint of optimizing process, it is vital to spend time early on to plan for potentially challenging billing issues.

- Effective internal controls during study initiation can help reduce risk.

- Oversight, tools, IT, and dedicated personnel at each step in the process continuum are essential.

- While this illustration highlights each step as its own process activity, many of these can be done simultaneously.
Clinical Trial Billing
What Can Happen if Your Audit Program Doesn’t Effectively Identify and Provide Action Steps for Remediating the Risk?

- No one wants to be the next Rush (CCA in ’05…$1MM) or UAB (settlement in ’05…$3.39MM)

- More recently, was Tenet
  – Pursuant to the CIA’s Reportable Event disclosure requirements, revealed to OIG that between December 2003 and October 2007, it submitted claims not entitled to Federal health care program reimbursement for clinical research-related items or services rendered at USC Norris Cancer Hospital.
  – Specifically, Tenet improperly received government reimbursement for:
    • (1) items or services that were paid for by clinical research sponsors or grants under which the clinical research was conducted;
    • (2) items or services intended to be free of charge in the research informed consent;
    • (3) items or services that were for research purposes only and not for the clinical management of the patient; and/or
    • (4) items or services that were otherwise not covered under the Centers for Medicare & Medicaid Services (CMS) Clinical Trial Policy.
Conducting a Clinical Trials Billing Audit
In assessing one’s own process for managing clinical trials billing, there are numerous questions asked and areas that are reviewed.

- Operations
- Financial Management
- Compliance Management
- Personnel

**Operations:**

- Segregation of charges
  - Are billable charges being separated from charges that should be debited against a study/grant account?
  - Who is determining what is billable to 3rd party payors? PIs? Coordinators?
  - Is this determination objective or subjective?
  - Is there a documented plan that is accessible by those performing charge capture so that they have reference material at this pivotal point in the billing continuum?
Auditing Clinical Trial Billing at Your Institution
Areas of Focus – Questions to Address Prior to Testing

Operations:

– Registration
  • Are study subjects identifiable in registration (or scheduling) systems?
  • Is there an easy way for check-in personnel to validate a patient’s status as a research participant?
  • Are all points of entry for your facility equipped to deal with various research patient scenarios?

– Charge Capture
  • Who is pushing the buttons?
  • Do clinicians not associated with the study (i.e., other than the PI, a research nurse, or coordinator) have a simple to understand approach to noting a patient as a research participant?
  • Do lab techs and other non-research personnel have training in how to route research charges or how to identify and route routine test/procedure charges?

– Billing
  • Is there a way to “scrub” charges before bills are dropped or prevent over- or inaccurate billing?
  • Is there a “bill hold” or some other manual, back-end bill review process?
  • What is the time line expectation for reviewing bills on hold and passing them along for final billing by a patient financial services staff member?
Financial Management:

- Budgeting
  - Is sponsor funding sufficient to cover costs of research? Of start up? Of performing a coverage analysis? Other fees?
  - Who drafts the budget? Where do they get access to charge master rates?
  - Is there a research rate schedule?
  - Is a coverage analysis being performed? Is it crafted using Medicare standards, the NCD, or LCDs?
  - What other medical literature is used to independently determine conventional care?
  - Do sponsor contracts/agreements clearly state which patient care costs are covered?

- Accounts Receivable
  - Are sponsors being billed and payments being collected (and credited to study accounts) in a timely manner?
  - When sponsors make payments, where do the checks go? Lock box? Who is accountable?

- Professional Fees
  - Are these being included in study budgets?
  - Being billed at all? Debited against the study budget?
Compliance Management:

– Investigations and Monitoring
  • Does compliance look at residual balances?
    ❖ Could be viewed as kickback or may indicate that non-billable patient care events are not being debited against study accounts
    ❖ PIs sometimes use surplus in a study to fund something else disconnected to the study
    ❖ PIs may use surpluses to fund coordinators on a different study
    ❖ What becomes of funds above a certain threshold?
    ❖ Is a policy in place that defines how surpluses (and deficits) are reconciled?
    ❖ If a deficit, is the PIs department accountable in any way for making up the difference?
  • Does compliance take a sample of studies and a sample of research participants on these studies and trace some bills through the process continuum to identify where (if any) control weaknesses may exist?

– Finders fees and other incentives
  • Are there conflicts of interest that are incentivizing shady billing practices or leading to cases of non-disclosure of other fees?

– Training
  • Is there a research compliance curriculum for PIs? Coordinators? Billing personnel? Those who develop coverage analyses?
**Personnel:**

- **Roles and Responsibilities**
  - Who is accountable for what?
  - Does your organization have appropriate controls in place to manage everyone from PIs to check-in personnel?
  - Are the often multiple competing interests and agendas understood?
    - PIs
    - Clinical trials office staff
    - Contracting / Tech transfer
    - Research finance & Billing
    - Department administrators
    - IT staff
    - Registration staff
    - Medical records & Coding
    - Pharmacy, lab, other ancillary services
    - Compliance
    - Counsel
    - Internal Audit

- **Communication**
  - Does your organization have a research portal or website with policies, information, downloadable forms, training, and FAQs?
  - Do PIs have a simple way to get information about their studies? Status of study initiation procedures? Financial status of study account?
Analysis & Testing: Study Level
What **Documents** Do You Need?:

- May choose to do a sample from an array of various departments
- May choose to deal with only outpatient-focused studies initially
- May choose to select studies from high-volume departments that do a lot of research
- May choose to select studies that have the highest enrollment of research participants
- For each study selected:
  - Study protocol (may want to look at list of all current, active trials prior to selection)
  - IRB-approved Informed Consent Form
  - Contract or NOGA
  - FDA Status of Investigational Item (IND or IDE)
  - Proposed / Sponsor Budget
**QCT Analysis:**

- **Purpose of trial** must be the evaluation of an item or service that falls within a Medicare benefit category and is not statutorily excluded.

- **The trial** must not be designed exclusively to test toxicity or disease pathophysiology. It must have **therapeutic intent**.

- **Trials of therapeutic interventions** must enroll patients with diagnosed disease rather than healthy volunteers. *NOTE: Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.*

- **Trials must be deemed to have desirable characteristics.**
  - Funded directly (or indirectly as in a cooperative group) by NIH, CDC, ARHQ, CMS, DOD or VA
  - IND has been reviewed by FDA or has been given exemption
**Routine Costs Analysis:**

- **Items and Services that are:**
  - Ordinarily provided to beneficiaries and covered by Medicare.
  - Typically provided absent a clinical trial (**conventional care**).
  - Required solely to administer the investigational drug.
  - Provided for the clinically appropriate monitoring of the effects of or prevention of complications from the investigational item.
  - Needed to deal with the diagnosis or treatment of complications.

- **Does not include items and services that are:**
  - Provided solely to satisfy data collection.
  - Provided free of charge.
  - Statutorily excluded or for which there is non-coverage decision.

Don’t forget to review the ICF. If it states that a patient shall have no monetary responsibility, then no items involved in the protocol may be billed to the patient.
Auditing Clinical Trial Billing at Your Institution
Analysis and Testing: Study Level

But, How Do You Know What Conventional Care Is?:

- **Review credible sources**
  - National Guideline Clearinghouse – AHRQ / NIH
  - National Comprehensive Cancer Network
  - American College of Cardiology (and others)
  - JAMA, NEJM, etc.
  - Attestation of PI

**Document the analysis:**

- **Medicare Coverage Analysis**
  - Use Protocol as foundation
  - Record the services analysis on a billing grid
  - Document the QCT analysis
  - Cite sources
  - CPTs?
Make Sure That You Understand Accountability for *Research Related Injury*:

**CMS**

- "The clinical trial sponsor’s agreement with participants that it will pay for medically necessary services related to injuries participants may receive as a result of participation in the trial constitutes a plan or policy of insurance under which payment can reasonably be expected to be made in the event such an injury occurs."

- "[CMS] believes that Medicare would not be the primary payor in such a situation."
  - Correspondence from CMS, Financial Services Group (April 13, 2004)

**Industry / Sponsor**

- Sponsor pays primary to Medicare if the sponsor is (1) a “primary plan,” *i.e.*, a liability insurance policy or plan (including self-insurance plans) with (2) a “demonstrated” responsibility to pay under the MSP laws.

- Both a “liability plan” and “demonstrated responsibility” turn on whether there is liability at issue. *A promise to pay for research-related injuries, in and of itself, does not suffice to create “liability” as that term has been defined by courts.*

- Indeed, a promise to pay may be made to further ethical principles of research and not to discharge a liability.
Medicare as Secondary Payor: CMS interpretation vs. Sponsor interpretation:

- **All or Nothing!!** Well, all or half…
  - Sponsor agrees to pay for **all** RRI – Site bills sponsor, not payor
  - Site agrees to absorb costs for **all** RRI – Site does not bill sponsor or payor
  - Sponsor agrees to pay for RRI of any federal health care program enrollee
    - Include affirmative provision that Site will **not** bill FHCP at all
    - Check managed care/commercial agreements for MFN
Analysis & Testing: Patient Level
What **Documents** Do You Need?:

- Select a sample of 2 to 3 research participants for each of the clinical trials selected for testing.

- For each patient, you need:
  - UB-04 (i.e., CMS 1450)  
  - CMS 1500  
  - EOB  
  - On-study & Off-study date  
  - Billing activity  
  - Medical record

**Where Do You Start?:**

- Verify that the patient received the services per the clinical trial protocol.
- With the MCA as your guide.....
  - Verify that the charges for each item or service associated with conventional care were posted to the **patient account**.
  - Verify that the charges for each item or service considered “research related” were posted (or written off) to the **research account**.
Check Bills for Appropriate **Modifiers**: 

- The Centers for Medicare & Medicaid Services (CMS) has discontinued the QA (FDA Investigational Device Exemption), QR (Item or Service Provided in a Medicare Specified Study), and QV (Item or Service Provided as Routine Care in a Medicare Qualifying Clinical Trial) HCPCS modifiers as of December 31, 2007.

- Effective for dates of service on and after January 1, 2008, CMS has created the following two new modifiers that will be used solely to differentiate between routine and investigational clinical services:
  - Q0 - Investigational clinical service provided in a clinical research study that is in an approved clinical research study.
  - Q1 – Routine clinical service provided in a clinical research study that is in an approved clinical research study.
How Do You Know When *Modifiers* Are Required?:

- **Depends on the type of claim**

  - **Inpatient: No**
    - Use V70.7 (i.e., Examination of a participant in a clinical trial) and,
    - Condition Code 30 only. This indicates that you are working with a “qualified clinical trial.” When this condition code is reported on a claim, it generally means the service is part of a CMS related clinical trial, demonstration or study.

  - **Outpatient: Yes-Q1**
    - Routine clinical service provided in a clinical research study that is in an approved clinical research study.
    - Use it to identify routine services provided in the trial/study

  - **Outpatient: Yes-Q0**
    - Investigational clinical service provided in a clinical research study that is in an approved clinical research study.
    - Use it to designate the item under investigation in the trial/study
What Else Should Be Looked At?:

- For conventional care procedures that are payable by Medicare but performed outside the normal allowable time limit, refer to the ICF to determine if they should be written off or billed to a research participant’s payor.

- Verify items charged to a payor on UB-04 agree with allowable items per the MCA.

- Verify that bills match the revenue that was paid.
  - Look for denials.
  - Look for partial payments on remittances.

- Calculate excess charges and then calculate excess reimbursement received.

- Cost Report
  - Research-related costs should not be included in relevant areas of Cost Report.
  - Calculate impact of the costs of those research-related procedures to the Cost Report.
Final Step:

- **Look at study accounts vis-à-vis budget**
  - High *surpluses* may imply that accountable persons are not consistently debiting study accounts for non-conventional care (i.e., non-billable, research-related activity).
  - High *deficits* may imply absence of effective planning, low accruals, or other issues.
    - Sponsor invoicing is not consistent.
    - Cash flow and collections from sponsor is slow.
    - Poor planning on budget assumptions.
    - Checks from sponsors not being deposited to correct account.
    - Too many patient care charges hitting study account and not enough being billed to 3rd party payors.
  - May choose to look into these sorts of irregularities and conduct a root cause analysis.

- **Confirm signed ICF is in medical record.**

- **Confirm summary of protocol is in medical record.**
Strategic Options for Reducing Risk and Addressing Audit Findings
Clinical Trials Billing
Strategies for Reducing Risk and Enhancing Compliance

- **Standardization and Central Support Services**
  - Whereas many departments used to “own” these processes, many organizations are creating Clinical Trials Offices where many of the critical pre-study and research initiation services are provided.
    - Regulatory coordination
    - MCA development
    - Research charge master oversight
    - Budget development
    - Contracting / negotiation
    - Sponsor invoicing
    - Cash management
    - Bill review / scrubbing
  - Other centralized services reside with the compliance office.
    - Research compliance specialists
    - Training & education
    - Auditing & monitoring
  - Reducing disparate approaches to budgeting, training, and planning helps to ensure that the “performance site” has a stake and some control in helping deliver a consistent approach to research taking place on its premises.
  - Many organizations have created a “fee for service” model to perform these services.
Clinical Trials Billing
Strategies for Reducing Risk and Enhancing Compliance

- **Implementation of clinical trials management systems (CTMS)**
  - Many software and hardware vendors have good systems that can handle key aspects of the research “life cycle” or “continuum”.
  - Costs remain high.
  - Implications for a major change in work flow and culture.
  - Some systems do different things. Finding one that can easily work with your billing, schedule, and registration systems is often difficult.

- **Realigning organizational designs**
  - Centralizing coordinators.
  - Establishing a chief research officer.
  - Establish a deputy compliance officer for research
  - Carving out clinical research from traditional pre- and post- award activities associated with bench/basic research.
  - Separate CTO for commercial sponsors versus federal grants.
Clinical Trials Billing
Strategies for Reducing Risk and Enhancing Compliance

- **Training**
  - Make it mandatory and a routine part of annual education expectations.
  - Dedicate FTEs to coordinate programming.
  - All stakeholders are accountable for training. Tone at the top implies that organizational leadership participate also.

- **Requiring development and use of a Medicare Coverage Analysis at the outset of the planning for any potential trial to be hosted by your organization.**
  - The Rush case catalyzed many organizations to insist upon MCAs as the lynchpin for study initiation.
  - When done properly and used as intended, an MCA can improve revenue for research.
Medicare Coverage Analyses (con’t)

- By identifying early on what items and services can be billed to a 3rd party (patient, Medicare, private payors, etc.), MCAs can improve an organization’s ability to better negotiate payments from sponsors.

- MCAs can help in many, meaningful ways
  
  • Determines if a trial is qualifying.
  
  • During pre-award it helps keep the budget, ICF, contract and other key documents consistent.
  
  • During post-award it can be useful as a resource for scheduling and registration.
  
  • Clarifies items that are provided by the study sponsor or promises free of charge to the research participant.
  
  • Can help enable allocation of fixed fee revenue to other non-covered services.
  
  • Demonstrates a good faith effort of trying to determine billable vs. non-billable tests and procedures. This could be valuable in the event of an audit.
Medicare Coverage Analyses (con’t)

- Other Uses

  • Providing Patient Access with a copy of an MCA (with appropriate training for how to read the document) can assist in obtaining clearance from 3rd-party payors for the billing of routine care charges in connection with a clinical trial.

  • Providing charge capture or charge audit staff a copy of the MCA (with appropriate training for how to read the document) can help assure research charges are not billed to a 3rd-party payor.

  • To the extent that a bill hold is in place for research participant’s bills, an MCA can be useful to patient financial services staff. It helps to simplify information and hopefully limit confusion over what is billable and what is not.
### Pulling Charges Apart

<table>
<thead>
<tr>
<th>Registration</th>
<th>Appointment Request &amp; Scheduling</th>
<th>Charge Entry</th>
<th>Charge Capture</th>
<th>Billing</th>
</tr>
</thead>
<tbody>
<tr>
<td>- 2 registrations</td>
<td>- Attach “R” to encounter specific identifier fields</td>
<td>- Note an “R” or “standard” when documenting encounter</td>
<td>- Assure research charges are captured against a designated research account</td>
<td>- Perform a manual, back-end charge review (i.e., bill hold) prior to dropping a bill. Use MCA as reference document.</td>
</tr>
<tr>
<td>- 1 registration</td>
<td>- Distinct appt. request forms</td>
<td>- Modify CDM to include research specific charges</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(multiple payor codes or visit level flag)</td>
<td>- Distinct (i.e., color coded, etc.) encounter forms</td>
<td>- Create research CDM</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- 1 registration</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>with patient level flag (implies need to implement bill hold)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### What can be done?

- Attach “R” to encounter specific identifier fields
- Distinct appt. request forms
- Distinct (i.e., color coded, etc.) encounter forms
- Note an “R” or “standard” when documenting encounter
- Modify CDM to include research specific charges
- Create research CDM
- Assure research charges are captured against a designated research account
- Perform a manual, back-end charge review (i.e., bill hold) prior to dropping a bill. Use MCA as reference document.

### What are the desired Outcomes?

- Study account debited with research-related tests & procedures.
- 3rd party payors are only billed for conventional care tests & procedures.
In general at least 4 major strategies for making this happen have emerged

1. **Patient-level “flag”**
   - Research participants are noted in registration systems by their flag.
   - All tests and procedures for that patient drop into a queue where the individual charges are reviewed and compared to an MCA.

2. **Visit-level “flag”**
   - Each visit is flagged during scheduling and Billing office gets a pre-notification.
   - Patient’s charges put on temporary hold (until visit concludes).
   - Charges for that visit are reviewed through a manual bill review process.

3. **CTMS**
   - Requires that CTMS (or a patient registry) can interface with a billing system to catch episodes of care prior to billing that may have included research (non-billable to a 3rd party payor) events.
   - Charges routed either to a bill review queue or a separate research billing system.

4. **Duplicate registrations**
   - Same patient registered twice using two different plan codes.
   - May complicate registration systems to have two of the same person present.
Questions & Additional Discussion
SNR Denton is a client-focused international legal and consulting practice delivering quality and value. We serve clients in key business and financial centers from more than 60 locations in 43 countries, through offices, associate firms and special alliances across the US, the UK, Europe, the Middle East, Russia and the CIS, Asia Pacific and Africa, making us a top 25 legal and professional services provider worldwide.