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(original release date: 10/1/2015)

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Clinical Trial Billing: *Solutions to a Complex Problem*

PEER REVIEWED | Mitchell Appleson, CPA, MBA

[DOI: 10.14524/CR-15-0025]

Managing a clinical trial used to be much easier. Years ago, when a research patient came in for a visit, a study team recorded basic information, kept it in a binder on a desk, and sent data to a sponsor as needed.

Today, we have multiple systems, numerous processes, and a myriad of rules and regulations. There are multiple individuals and departments that must be contacted before, during, and after a clinical trial is conducted. Within this environment, accurate billing has become both more challenging and more vital.

Facing the Challenge (or Not)

As medicine and research have become more complex, the billing processes to support that complexity have not kept pace. Historically, the focus for most institutions has been on the actual research taking place, with little thought placed on the billing associated with the research.

Until recently, many institutions did not have centralized offices to handle budgeting, billing, and other administrative functions for clinical research. Therefore, many responsibilities were handled by the study team, or not at all.

The state of research billing was often a reactive one. If a bill was sent out incorrectly, it only became known when a patient called to question the bill.

Once a problem was identified, there was not always a clear process for how to fix it. If a patient's insurance was billed incorrectly, the insurance needed to be refunded and the research grant had to be charged. However, unless a patient called multiple times to follow up on the erroneous bill, it was often difficult to know whether the problem had been fixed. Not all patients check their explanation of benefits, and they would not be aware if their insurance had been billed incorrectly.

We therefore lived in a very reactive state, in which a problem was only known if someone outside the billing function raised it as a problem. Due to this lack of transparency, it was difficult to identify the problem to begin with, and it was just

as difficult to identify whether the problem had been resolved.

This lack of transparency became more glaring as audits became a regular part of institutional processes. Federal regulations mandate that Medicare, Medicaid, and other payers may not be billed for services that are not considered standard of care. Standard of care procedures are those that the patient would receive regardless of study participation. In addition, if a service is paid by a clinical trial sponsor, it may not also be billed to a third-party payer.¹

Whether through a federal audit, sponsor audit, or internal audit, the pieces of the billing process must all come together to create an audit trail. That can be difficult enough for a simple study with only two procedures and visits; it is much more complicated when the study has 50 visits, each visit has 35 procedures, and some are considered research and some standard of care.

An Example of What's at Stake

One of the audits that raised awareness of research billing problems came in 2003 at Rush University Medical Center in Chicago. Rush internally reviewed the Division of Hematology and Oncology, and identified certain services performed in research that had incorrectly been billed to Medicare. Rush took immediate action by instituting a bill hold for all clinical trial services within the

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LEARNING OBJECTIVE

After reading this article, the learner should be able to analyze key resources and tools available to address the challenges in clinical trial billing.

DISCLOSURES

Mitchell Appleson, CPA, MBA:
Nothing to disclose

division, while expanding its investigation. Rush also disclosed these billing issues to the federal government. This self-disclosure resulted in a \$1 million fine.²

Many hospitals and academic medical centers, concerned with the fines levied against Rush and other large institutions over the past decade, have looked at Rush's self-disclosure and the government's response for lessons on how to approach clinical trial billing properly and effectively. The root cause of Rush's billing issues was a lack of coordination between its research and billing operations, and its corrective action focused on the centralization of clinical trial billing processes within the medical center.²

One result of the situation at Rush was the creation of a centralized clinical trials office, which conducts coverage analyses of all clinical trials using the protocol, informed consent, and sponsor budget. The office is also a liaison between the medical center's research and billing arms.

Getting a Grip on the Issues

To understand research billing and how to properly address it, we need to start by understanding budgeting, which is the first step toward correct billing.

The purpose of creating a clinical trial budget is two-fold: 1) To determine the total costs incurred as part of the study; and 2) to determine which procedures are to be billed to a research grant and which are to be billed to a patient's account.

When preparing a clinical trial budget, some people prepare a "funding-based" budget. Using the funding provided by the sponsor, individual line items are determined as a proportion of those funds to prepare the itemized budget. For example, if 10% of a budget is allocated to startup costs, and the total funding for the study is \$20,000, a total of \$2,000 would be allocated for startup costs.

A problem with a funding-based budget is that it does not consider the actual startup costs incurred. It may cost more than \$2,000 to get the study up and running, which will cause the study to be in a deficit or not to run properly—and the same problem can occur with other study activities. Rather than backing into a budget, best practice is to prepare a total internal budget.

Preparing a total internal budget begins with reviewing the protocol and using actual internal

KEY QUESTIONS FOR SITES TO CONSIDER WHEN PREPARING A BUDGET

Does the budget include:

- ? Resources required by other departments or vendors?
- ? An appropriate estimate for startup costs?
- ? Screening costs?
- ? Coverage for unscheduled visits?
- ? Costs associated with the purchase or lease of required equipment not provided by the sponsor?
- ? The cost of phone queries from the sponsor as part of a remote monitoring system?

Other Questions:

- ? Does the informed consent form clearly address participant financial responsibilities?
- ? Will the sponsor pay for additional tests and procedures if they are requested during the course of the trial?
- ? Under what conditions are additional payments made?
- ? What are the expectations for timely payment?
- ? How will the accounts receivable from the sponsor be tracked?
- ? Who is responsible for billing sponsors of clinical trials?
- ? How is the information included in the budget communicated to the billing office to ensure billing accuracy?

costs to develop a detailed budget. To determine the internal costs of a study, the study protocol must be thoroughly reviewed to identify all procedures and visits to be performed as part of the study.

Each procedure is then assigned a corresponding charge, which should be pulled from the institution's charge master—a comprehensive list of institutional charges billable to a patient or his or her insurance. The charge master should be the sole source of identifying individual charges when creating the budget, to ensure that all pricing information comes from the same source.

LESSONS LEARNED

- ✓ Prepare an internal budget to assess the costs of a study
- ✓ Identify a sole source of pricing data
- ✓ Communicate with key stakeholders involved with the study
- ✓ Know which charges are research and which are standard of care
- ✓ Perform a root cause analysis when a billing error occurs
- ✓ Ensure that study participants understand their potential financial obligations
- ✓ Engage your institution's billing office when deviating from institutional processes
- ✓ Create an environment of transparency and crossfunctional coordination
- ✓ Consider the use of a CTMS
- ✓ Review the payment terms in each study agreement

The internal budget should establish the cost to perform the trial. Upon completing the internal budget, the total budget amount should be compared to the sponsor offer and any shortfalls should be addressed, either with more aggressive sponsor negotiations or identifying supplemental sources of funding.

Any departments that will participate in the clinical trials should be given an opportunity to review and approve the budget for coding accuracy and feasibility. For example, if a study involves an MRI during each visit and the intention is to enroll 100 participants over the next six months, radiology should know of the expected volume and confirm that the proper codes have been added to the budget. Finally, ensure accurate costs in the budget via one institutional source for pricing.

And...Who's Paying for All This?

Knowing the costs of a study is not sufficient; the budget must delineate who is paying for which costs. If a visit has 10 procedures, and five procedures will be paid by Sponsor X, three by Sponsor Y, and two are standard of care, the budget should reflect this. Using this method, a billing office will have an easier time determining which charges must be billed to which sponsor, and which charges must be billed to a research participant.

There are several purposes in creating a clinical trial budget, besides documenting all procedures and costs. The budget should contain the approvals of the investigator, study coordinator, and any ancillary departments. These approvals document the signatories' ability to provide technical and professional services, as required by the study.

The budget also:

- Clarifies which procedures in the protocol are considered research and which are standard of care
- Assists study coordinators with registration and scheduling of research patients
- Supports charge auditors as they review and adjudicate charges

Finally, when billing errors do occur, the budget should be reviewed during the root cause analysis to understand what went wrong.

Once the budget is complete, the informed consent form must articulate which procedures are

standard of care. This will mitigate confusion when a patient receives a bill for what he or she thought was a study-related visit, but was approved to be billed as standard of care. An institutional review board (IRB) should review the informed consent form's financial language for clarity.³

Taking the Next Steps

Now, we should get a better understanding of why an accurate budget is critical to getting correct billing. Let's take a look at two key issues.

CONFUSIONS AND COMPLICATIONS

First of all, a billing office can follow the budget when determining how to post charges from a research visit. When a patient, or his or her insurance, is billed incorrectly, a root cause analysis should be performed. Starting with a review of the budget, it should be readily apparent whether the process was followed correctly. Research procedures may not be listed correctly, or a research procedure may be listed as standard of care.

An alternate cause of confusion may be that the participant was not correctly identified as a research participant at the time of registration. The participant may have been registered for procedures not included on the budget, and therefore the participant was charged for study-related procedures. Another option is that the bill is correct, and the participant was not provided with a clear sense of his or her potential financial obligations. Having an accurate budget is central to the root cause analysis.

Yet another possible complication may be that a clinical department created a workaround outside the billing system to handle financial interactions with hospital ancillary departments. Dr. X has limited funding and has asked Dr. Y to perform a test for free. Although Dr. Y agrees, neither Dr. X nor Dr. Y realizes that a charge may be automatically generated in an electronic medical system. If clinical activity is not entered into systems, productivity and utilization data may be skewed. Therefore, include the billing office when deviating from institutional processes to handle financial interactions.

Some additional causes of improper billing relate to a lack of training to properly identify and bill research participants, use of paper processes that do not provide transparency, and a lack of coordination across functional areas. Creating an

Whether through a federal audit, sponsor audit, or internal audit, the pieces of the billing process must all come together to create an audit trail.

internal budget and implementing robust financial processes while tracking participant visits can mitigate these issues.

HAVING A SYSTEM

To successfully manage the finances of a clinical trial, there must be a system in place to track participant visits and procedures throughout the trial. The system must be easy to use for both research and finance staff, as research staff should enter all visits that would cause billable activity. Further, finance staff should invoice the sponsor of the study and follow up on outstanding receivables. The total outstanding balance should be clear for any study, as well as which procedures specifically make up that outstanding balance.

Consider utilizing a clinical trial management system (CTMS) to track individual studies, participants, and visits. In many systems, once a budget is entered for a study, the registration process entails entering a participant's medical record number and date of visit, and specifying which visit is being scheduled (screening, visit 1, etc.). Once the visit has been chosen, the individual procedures for that visit should automatically populate on the registration form. This eliminates the possibility of procedures being scheduled that were not initially budgeted, which can cause a patient to erroneously receive a bill.

The processes for invoicing, cash receipts, and accounts receivable tracking should be clear to all stakeholders. A CTMS can be helpful with this, as many systems allow an invoice to be generated from the visit, and cash receipts and accounts receivable can be tracked using the system.

When using a CTMS is not an option, the need for communication is even more critical. Whose responsibility is it to do the invoicing? Often, a central office in an institution receives the cash and posts the funds to an account. Do staff in this office know what invoices have been sent? Do the people who sent the invoices find out the detail of what was paid? If not, it will be very difficult to establish how much money is outstanding for clinical trials.

REVIEWS AND REPORTS

It is important to review the payment terms associated with each clinical trial to understand when sponsor payment will be made and what needs to be done to receive payment. These terms should be

reviewed carefully when negotiating the Clinical Trial Agreement, prior to executing the agreement.

Many payment terms indicate quarterly site payments. According to a recent CenterWatch survey, 60% of investigative sites have less than three months of operating cash on hand.⁴ When employees are paid biweekly, vendor terms are monthly, and utilities and rent must be paid monthly, sites end up funding the study until payment arrives.

If a site does not have significant cash on hand, quarterly payments from the sponsor are not sustainable and must be negotiated to a term that a site can manage. Ideally, this would be monthly payments from the sponsor.

Whatever payment terms are agreed to, review them carefully and make sure they are feasible for your site before agreeing to them.

Finally, consider establishing a reporting process in which study teams are sent a detailed report of all charges posted to their account during a particular time period. Encourage study teams to review their reports and respond if the information on the report is accurate.

The report should also include total funds received and balance outstanding. This proactive approach will serve as a final check to ensure that charges have been captured correctly in a timely manner, while also providing a strong level of transparency into the study's finances.

Wrapping it Up

In conclusion, managing the finances of a clinical trial is challenging and requires significant collaboration across different functional areas. While it may seem to be a daunting task, take incremental steps and create a realistic timeframe for each milestone.

Consider ways to make your processes more transparent, such as via the use of a CTMS to create an integrated, transparent system that serves as a single portal for all clinical research studies. Allow for the ability to track the status of budget negotiations, contract execution, and IRB approval for any study, and institute reporting processes that incentivize study teams to regularly review their account.

Finally, build long-lasting relationships with your institution's billing office, and partner with its staff to ensure that the billing is done correctly.

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Mitchell Appleson, CPA, MBA, (applesonm@email.chop.edu) is director of clinical trials financial management at the Children's Hospital of Philadelphia.

Key Financial Audit Strategies and Considerations: A Research Compliance Officer's Perspective

PEER REVIEWED | Emmelyn Kim, MA, MPH, CCRA, CHRC

[DOI: 10.14524/CR-15-0029]

Clinical research is a constant source of excitement, evolving regulatory changes, and challenges—all at the same time. As a research compliance officer, I can honestly say that financials have been the most challenging aspect of research to manage and audit.

The issues that arise are broad, always different, and sometimes interconnected. Among many other issues, a research compliance officer's day-to-day duties may include ensuring compliance in coverage analysis and in billing, coding, and charging of accounts tied to grants or contracts. Other issues that may crop up along the way can run the gamut from ensuring appropriate research sponsor contract language to handling financial issues affecting research participants.

When I attend research compliance conferences, financial compliance is often a “hot topic,” which is understandable, because ensuring compliance requires a smooth-running and well-equipped machine involving multiple players. This means that operational processes have to be aligned with trained personnel, adequate resources, and ongoing checks and balances.

However, creating and maintaining a smooth-running operation may be challenging for institutions that are constantly balancing growing business and regulatory demands against limited resources. This rings true for me, as I am based out of a large, decentralized, and expanding health system. In my experience, most financial compliance sessions I've attended during conferences have been well attended, leading me to believe that this area is one that many institutions are struggling with today.

Regardless of the types of challenges your institution may have, using the right strategies and allocating resources wisely are key elements to the success of your audit or quality improvement programs. In this article, I'll share practical research compliance audit strategies and considerations from a research compliance officer perspective.

Planning Reviews by Performing Risk Assessments

After working in research compliance for many years, I have come to realize that there are different ways to identify and resolve issues; some are easy to detect and fix, while others are hard to uncover and need fixing “upstream,” which may take months to ultimately close the loop.

As the central point of contact for all research compliance issues, I sometimes found it challenging to tease out audit priorities amongst all of the noise from urgent and ongoing issues. One thing I learned was that I could not identify (let alone fix) financial compliance issues by myself, and needed to partner with or rely on other departments to identify and resolve problems. The habits that I have grown accustomed to over time are planning, preparation, and communication, which are important skill sets for any auditor.

These concepts are incorporated into the annual research compliance work plan development process where I work. The work plan provides

LEARNING OBJECTIVE

After reading this article, the learner should be able to use strategies to effectively evaluate financial compliance in research.

DISCLOSURES

Emmelyn Kim, MA, MPH, CCRA, CHRC:
Nothing to disclose

an overview of audits and reviews of various areas scheduled for evaluation in the coming year, and is presented to and vetted by executive audit and compliance committees and institutional research committees.

The priority areas of the work plan are based on a risk assessment that occurs during the last quarter of every year, involving the following:

- interviews with key stakeholders (e.g., research teams, administrative and financial department staff, research support offices, compliance and research leadership) about what they believe are the top risk areas;
- an assessment of the current regulatory environment and focus (e.g., work plans, reviews and regulatory notices from the Office of the Inspector General, Centers for Medicare and Medicaid Services [CMS], Office of Management and Budget, etc.); and
- evaluation of past compliance or internal review findings.

Other factors are taken into consideration, such as new acquisitions and mergers, and an evaluation of the facilities or departments that will be conducting research studies involving grants or contracts and billing.

Taking the time to prioritize and plot out reviews using a workable timeframe (e.g., monthly or quarterly), based on regulatory compliance deadlines or institutional priorities will allow you to strategically perform reviews throughout the year. Building in enough space between reviews always helps, as there may be incidental reviews that pop up along the way, or ongoing reviews may take longer than anticipated.

Knowing Your Strengths and Weaknesses

Employing an effective audit strategy requires having a high level of self-awareness, a keen understanding of the environment in which you operate, and knowing your limitations. Questions to ask yourself include:

- Are clinical research financial processes at your institution handled manually or facilitated through mostly electronic systems (e.g., an electronic medical record, a billing registration system, a clinical trial management system, etc.)?
- What are the environments in which research billing may occur (e.g., inpatient, outpatient, and ancillary services)?
- Is the billing process centralized or spread out among many departments?
- What are the key departments that touch this process?

It is also important to know what processes people are handling well and where there are gaps. In order to identify areas of concern you have to investigate further and understand the root causes.

Are there areas with weak internal controls or a high potential for human error? For example, if your financial activity is driven by paper processes and multiple players, you may want to audit upstream manual processes that have a high impact on overall compliance. If your activity is largely automated through electronic systems, you may want to run reports that can detect problem areas throughout the process.

Focusing on high-risk areas where there are likely to be gaps may bring attention to operational kinks that have to be worked out, or additional education that may be needed. For example, are research participants and research-specific services flagged up front so that correct billing occurs on the backend?

If processes are in place, it's a matter of testing the system to ensure that it's working effectively. Conversely, if you know that you have a fundamental issue—for example, an up-front financial evaluation of research is not done (e.g., a coverage analysis and billing grid does not exist)—you may want to take a different approach, as it may be difficult to perform a financial audit without this step.

You may want to initially evaluate clinical trials billing more holistically and provide leadership with an idea of where operational resources need

Among many other issues, a research compliance officer's day-to-day duties may include ensuring compliance in coverage analysis and in billing, coding, and charging of accounts tied to grants or contracts.

Focusing on high-risk areas where there are likely to be gaps may bring attention to operational kinks that have to be worked out, or additional education that may be needed.

to be allocated. You should also be aware of what people are doing well, and which departments have strong leadership to leverage change.

The same concepts apply to departmental resources needed to perform financial research audits or reviews. Do you have personnel with the appropriate qualifications and enough resources to conduct compliance reviews? If so, are they properly equipped with the right tools, training, and support to perform the audit?

If you don't have internal staff, you may want to consider outsourcing and working with consultants who can provide the appropriate level of expertise and assist you in developing a strong program.

Evaluating the Financial Life Cycle

There are many components that make up the financial life cycle, and you can choose to break them down and prioritize reviews based on risk and the overall maturity of your program. Reviews can be of a study-specific nature or broad, in the sense that programmatic processes from different departments are evaluated.

The following are examples of financial areas to consider for review:

- Budgeting and contracts process (initial and modifications)
- Harmonization of research documents (e.g., contract, protocol, and consent)
- Coverage analysis process and billing grid development
- Front-end registration, charge capture, and segregation processes
- Evaluation of services at various entry points, such as inpatient, outpatient, and specialized ancillary services
- Insurance-based reviews, such as Medicare Advantage Plan billing
- Investigational device studies and CMS review process
- Back-end billing, scrubbing, and coding (e.g., professional, technical, and National Clinical Trial number) processes

- Capturing and posting of correct charges to research accounts
- Research account deficits or residual balances
- Sponsor invoicing process
- Cost allocation on federal grants (e.g., allowable costs and time and effort)
- Research and medical record documentation to support billing
- Participant issues (e.g., billing at external institutions and indigent populations, insurance denials, or study-related injury)

Looping Back from Findings to Improvements and Evaluation

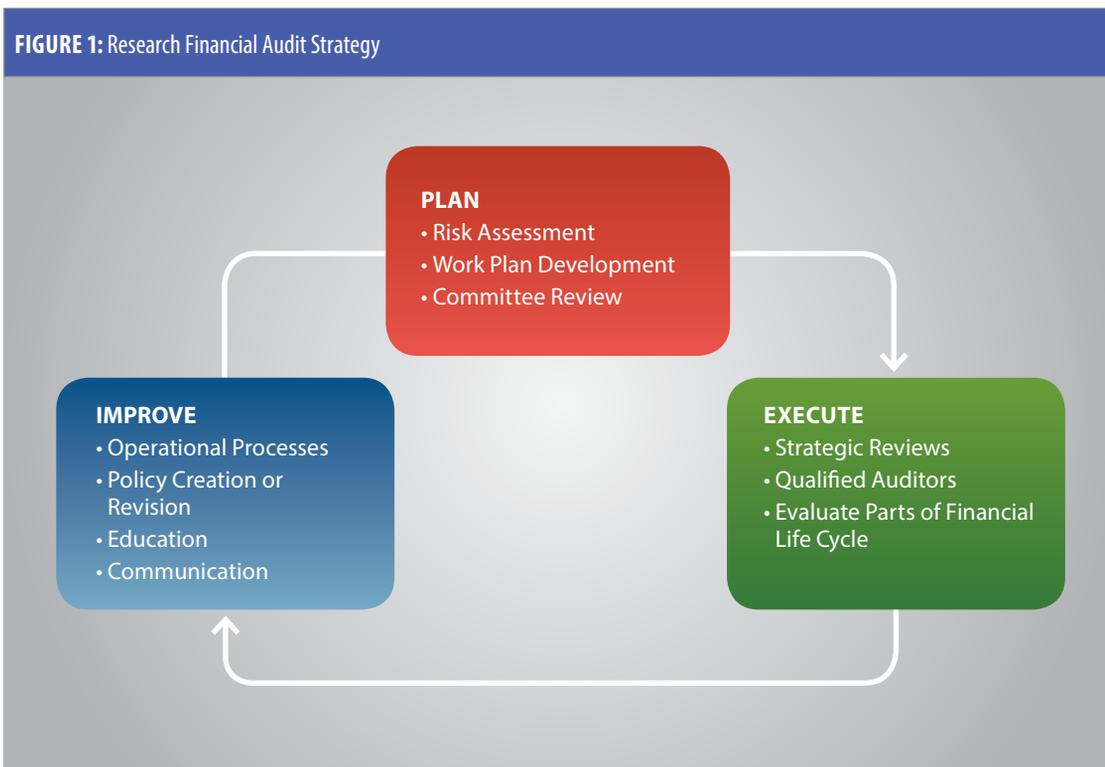
Information gleaned from reviews should be used to inform institutional leadership and the stakeholders of key findings. For example, significant issues can be discussed at executive audit and compliance committees or operational level committees. Identified gap areas can subsequently be used to improve operational processes and inform policy creation or revisions to standardize processes and set expectations.

Financial hotspots should be included in ongoing education, training, and communication to raise awareness and prevent continued issues. A comprehensive training program or event that brings together all the players that touch the process is ideal. Training can be facilitated by key individuals within operational or compliance departments and supplemented by experts in the field, whether it be through consultants or individuals from other institutions.

Lastly, findings and processes developed as a result of the reviews should be used to inform future reviews. For example, if a new policy was created or revised or an operational issue resolved, a follow-up review should be performed at the right time to ensure that processes were fixed and operating smoothly.

The timing of reviews is crucial; reviewing a process that you know is lacking or still undergoing changes too soon may not provide meaningful

FIGURE 1: Research Financial Audit Strategy



information. The key factor is understanding that change is inevitable—departmental staff will turnover, electronic systems will change, institutions may acquire facilities or undergo mergers/acquisitions, and rules and regulations will change. Applying a loop back through well-planned and regular reviews, training, and education will ensure continued effectiveness of your program (see Figure 1).

Standing on Solid Ground

In today's complex and ever-changing business and regulatory environment, it is more important than ever to have solid strategy built into your financial audit program. This involves planning and prioritization, which should be developed and shared with stakeholders. It also involves being grounded and understanding strengths and weaknesses of your program to effectively target reviews and leverage leadership to effect change.

Ensure that your audits cover the full spectrum of risk and priority areas, and that they continually evaluate both internal and external environments to determine the scope of future reviews. Finally, ensure that you have a process to close the loop and continue the cycle through effective policy development, training, and communication.

Taking the time to prioritize and plot out reviews using a workable timeframe (e.g., monthly or quarterly), based on regulatory compliance deadlines or institutional priorities will allow you to strategically perform reviews throughout the year.

Emmelyn Kim, MA, MPH, CCRA, CHRC, (Ekim@NSHS.edu) is a research compliance officer for the North Shore-LIJ Health System, based in the New York Metropolitan area.

Medicare Coverage in Clinical Trials: Are Your Clinical Research Billing Practices Compliant?

PEER REVIEWED | Lisa Murtha, JD, CHC, CHRC | Nicole Visyak, MS, MA, CCRC

[DOI: 10.14524/CR-15-0030]

Clinical research billing remains a source of discontent for most research centers around the United States, due to its inherently complex operational and regulatory challenges. The U.S. federal regulations surrounding clinical research billing are arguably ambiguous and difficult to interpret, presenting significant compliance challenges for sites conducting clinical research.

The Centers for Medicare and Medicaid Services (CMS) published the National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1) (sometimes referred to as the “Clinical Trial Policy”) in 2000, and a second version in 2007, which remains in effect today. NCD (310.1) states that only “routine costs” in “qualifying clinical trials” are billable to the Medicare program.

The formalized process of determining what is considered a “qualifying clinical trial” (QCT) and “routine cost” has been cultivated over the past 10 years, and today is known as a Medicare coverage analysis (MCA) or a coverage analysis. The outcome of an MCA is a coverage memorandum, which outlines whether the study meets Medicare’s qualifying criteria, and a coverage grid/billing grid, which stipulates what items and services performed in a clinical trial can and cannot be billed to Medicare and Medicaid.

Addressing research billing compliance is often not a glamorous subject, but its implications for research centers are tremendous, and cannot be avoided. Rush University Medical Center was the first institution to reach a public settlement with the government in 2005 for research billing irregularities under the False Claims Act, which

subsequently cost Rush more \$1 million dollars in fines and penalties. Rush was obligated to implement a process to analyze research protocols and CMS billing rules to document which items and services are billable and which should be invoiced to a research sponsor. It was this process that led to the inception of the MCA.

MCAs are now not only expected by CMS, but it is widely accepted that they are the safest way to mitigate research compliance billing risks. The coordination and communication of information entailed in the MCA is equally imperative in building a robust compliance program.

Why Perform a Coverage Analysis?

The concept seems relatively simple: Do not bill Medicare for services that do not meet the requirements in NCD (310.1), and do not bill Medicare for items and services that are paid for by the sponsor. However, those familiar with performing an MCA often agree that the process is not always so straightforward, and can be incredibly arduous; yet the billing compliance risk that sites face when this procedure is not implemented can result in a myriad of unfavorable outcomes.

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LEARNING OBJECTIVE

After reading this article, the learner should be able to define what a Medicare coverage analysis (MCA) is and demonstrate an understanding of how an MCA is used to mitigate research billing compliance risks.

DISCLOSURES

Lisa Murtha, JD, CHC, CHRC, and Nicole Visyak, MS, MA, CCRC:

Nothing to disclose

Addressing research billing compliance is often not a glamorous subject, but its implications for research centers are tremendous, and cannot be avoided.

In addition to stiff financial penalties—as was seen in the Rush case—sites and individuals can be charged with civil and criminal penalties under the False Claims Act, with ramifications potentially as severe as termination of all research activity. Several other institutions have entered into public settlements with the government since 2005, but the Rush case was the first to heighten awareness of the confusion surrounding NCD (310.1), and forced institutions to take a more serious look at clinical research billing compliance.

Beyond the purposes of billing compliance, the MCA can provide several benefits to clinical research operations. For example:

- MCAs become a very useful tool in negotiations for payments from sponsors during study start-up processes;
- Revenue recovery can be improved when sites preemptively determine which items/services are not billable to Medicare, by ensuring that the study sponsor is providing payment for those items; and
- The MCA can be a useful tool in the institutional review board (IRB) review process.

In terms of the last item mentioned above, the IRB is charged with approving the final informed consent form, and part of this process includes informing research subjects of any financial burdens they may accrue as part of their participation in the clinical trial. The informed consent form must clearly state which items/services in the clinical trial are subject to payment from the patient and/or his/her insurance.

Research coordinators may also find the MCA to be a helpful resource for scheduling and registration. Furthermore, in the event of an audit or investigation, the presence of an MCA demonstrates a good faith effort by your site to maintain compliance in clinical research billing practices.

Routine Costs in a Qualifying Trial

NCD (310.1) from CMS stipulates that Medicare will cover the routine costs of QCTs, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in these qualified trials. Routine costs, as defined by CMS, include¹:

- Items or services that are typically provided absent a clinical trial (e.g., conventional care);
- Items or services required solely for the provision of the investigational item or service (e.g., administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service in particular, for the diagnosis or treatment of complications.

NCD (310.1) identifies the following items as being excluded from coverage¹:

- The investigational item or service itself, unless otherwise covered outside the clinical trial;
- Items and services provided solely to satisfy data collection and analysis needs, and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and
- Items and services customarily provided by the research sponsors on a free-of-charge basis for any enrollee in the trial.

A study must meet QCT criteria as part of the MCA process and be documented accordingly in a billing grid. Generally, a study is considered a QCT if it meets the following criteria¹:

1. The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (e.g., physicians' service, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).
2. The trial must not be designed exclusively to test toxicity or disease pathophysiology (i.e., it must have therapeutic intent).
3. Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers; however, trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.
4. The clinical trial must be "deemed" to qualify (see below).

NCD (310.1) defines seven desirable characteristics a clinical trial must possess to be considered "deemed." The Agency for Healthcare Research and Quality (AHRQ) is an agency within the U.S. Department of Health and Human Services that has identified the following types of trials to be considered "automatically qualified" to receive Medicare coverage for routine costs¹:

- Trials funded by the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), AHRQ, CMS, Department of Defense (DOD), and Department of Veterans Affairs (VA);
- Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD, and VA;
- Trials conducted under an Investigational New Drug application (IND) reviewed by the U.S. Food and Drug Administration (FDA); and
- Drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1) in the *Code of Federal Regulations* will be deemed automatically qualified until the qualifying criteria are developed and the certification process is in place. At that

In the event of an audit or investigation, the presence of an MCA demonstrates a good faith effort by your site to maintain compliance in clinical research billing practices.

time, the principal investigators of these trials must certify that the trials meet the qualifying criteria in order to maintain Medicare coverage of routine costs. This certification process will only affect the future status of the trial, and will not be used to retroactively change the earlier deemed status.

Local and National Coverage Determinations

In addition to the national coverage determinations detailed in NCD (310.1), coverage limitations may be determined by state governments. These are known as local coverage determinations (LCDs), and must also be considered when billing clinical research items to Medicare. The coverage analysis must reflect any relevant LCD or NCD for each item and service evaluated.

LCDs are determined by each state's Medicare Administrative Contractor, formerly known as the Fiscal Intermediary. These contractors make the majority of coverage determinations, so it is imperative that LCDs are researched, analyzed, and interpreted appropriately to determine if an item is billable to Medicare. This can be a major pitfall in clinical research billing compliance if not done properly.

NCD (310.1) and Medical Devices

Generally, NCD (310.1) does not apply to research billing for medical device studies. Through an interagency agreement, CMS and the FDA have developed a process to categorize all FDA-approved Investigational Device Exemptions (IDEs) for Medicare coverage and payment purposes.

There are two categories for devices for payment purposes:

- **Category A** devices are considered experimental and/or innovative devices, and are not covered by Medicare. However, the regulations do allow for the coverage of routine care services related to Category A devices furnished in conjunction with an FDA-approved clinical trial.
- **Category B** devices are nonexperimental and/or investigational devices, and may be submitted to Medicare for reimbursement in conjunction with routine care services related to the device.

Effective for Category A and B IDE studies approved by the FDA on or after January 1, 2015, study sponsors must submit a request to CMS for

review and approval for Medicare coverage. Further details regarding this process and device coverage can be found in *The Medicare Benefit Policy Manual* (Chapter 14 is devoted to medical devices).²

How to Perform an MCA

As explained further in this section, the six-step process for completing an MCA consists of:

1. Gather essential documents
2. Conduct QCT analysis
3. Document patient care costs
4. Document which patient care costs are promised free of charge
5. Assess routine care items
6. Assign appropriate codes and modifiers as necessary

STEP 1: GATHER ESSENTIAL DOCUMENTS

The essential documents include the study protocol, clinical trial agreement, budget, and informed consent form. If FDA IND/IDE approval letters or Medicare Administrative Contractor approval letters are available, they should also be collected and referenced in the MCA.

The coverage memo should list which documents were used in the process and reference their version numbers/dates. The coverage memo will also contain all of the study identifying information (i.e., protocol name, number, principal investigator/coordinator name and contact info, etc.). The National Clinical Trial number listed at ClinicalTrials.gov should be referenced in the MCA.

STEP 2: CONDUCT QUALIFYING CLINICAL TRIAL ANALYSIS

The study must be reviewed to determine if it meets QCT status using the criteria mentioned above. This information should be clearly documented in the coverage memo.

The first criterion asks if the study is an investigation of a product or service that is covered by Medicare (e.g., drugs and biologics, lab services, etc.). The protocol title should often answer this question.

The second criterion is whether the study has therapeutic intent. This can be answered by referencing the study objectives or the study endpoints. For example, a statement indicating that the study intends to assess "progression-free survival rates" in a chemotherapy trial implies that the study drug or treatment regimen is intended to slow or

halt tumor progression, suggesting anticipated therapeutic intent.

The third criterion asks if the study enrolls patients with a diagnosed disease. This information is often identified in the protocol title or study eligibility criteria.

Finally, the study must be deemed, as described earlier. If the study does not meet one of the automatically “deeming” criteria, it must demonstrate that it meets the seven desirable characteristics. Identifying the study as “deemed” is not the same as meeting the QCT criteria; deemed trials meet one of the four criteria for QCT, but the other three criteria also must be met.

STEP 3: DOCUMENT PATIENT CARE COSTS

Patient care costs include all the items and services that are performed in the trial. This information is most often easily found in the protocol’s Schedule of Activities grid. This information should be replicated in the Coverage Grid of the MCA.

A thorough review of the protocol should be conducted to ensure that required items/procedures were not left out of the Schedule of Activities. An “X” should be placed in the grid for each item required on its corresponding study day.

STEP 4: DOCUMENT PATIENT CARE COSTS PROMISED FREE OF CHARGE

The Clinical Trial Agreement and study budget provided by the sponsor should clearly detail what is provided to research subjects free of charge. For these items, any “X” in the coverage grid should be replaced by an “S” to indicate that the item is being paid for by the study sponsor.

It is helpful to include a “Comments” box for each line item in the coverage grid for making notes of where payment obligations reside (i.e., Clinical Trial Agreement, sponsor budget, etc.).

STEP 5: ASSESS ROUTINE CARE ITEMS

The remaining items must be assessed to determine if they meet CMS’s description of a routine cost in a clinical trial, as listed above. In determining “routine/conventional care,” a rigorous review of relevant medical literature must be performed to obtain objective support for what is typical care for patients absent a clinical trial.

For cancer trials, the National Comprehensive Cancer Network Guidelines are often consulted. The *New England Journal of Medicine*, Medline, and publications from professional societies, such as the American Academy of Cardiology, are also good resources that may be utilized.

Input from the principal investigator may be necessary in determining what is considered conventional care, if it is not always clear from published treatment guidelines. The source used

in making a routine care determination should be referenced in the Comments section of the coverage grid. These items should have any “X” replaced with an “M” to indicate that the item can be billed to Medicare.

All items marked as billable to Medicare need to be evaluated for potential LCDs or NCDs. Details of any relevant LCDs/NCDs must be documented in the Comments section, as well.

STEP 6: ASSIGN APPROPRIATE CODES AND MODIFIERS AS NECESSARY

Finally, for all items marked as billable to Medicare, appropriate medical billing codes should be assigned. Coding professionals should be consulted to ensure that the proper codes are identified for the required protocol items/services. Online coding resources may be utilized, as well.

Effective January 1, 2015, the study’s aforementioned National Clinical Trial number must also be included on a Medicare Claim. The V70.7 Code designated by Medicare should also be placed in the secondary diagnosis position on a Medicare Claim to note that this is a research participant. In some cases, Condition Code 30 (for nonresearch services provided to all patients, including managed care enrollees, enrolled in a QCT) will also be applicable.

What are known as Q0 and Q1 modifiers must be used to differentiate between routine and investigational items and/or services on outpatient claims submitted to CMS. Investigational items or services provided during, or as part of, an approved clinical research study should have a Q0 modifier. Q1 modifiers should be used for a routine item or service provided during, or as part of, an approved clinical research study.

Conclusion: A Solo Mission Impossible?

It is nearly impossible to find one individual qualified in all aspects of completing an MCA, so the best approach is generally to make it a team effort.

For the best results, the process should be centralized to ensure that all clinical trials are being analyzed with the same rigor on an institutional level. Operationalizing the information in the MCA within the revenue cycle is another challenge that most sites face, but the simplest solution starts with effective and ongoing communication.

Without proper controls in place and clear lines of communication identified among all parties involved in the clinical research enterprise, the MCA will not serve its purpose in avoiding billing risks. A commitment from leadership and concerted effort from all research professionals are necessary to implement these steps involved in building and maintaining a successful and compliant clinical research program.

A thorough review of the protocol should be conducted to ensure that required items/procedures were not left out of the Schedule of Activities.

References

1. Center for Medicare and Medicaid Services, National Coverage Determination for Routine Costs in Clinical Trials, July 2007, <https://www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies/index.html?redirect=/clinicaltrialpolicies/>
2. *The Medicare Benefit Policy Manual*, Chapter 14 Medical Devices, November 2014, Centers for Medicare and Medicaid Services, www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c14.pdf

Lisa Murtha, JD, CHC, CHRC, (lisa.murtha@fticonsulting.com) is senior managing director with FTI Consulting in Philadelphia, Pa.

Nicole Visyak, MS, MA, CCRC, (nicole.visyak@fticonsulting.com) is a senior consultant with FTI Consulting in Boston, Mass.

Clinical Trial Billing

OPEN BOOK TEST

This test expires on October 31, 2016

(original release date: 10/1/2015)

Clinical Trial Billing: Solutions to a Complex Problem

1. What has prompted the recent increased attention on clinical trial billing?
 - A. Medicaid regulations
 - B. Audits
 - C. Whistleblowers
 - D. Budget constraints
2. Some institutions have implemented the following office to address billing challenges:
 - A. Centralized clinical trials office
 - B. Research compliance office
 - C. Technology transfer office
 - D. Sponsored projects office
3. Which of the following most accurately describes the purpose of creating a clinical trial budget?
 1. To estimate how much will be left over at the end of the project
 2. To determine the total costs that will be incurred as part of the study
 3. To determine which procedures are to be billed to a research grant and which are to be billed to a patient's account
 4. To compare costs at one site with costs incurred at other sites
 - A. 1 and 3 only
 - B. 1 and 4 only
 - C. 2 and 3 only
 - D. 2 and 4 only
4. What is the best way to prepare a budget?
 - A. Take your best guess
 - B. Take the sponsor's offer and make it work
 - C. Identify all costs that will be incurred during the study
 - D. Double the best estimate
5. Which document is needed to begin the first step of creating the budget?
 - A. Protocol
 - B. Sponsor budget
 - C. CMS regulations
 - D. Institutional code of conduct

6. At what point during budget development should the sponsor's offer be considered?
 - A. As soon as the sponsor's offer is received
 - B. Once the IRB has approved the study
 - C. Once the study is open to enrollment
 - D. Only after an internal budget has been completed
7. What role does the informed consent form have in clinical trial billing?
 - A. It must articulate which procedures are standard of care
 - B. It assures participants that they will never have a financial obligation when involved in the study
 - C. It must state that any bills received while participating in the study should be sent to the study team
 - D. It lets the reader know that the IRB approves all bills received by a participant
8. Which of the following resources can be helpful in tracking critical information related to clinical trial budgeting and billing?
 - A. Institutional compliance office
 - B. IRB submission
 - C. Study protocol
 - D. Clinical trial management system (CTMS)
9. Reviewing a contract's payment terms allows a reader to:
 - A. Prepare for sponsor negotiations
 - B. Submit full information to the IRB
 - C. Understand when and how a sponsor payment will be made
 - D. Determine whether a conflict of interest exists
10. Which of these is a good example of a proactive approach to managing clinical trial billing?
 - A. Distributing a monthly report that allows study teams to review current charges that have not yet been paid
 - B. Implementing a closeout process that requires a review of all past charges billed to a study
 - C. Calling all participants in a study and inquiring whether they received a bill
 - D. Requesting an audit to review past billing

Key Financial Audit Strategies and Considerations: A Research Compliance Officer's Perspective

11. Research financials are often difficult to manage and audit because issues arise that are:
 1. Broad
 2. Different
 3. Interconnected
 4. Costly
 - A. 1, 2, and 3 only
 - B. 1, 2, and 4 only
 - C. 1, 3, and 4 only
 - D. 2, 3, and 4 only
12. What are important skill sets for any auditor?
 - A. Planning, preparation, and communication
 - B. Coding, presentation skills, and planning
 - C. Report writing, communication style, and preparation
 - D. Problem solving, organization, and flexibility
13. What are priority areas of compliance that work plans are typically developed from?
 - A. Recent news articles, legal cases, and internal review findings
 - B. Recent internal audit findings, budget data, and regulatory notices
 - C. Stakeholder interviews, current regulatory environment, and past internal review findings
 - D. Hospital patient satisfaction surveys, review of top risk areas, and new acquisitions
14. What does OIG stand for?
 - A. Office of Inspections Guidance
 - B. Office of the Inspector General
 - C. Organization for International Guidance
 - D. Organization for the Inspector General
15. Which quality is important when employing an effective audit strategy?
 - A. Being diplomatic with all parties involved in the process
 - B. Including enough charts and figures in the work plan
 - C. Knowing how to use the electronic medical record system
 - D. Understanding the environment and knowing limitations

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- 16. What are important types of up front financial processes one can evaluate?**
A. Flagging of research services or subjects
B. Application of billing modifiers
C. Transfer of charges to research fund accounts
D. Time and effort certification
- 17. What is a key financial area to consider for review in research?**
A. Tax return forms for research subjects
B. Coverage analysis for a study
C. Hospital patient billing system security
D. Research review committee turnaround time
- 18. Which group of people should information from reviews be used to inform?**
A. Patients and patient advocates
B. Registrars, billers, and coders only
C. Research investigators and coordinators only
D. Institutional leadership and stakeholders
- 19. What should review findings and processes developed as a result of the reviews be used for?**
A. To review processes that are still undergoing changes
B. To develop manuals for appropriately registering research subjects
C. To prevent turnover of staff who are involved in billing
D. To inform future reviews to ensure past issues were resolved
- 20. What are the three elements of an effective loop back?**
A. Planning, educating, and communication
B. Evaluating, strategizing, and auditing
C. Planning, executing, and improving
D. Risk assessment, committee review, and policy creation
- Medicare Coverage in Clinical Trials: Are Your Clinical Research Billing Practices Compliant?**
- 21. The federal policy that states only “routine costs” in “qualifying clinical trials” are billable to the Medicare program is known as:**
A. NCD 310.1: National Coverage Decision for Clinical Trials
B. NCD 310.1: Local Coverage Decision for Clinical Trials
C. 45 CFR part 46
D. 21 CFR 812
- 22. Which of the following are examples of routine costs as defined by the Centers for Medicare and Medicaid Services?**
1. Items or services required solely for the provision of the investigational item or service (e.g., administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications
2. Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service in particular, for the diagnosis or treatment of complications
3. Items and services customarily provided by the research sponsors free-of-charge for any enrollee in the trial
4. Items or services that are typically provided absent a clinical trial (e.g., conventional care)
A. 1, 2, and 3 only
B. 1, 2, and 4 only
C. 1, 3, and 4 only
D. 2, 3, and 4 only
- 23. Which one of the following criteria must be met for a study to be considered a Qualifying Clinical Trial as stated in the Clinical Trial Policy?**
A. Trial must evaluate drug safety and tolerability
B. Trial must be funded by the NIH
C. Trial must enroll healthy subjects
D. Trial must have therapeutic intent
- 24. Which category of medical devices may be submitted to Medicare for reimbursement?**
A. Category A devices
B. Category B devices
C. Category C devices
D. Category D devices
- 25. Which of the following are essential documents required to perform a Medicare coverage analysis?**
1. Research charge master
2. Study protocol
3. Informed consent form
4. Study budget
A. 1, 2, and 3 only
B. 1, 2, and 4 only
C. 1, 3, and 4 only
D. 2, 3, and 4 only
- 26. Qualifying Clinical Trial analysis requires a review of:**
1. Medicare benefit category
2. Progression-free survival
3. Therapeutic intent
4. Diagnosed disease
A. 1, 2, and 3 only
B. 1, 2, and 4 only
C. 1, 3, and 4 only
D. 2, 3, and 4 only
- 27. Which essential document provided by the sponsor details which items and services are provided to subjects free of charge?**
A. Clinical Trial Agreement
B. Study protocol
C. FDA IND letter
D. Schedule of activities
- 28. Routine care items determined to be billable to Medicare are indicated in the coverage grid with which letter?**
A. B
B. S
C. M
D. X
- 29. Which of the following are required to be affixed to Medicare claims for items/services performed in a clinical trial?**
1. Patient study ID number
2. V70.0 code
3. Condition code 30
4. NCT number
A. 1, 2, and 3 only
B. 1, 2, and 4 only
C. 1, 3, and 4 only
D. 2, 3, and 4 only
- 30. Investigational items or services provided during or as part of an approved clinical research study should have which modifier?**
A. V70.0
B. Condition code 30
C. Q0
D. Q1