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Compliance to Competency: Optimizing Clinical Research Billing in Revenue Cycle Operations

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Abstract: *Clinical research sites must develop a compliant clinical research revenue cycle. This article evaluates examples of billing conundrums and their impact on the research billing and revenue stream. Ways to determine coverage limitations of clinical research services for research protocols are covered along with compliance strategies to ensure partnerships among various stakeholders.*

Introduction

While establishing the operation of the clinical research revenue cycle, there are important clinical and administrative functions in the conduct of clinical trials from pre-award to post-award and billing. Properly performed, these features will help clinical research sites meet regulatory requirements for research billing process.

The Medicare Coverage Analysis (MCA) is the cornerstone of research billing compliance. MCA cannot solve all billing issues; however, it provides directions for the segregation of charges at the back end of the research revenue cycle process.

Organizations succeed if they follow essential steps in research revenue cycle management. Missing even a single piece in the sequence of events could affect the entire operation.

Billing errors may occur within:

- Study budgeting and contracting
- Patient consent and identification
- Charge segregation
- Billing and coding
- Invoicing and collection
- Reconciliation

Several risks may occur when trying to optimize the clinical research revenue cycle operations. The research billing compliance component that involves MCA is really pursuant to the clinical Medicare services determination of what is an allowable expense and what can or cannot be covered in terms of financial reimbursement for the purposes of research. An MCA is required to minimize

potential errors in research billing and to ensure that the items and services provided are efficiently and effectively billed to Medicare and other third-party payors. Performing an MCA also reduces the risk of submitting false claims. The False Claims Act, targeted at fraud, may be triggered by inaccurate billing. Compliance with federal regulations reduces the risk of non-compliance and prevents adverse audit results that could lead to consequences for the organization.

Also, the MCA provides a template for budget development and is helpful in budget negotiations. This reduces the potential for revenue loss to the organization. Errors can be easily made as there are many items and services required within each clinical trial protocol. The MCA also facilitates billing compliance and understanding of the cost section of the informed consent document and the subject liability (21 CFR 50.25/45 CFR 46.116). Clinical research professionals must advocate on the behalf of patients and inform them properly about their obligations for certain costs of participating in a clinical trial as stated in the informed consent. Accurately capturing costs prior to enrolment significantly reduces patient anxiety about participation.

The Medicare standard for coverage of items and services in qualifying clinical trials is reasonable and necessary, however, necessary items and services are not always covered. Care must also be considered reasonable relative to existing medical standards. Medicare coverage is based on three main factors:

1. Federal and state laws
2. Medicare National Coverage Determination
3. Local Coverage Decisions

As per the Medicare Program Integrity Manual,[1] an item or service is considered "reasonable and necessary" if the service is:

1. Safe and effective;
2. Not experimental or investigational; and
3. Appropriate, including the duration and frequency that is considered appropriate for the
4. item or service, in terms of whether it is:
    - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
    - Furnished in a setting appropriate to the patient's medical needs and condition;
    - Ordered and furnished by qualified personnel;
    - One that meets, but does not exceed, the patient's medical need; and
    - At least as beneficial as an existing and available medically appropriate alternative.

TABLE 1
A Culture of Compliance

- Do the right thing from the beginning
- Do not bill for items and services that:
    - Are offered free to any enrollee or promised free in the informed consent
    - Have no therapeutic benefit or intent in the research study
    - Are purely research related

A Culture of Compliance

It is important that we develop a culture of compliance (Table 1). This includes not charging for items or services that are paid for by the sponsor, that are promised free of charge, or that are not designed to offer a therapeutic benefit or intent. Additionally, organizations cannot charge for items or services that are solely for research purposes, such as data collection. It is the right thing to do early in the clinical trial. Organizations should start establishing compliant clinical research revenue cycle operations by examining the current state of their operations. A robust research billing compliance program includes monitoring research billing activities before, during, and after a study is initiated. There are several areas of risk that can arise without a clear research billing process.

It is therefore essential to develop the right sequence of activities for the research billing compliance program. This includes determining if the program is centralized or not, which determines the degree of control that the research billing staff has over the process. If the organization has a strong research billing compliance program that is structured appropriately, the research billing staff will be able to make corrections.

The clinical research revenue cycle and the regulatory environment, which impacts research billing, must be analyzed. Securing sufficient funding contributes to the success of any clinical trial. Research billing staff must take into consideration access to protocol procedures, space, time, and key personnel. Before starting a study, staff should conduct a feasibility analysis to determine what additional costs affect the overall conduct of the clinical trial. Research billing staff should use a checklist to determine the study start-up and to examine the upstream and downstream dynamics of clinical trial operations. The checklist should include recruitment and enrollment for the study, the duration of the study, and the need for additional personnel.

The clinical research revenue cycle has a front-end and a back-end pathway. Communication channels should be established between the research billing team and the study team. Research billing staff should be aware of who is involved and how to engage them, including the appropriate type of communication. Diverse core competencies are required for research billing activities such as drafting an MCA, budget development and negotiations, reviewing of contract language, etc. Organizations should provide the necessary training, education, and support. Some research coordinators have never seen an MCA. Research billing knowledge needs to be translated from the finance side to the research side. Also, it is necessary to understand the relevant job functions. Some individuals are more knowledgeable than others. Organizations need to have processes in place for proper research billing documentation. This includes the list of details for all items and services and if they are study related. Within the MCA, documented rationale, justifications, and therapeutic intent, etc. As with medical records, documentation must be substantiated.

Clinical investigators should document which items and services are a part of the standard of care and a process is necessary for research billing staff to put the items and services in the standard of care or research buckets. It is important to help clinical investigators understand the importance of proper documentation for compliant research billing. All of this sets the stage for a strong MCA supported by knowledge of applicable regulations. The MCA may be done in different ways, depending on the expertise of the research billing staff.

Case Studies

The following case studies show how to identify which items and services are billable and which services are not.

Case study 1 focuses on GI cancer. The protocol calls for a once-in-a-cycle CBC and lipid test during treatment. Whether this is billable depends on several factors and requires evidence as follows.

1. Is this done for the clinical management of the patients, i.e., to monitor, detect, and assess the side effects of the drug
2. If the study drug causes toxicity
3. What does the National Coverage Determination (NCD) tell you about the coverage?

Research billing staff should use the protocol and the informed consent document to determine whether the study drug is known to cause side effects. As per NCD 190.15, indications for CBC related to RBC parameters include signs, symptoms, test results, illness, or disease that can be associated with anemia or other red blood cell disorders. It is known that this study drug causes blood and lipid side effects. Lipid tests are covered by NCD 190.23. Thus, CBC and lipid tests in this protocol are used to prevent and detect adverse effects of study drugs, supported under NCD 310.1.

The coverage limitation is that this is not a covered service for testing patients who are asymptomatic or who do

not have a condition that could be expected to result in abnormality at screening. Based on NCD 310.1, clinically appropriate monitoring of the side effects and preventing complications from the underlying condition and on cancer treatment is reasonable and necessary. Thus, the test meets all the criteria based on the guidelines for clinical management. Based on the protocol, the study drug is causing toxicity such as thrombocytopenia, neutropenia, and lipid side effects.

According to NCD 190.15, in some patients who present with certain symptoms, a single CBC is appropriate. Re-testing may not be indicated unless the results are abnormal, or it is likely that the patient's clinical condition will change. Organizations should negotiate with sponsors for reimbursement for blood panels required by the protocol that are not standard of care. Thus, in this case study, the service is covered and billable to insurance once per cycle for CBC and Lipids throughout the treatment.

Case study 2 involves a non-qualified clinical trial. Externally funded studies with a fixed budget, such as the one funded by the National Cancer Institute, are sometimes non-qualified clinical trials. Under NCD 310.1, organizations cannot bill Medicare and other third-party payors for items and services since this is a non-qualified clinical trial. All the items and services would need to be paid for by the sponsor or the organization.

TABLE 2
Evaluating and Assessing the Budget, Protocol, and Cost

- Budget type:
  - Services:
    - Adult vs. pediatrics
  - Research:
    - Treatment vs. prevention
  - Setting:
    - Inpatient vs. outpatient
  - Duration
- Protocol complexity:
  - Multiple arms
  - Enrollment challenges and the specific population
  - Type of requirements
  - Intensive training
- Cost assessment:
  - Research cost
  - CPT code
  - Professional and technical fees
  - Charge master
  - Hidden costs and fair market value

The protocol requires laboratory tests at the baseline visit. Unless the test or bloodwork is required for that disease group and is a part of routine care which is done outside the scope of clinical trial, it is not otherwise billable since this is a non-qualified clinical trial. Also, the protocol includes an intravenous study drug. According to NCD 310.1, routine costs include items and services required solely for the provision of the investigational item or service (e.g., IV administration of an investigational drug) and is covered in a qualified clinical trial. However, IV administration of the study drug in this case study is not billable as it is not a qualified clinical trial.

Evaluate, Assess, Control, and Monitor

Next, the budget, protocol, and cost must be evaluated and assessed (Table 2). This starts with evaluating the type of budget, including whether the services are for adults or children and whether the research is for the treatment or prevention of a disease or condition. The setting, such as inpatient or outpatient, is another consideration. Hospitalization might be required. It is necessary to know precisely the timepoints that must be captured in the MCA and the budget.

For the duration of the study, it is important to know treatment cycles and follow-up visits.

The length of the follow-up visits and whether they will be done in person or remotely must be determined. This information will facilitate the accurate budgeting of the scheduled assessments. Also, it is necessary to be aware of the planned completed visits in the schedule grid while preparing the study budget.
Depending on the intricacies of the protocol, there can be challenges based on multiple arms and subject recruitment. These elements must be considered during the construction of the MCA and budget. If there are enrollment challenges in terms of eligibility criteria, an appropriate feasibility analysis of the study protocol is required in terms of clinical trial complexities, enrollment goals, and required workload, for example, for a long blood draw.
It is necessary to have a thorough understanding of the study costs. This includes.

- Research costs (direct, indirect, and passthrough)
- CPT code
- Professional and technical fees

Also, the administrative burden of doing business and negotiating with the sponsor must be considered. To do this, research billing staff should use the charge master (a database containing the description of billable items and services and the codes) used for billing, as well as the fee schedule. It is necessary to identify who owns the budget and who will pay for which items and procedures. Hidden costs and research-related versus standard of care items and services must also be identified.

The fair market value (FMV) of items and services is the guiding principle in study budgets. The budget should be presented to the sponsor in a way such that the organization not only receives coverage for the costs but also for the value of the work being done. Budget tools should be used wisely.

Billing conundrums that occur during the billing process can be improved. The clinical research revenue cycle begins with entering the patient into the system. Patients are usually identified as research subjects by flagging in the billing system or electronic medical record (EMR). If the patient is not flagged or linked, then it is challenging to identify the study subjects, which creates research billing risk for the organization, as staff will not know which charges to review, segregate and validate for future billing.

If research billing staff work for a multi-state healthcare delivery system covering patients in a variety of geographic areas, it is necessary to discuss research billing with the commercial contracting team and to understand commercial payor requirements as part of the coding guidelines and to identify the complexities of working with commercial payors in different states.

Sometimes tests and orders do not contain the necessary information for research billing staff to bill correctly. For example, the coverage analysis may say that everything on Visit 3/Day 15 is research; however, the orders are not in the schedule of assessments or may use different language that the research billing staff do not recognize.

In research, subjects sometimes do not follow the visit schedule. For example, adverse events and toxicities can interfere with the scheduled visits. When this happens, it is necessary to document this clearly in the EMR. During the follow-up stage, the EMR must note whether visits are in person or remote. If visits are not being tracked, then bills can go out of the door quickly without a research billing review.

Errors occur when protocol amended tests and procedures in study budgets are not completely processed through to the harmonization phase. Amendments occur, there may be changes to items and services, tests, and procedures, adding new treatment arms etc., so all documents should be updated to reflect such changes.

Research billing personnel should identify why the costs requested for tests and procedures are relevant to the protocol. Negotiations have been difficult when organizations have requested things that are not reflected in the current amendment such as fresh tissue biopsies when the protocol calls for archival tissue biopsies, or additional fees for an informed consent request beyond the main informed consent document.

Screening items and procedures can also lead to billing conundrums. For example, laboratory tests performed for eligibility purposes or testing of patients who are asymptomatic or who do not have a condition have limitations based on NCDs and are generally not a covered service. Billing errors can be made, and claims can be reviewed and missed due to unscheduled visits that are not recorded as study visits in the medical record.

Compliance requires control and monitoring, which covers risk assessment and risk mitigation (Table 3). Risk assessment covers both inherent and residual risk. Risk should be identified and measured. Controls would need to be established for high-level risks, bringing value to the compliance function.

Coordination of study information is another challenge in research billing. For all items and services described in the schedule of events, research billing staff must determine which items are investigational and are being paid for by the sponsor. Coordination with the institutional review board is also necessary for the billing and payment process during the clinical trial.

Another challenge to research billing is claims with errors. Claims must be certified as accurate for the items and services being provided and meet all the necessary conditions for payment. Patient identification and insurance should be accurate and complete to avoid delays in processing service eligibility or denial of claims.

TABLE 3
Controlling and Monitoring

- Risk assessment:
  - Claims with errors
  - Research billing coordination
  - Revenue lost
  - Work plan
- Risk mitigation:
  - Engagement with the legal and contract teams
  - Invoices for milestones, study start-up, and study close-out
  - Education and training
  - Staffing
  - Structure and policy

A research billing coordination system should be in place for tracking and reporting charge capture for research billing. Despite every effort to comply with the rules and regulations, claims could still be delayed or denied. When this occurs, organizations may lose revenue and providers may lose privileges in the hospital.

Coordinating along with self-monitoring and internal assessment are essential to avoiding these external risks. Everyone must understand the MCA and how to use it correctly. Before completing the MCA, research billing staff should understand the inconsistencies in the coverage analysis and seek feedback from the study team.

Unpaid claims have an impact on the research revenue cycle. Charges which are otherwise recoverable can be written off. Research billing staff must ensure that the claims they process for investigational devices have been approved by the Centers for Medicare & Medicaid Services (CMS) and the local Medicare contractor. A documented work plan should be available to research billing staff who are doing charge capture.

In terms of risk mitigation, it is important to cooperate with the legal and contract teams on research billing language. Failure to submit invoices for the research services provided is often caused by a lack of cooperation. Another common issue is a sponsors' payment held up until the site meets the milestones of the protocol related items (10% or 15% hold up, etc., or contingent upon the completion of a study) or there are invoices for procedures that are not associated with the study. Appropriate reconciliation of invoices should be made for various items, services, and milestones to maximize the research revenue cycle.

Subject completion or termination should also be coordinated. Staff should inform the sponsor when a subject goes off the study. If a subject is lost to follow up, the billing office must be informed. Both the clinical research site and the sponsor are responsible for coordinating the protocol tasks and expectations.

Research teams and financial personnel should speak the same language. For example, the study manager should know how finance defines accruals (record of revenue or expenses that have been earned) and their responsibilities in supporting tracking of funds.

Education and training on research billing and compliance is necessary. Develop training specific to billing and research compliance at all levels, from billers, to coders, to physicians. Understanding team members and having a competency-based approach is important. It takes a village to do research billing correctly.

The research billing structure determines the process, which affects the outcomes. Organizations must have strong, clear, and effective policies.

Claims must be accurate and properly coded. Documentation related to the medical necessity for items and services must be adequate. The mandatory National Clinical Trial (NCT) number should appear on the claims and Q0/Q1 modifiers may be included.

Billing Compliance Change Model

Table 4 highlights a billing compliance change model that can help organizations develop a robust research billing compliance program. The model is based on creating a climate of change. The team must be engaged in implementing and sustaining the momentum of change.

There are many considerations in using the research billing compliance change model. The creation of a centralized research billing unit and office facilitates consistency, streamlines, and standardizes various activities related to research billing including support for MCA, budget development, negotiations, invoicing, contracting, and claims review. The office works with various clinical service areas to adapt plans to meet requirements for compliance.

A process for catching errors is necessary, along with the fortitude to stick with the program and to have a continual improvement process. It is essential to develop a process map/ flowchart to analyze and improve the process and ensure compliance. Each step of research billing should be part of the workflow. Tools for research billing compliance include a sound research compliance program, robust patient tracking and billing systems, a clinical trial management system (CTMS) and electronic medical records (EMRs).

Congruence (alignment) or document concordance means that the budget, MCA, informed consent document, and clinical trial agreement are all in sync. That really facilitates review and process improvement. The Medicare contractor expects clinical research sites to develop an MCA and to do their best to only bill what should be billed. This should be a part of the audit work plan.

TABLE 4
Billing Compliance Change Model

- Centralized research billing process
- Process map
- Billing compliance resources
- Congruence (alignment)
- Documentation
- Policies, standard operating procedures, and the Clinical Trial Policy
- Competencies
- Bill hold and auditing
- Reconciliation and monitoring
- Denial management

Proper documentation is necessary for gaining buy-in from stakeholders such as clinical investigators, as well as for compliance. Feedback from investigators is required to ensure research compliance and compliant billing activities.

Policies and procedures, including standard operating procedures, must be effective with a centralized approach to research billing. The compliance program should comply with federal guidance. Under the Clinical Trial Policy, Medicare may cover the routine costs of certain items and services for qualifying clinical trials (provided it meets the definition of routine cost) if the sponsor does not pay for them and they are not promised as free in the informed consent document.

A member of the research revenue cycle team should be aware of the regulations and rules for Investigational Device Exemptions and for device trials, to prevent generating false claims.

The competencies required for research billing compliance should be identified. It is generally easier to expand on existing competencies than to start from scratch. Technical skills should be identified that are specific to the knowledge and skills required for a specific job function. Behavioral competencies should also be identified. It is necessary to understand the skills of people who work in the revenue cycle because each person has specific tasks to accomplish. Documenting roles and responsibilities is a key component of compliance.

Institutions should have internal processes for auditing, reconciling, and monitoring. It is also important to understand the steps in claim adjudication and who manages claims, and the causes of denials. A bill hold mechanism must be in place to segregate charges and MCA must be the part of that culture.

Questions to ask when reviewing claims include:

- Were the items and services billed to a third party?
- Was a clinical research flag attached to the patient encounter in the EMR?
- Was there an appropriate Q0/Q1 modifier on the research claim if applicable?
- Was the diagnosis code included on the claim?
- Was the correct (NCT) identifier number reported on the claim?
- Does the service rendered match what is in the MCA?
- Who reviewed the research claims?
- How was the research billing review completed?

Keep track of and recover accounts receivable in a timely manner (amount due, time of payment, receipt of payment, etc.). Research billing staff should generate bills promptly and collect payments.
Once the clinical trial is open to enrollment, billing should be monitored periodically. Monthly reviews of reports and running queries to perform these checks and balances is critical. The validity of tests and procedures entered as linked encounters in the EMR and subject as well as financial tracking in the CTMS should be validated. These two systems should mirror each other. When the site or study team think that billing is not happening as anticipated due to the conduct of the trial, they can go back to the sponsor to request and initiate an amendment. Specific and unique skillsets are required for auditing and monitoring research billing in the research revenue cycle.

Denial and appeal management is an area that can easily be missed. It is important to learn from claims denials at the back end of the research revenue cycle to improve and put in place research billing processes to optimize reimbursements.
The benefit verification process should be part of financial clearance.

Organizations should exercise vigilance and take measures to prevent non-compliance in research billing. These steps include ensuring that all the patient identification information is correct during pre-registration and registration, and that claims have the required codes and modifiers and there are no outstanding or invalid claims data. Workflow must be optimized, and accurate research documentation must be in the EMR. The criteria for medical necessity must be documented. Peer review should be done, and staff should be engaged in a peer review process. Verify that all clinical documentation submitted is assessed, compared, ordered, and performed against the authorization.

A Systemic Approach to Competencies

Organizations should adopt a systemic approach to competencies (Table 5). The right people must make the right decisions at the right time. Key stakeholders need to be engaged and it is important to establish a chain of communication between key stakeholders that facilitates compliance. It is critical to identify key stakeholders and list support from the "front end" and the "back end" staff that facilitate the process of achieving total compliance. Communication must include which procedures were and were not completed as planned.

The key players, contacts, and processes should be determined from the beginning. On the front end, the MCA process synchronizes the study information and documents and the billing determination for the study. On the back end, processes should use the tools developed from the front end to direct the actual charges to the appropriate payer.

Communication workflow is necessary between Hb and Pb (Hospital billing and Professional billing) billing teams regarding scheduling research-related items and services. The research billing team should communicate with study staff on a regular basis. Soliciting feedback from the staff who are doing the charge process is recommended.

TABLE 5
A Systemic Approach to Competencies

- Key stakeholders
- Flow of patients enrolled and information to the key stakeholders
- Mapping standard of care and research-related events
- Coding, charges, and claims communication
- Informed consent execution
- Tracking communication with subjects

The organization must determine who will triage the standard of care and research related events according to the MCA and what fees will be charged to third party payers. If changes are required during claims review, what are the changes? Changes should be reviewed to determine if there is a need to update the EMR or any other process used to avoid similar changes going forward. The system should be designed to allow time to obtain authorization for services to be performed.

Patient satisfaction plays a significant role in the hospital scores. Efficiency and ease of patient engagement are critical. Miscommunication or poor communication should not leave a gap in revenue cycle processes. Team members' time and effort in identifying, updating, and correcting billing errors is valuable.

Conclusion

An effective research billing compliance program reduces or eliminates legal and regulatory risks for health care providers and organizations in a complex and constantly changing health care environment. Engagement of stakeholders in an empowered, multi-disciplinary team is a major asset in a research billing compliance program. The team should include the research business office, service lines, departments, research team, billing offices, investigational pharmacy, patient financial service (PFS), health information management (HIM), funding sources, physician practices, and patients. As good as your processes might be, we count on the right people to do the right things and to have a clear organizational direction and responsibility about research billing in revenue cycle operations.

References

1 CMS Publication 100-08, Medicare Program Integrity Manual, Chapter 13 – Local Coverage Determinations, §13.5.4.