Building a Successful Clinical Research Billing Initiative

By AEGIS and forte
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Clinical research billing (CRB) continues to present challenges to health care providers. Getting it “right” requires coordination of study information among people who may never have worked with each other before. The key to compliant clinical research billing is exchange of information. The more the parts of a research enterprise can communicate with each, the better chance the organization has to safeguard the accuracy of the claims.

One of the first questions an organization needs to tackle in its CRB initiative is to understand what clinical research billing entails and who it involves.

**What is CRB?**

CRB compliance involves any charge for a service that could be directed to a third-party payor. Even small services, such as blood draws, could be charged erroneously. Many parts of a research enterprise may not understand how charges are captured. Understanding the charge capture system is an important first step.

CRB also involves correctly charging the study funds or sponsor. The same charges that could go to a third-party payor could also be erroneously charged to the study.

**Who is involved in CRB?**

The short answer is: just about everyone. Charges are captured and directed typically by the provider sites — the hospital and the physician practice. The study may not originate with the hospital or the physician practice, but with a School of Medicine or a research institute. In those instances, the school or the institute must realize that it is the hospital and physician practice that carries the CRB risk. The basic study information for CRB must be transmitted in one way or another to the hospital and physician practices.
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CHAPTER 1: COMPLIANCE RISKS OVERVIEW

CRB errors usually occur because communication has broken down. Some part of the research enterprise has not communicated to another part.

For example, if a hospital billing office does not know that a patient is enrolled as a subject in a research study, then there would be no reason for the billing office to do anything differently with the charges for that patient. Likewise, if a School has taken money for a protocol required service and does not communicate that to the hospital or physician practice, then the hospital billing office would likely bill patients or the patient’s insurer for that service and the physician practice would also likely bill for the physician’s professional fees.

CRB compliance hinges on information getting from study documents to the right people managing charges for clinical services.

When CRB communication breaks down, there are five general risks ...
Risk #1: Billing for Services That Are Paid for by the Sponsors

When a research site takes money for a clinical service from the sponsor, that service cannot be billed to the patient or the patient's insurer. If it is billed, then it could be viewed as a “double billing” situation. Double billing occurs when the same service is paid for by two different sources.

In order to manage this risk, the research site must understand what the sponsor is paying for. The budget should be clear as to what is or is not covered by the sponsor’s payment. Likewise, if the study is funded by a grant, there should be a document or an internal budget which clearly identifies what the grant is or is not paying for.

Sites should also realize that the legal portions of the clinical trial agreement can be just as important as the budget exhibit. Usually the “budget” is an exhibit to the clinical trial agreement, which makes the budget and the clinical trial agreement all one legal document. What might look like two documents is in reality one, and must be read and interpreted as one document.

Even if the budget information is clear, that information must be communicated to the billing process at the hospital and physician practice.
Every research informed consent form must identify any “added costs” for the subject if he or she enrolls in the study. Sometimes this part of the informed consent form lists items and services that will not be charged to the patient or the patient’s insurer.

All parts of the research enterprise must live up to the promises in the financial discussion of the informed consent form. If the informed consent states that no services required by the study will be charged to the patient or the patient’s insurance, then that is a promise which must be kept.

It is important to keep in mind that the informed consent form is interpreted from the perspective of the subject and not from the perspective of the investigator or study team.
Risk #3:
Billing for services that are for research purposes only

Most provider billing services are not yet able to tell whether a service is for research purposes only or is clinically necessary. Sometimes medical necessity software will be able to flag a service as possibly not medically necessary, but generally if someone does not tell the billing system that a service is for research purposes, the billing system will not know.

When a billing system does not know that a service is for research purposes, then it likely will bill the patient or the patient’s insurance company in the normal way it bills.
Risk #4:

**Billing for non-covered services during a non-qualifying clinical trial**

The concept of a “qualifying clinical trial” is a Medicare-specific term, but the idea is increasingly becoming used in private health insurance. The Medicare program will pay for items and services that are considered “routine costs” during a “qualifying clinical trial.” If the study is not a qualifying clinical trial, then reimbursement is limited and some Medicare contractors are reluctant to pay for anything during a non-qualifying clinical trial. Providers should know their Medicare Contractor’s views.

Research sites need to determine whether their studies are qualifying clinical trials in order to assess which services are billable to the Medicare program. While Medicare Contractors differ around the country in how they view non-qualifying clinical trials, at a minimum, what cannot be billed is the administration of the investigational article. For example, in a non-qualifying clinical trial involving a study drug, the administration or infusion of the drug is not allowed to be billed.
Risk #5: Billing Medicare Advantage Plans for Services That Should Be Paid For by the Medicare Administrative Contractor

There are special rules for CRB when a research subject is enrolled in a Medicare Advantage Plan (Medicare Part C). For non-device studies (e.g., drug studies), any service which meets the definition of a “routine cost” must be billed to the provider’s Medicare Administrative Contractor instead of to the Medicare Advantage Plan. Any service which does not relate to the research study must be billed to the Medicare Advantage Plan, even if it occurs on the same day as a “routine cost” of the research study.
CHAPTER 2: DEBUNKING COMMON BILLING COMPLIANCE MYTHS

There are several myths about CRB that have floated around for several years. We will attempt to debunk these.
Myth #1:

The Medicare program’s CRB rule simply divides services between “standard of care” and “research.”

Fact:

Many people think that Medicare has a binary approach for all research studies — merely dividing the services between standard of care and research. In reality, the term “standard of care” is not used in the Medicare billing rules.

Under the Medicare Clinical Trial Policy (National Coverage Determination 310.1), Medicare covers items and services which meet the definition of a “routine cost” during a “qualifying clinical trial.” For most device studies, the qualifying status involves an approval process by the local Medicare Contractor.

The Medicare term “routine costs” comes close to being what the research community means by “standard of care,” but it’s not a one-for-one interchangeable concept.

- Ryan Meade, JD, Partner, Meade, Roach & Annulis, LLP; Managing Director, Aegis Compliance & Ethics Center, LLP
Myth #2: All services not reimbursed by the cooperative group are billable.

Fact: While many cancer cooperative group studies are designed so everything is billable, not all of them are. Just because a service is not reimbursed by a cooperative group, does not necessarily mean that the service is billable to insurance.

For CRB purposes, cooperative group studies must be assessed just like any other research study.

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- Julie Colasacco, Managing Director, Aegis Compliance & Ethics Center, LLP
**Myth #3:**

**If NIH does not fund a service through a grant, then that means it is billable to insurance.**

**FACT:**

If a research study is sponsored by the NIH or is funded with funds from a federal agency, it does not follow that whatever the grant does not pay for is billable to the subject’s insurance. There could be many reasons why the agency is not funding a certain service, but non-funding should not be taken as a signal that the service is billable. All government-funded studies need to be assessed for CRB proposes just like any other research study.

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Building an accurate and consistent compliance process is a complex task. It revolves around ensuring the entire team is effectively communicating across an institution and that the rules are properly interpreted and applied. Here are some steps that an institution can take to begin the process.
A TEAM EFFORT

One of the biggest challenges in CRB is coordination and communication. There are many people who need to exchange information. Key information may be in different parts of the research enterprise.

“It takes a team” to get CRB right. Here are just some of the people and groups to consider involving in the process:

- Principal Investigator
- Clinical Research Coordinator
- IRB process
- Budget negotiators
- Clinical Trial Agreement negotiators
- Grant administration
- Information Technology
- Health Information Management
- Registration/Scheduling
- Medical center billing and coding
- Physician professional fee billing and coding
- Study fund managers
- Managed care contract negotiators
Key questions to achieve compliance

There are many operational questions which must be asked in order to plot out a confident information flow for CRB. The following are some of the most important.

Who are the patients enrolled in a research study?
The billing process must be able to identify the research patients. If the billing offices do not know who the research subjects are, billing will usually be done in the normal fashion.

Which services are part of the protocol?
Along with needing to direct certain charges to the study, even those services which can be billed to the Medicare program require extra work. There are special codes which must be used on Medicare claims that involve “routine costs.”

Is the hospital billing office and the physician billing office treating the study in the same way?
Most times, if a service cannot be billed to insurance, then both the hospital technical charges and the physician professional fees must be directed to the study. If the hospital and the physician practice are interpreting the study information differently, then one of the provider entities could be getting the billing wrong.
For CRB for Medicare program beneficiaries, there are two important concepts which must be understood: “qualifying clinical trial” and “routine costs.”

Medicare covers services that are “routine costs” during “qualifying clinical trials” as long as the services are not paid for by the sponsor or promised free in the informed consent form, and it is a service that Medicare generally pays for outside of a study.
Chapter 3: Building a Successful Compliance Process

Qualifying Clinical Trial

The concept of a qualifying clinical trial is a difficult one. The rules set out in NCD 310.1 can be difficult to follow. And there are different rules for device studies and non-device studies.

Generally, a qualifying clinical trial is a study that meets the following criteria:

1. Is one of the four types of “deemed” studies
2. Studies an item or service that is generally covered by Medicare under a “benefit category”
3. Enrolls subjects with diagnosed disease
4. Is designed for therapeutic purposes

For Category A and Category B, and certain other device studies, the qualification process is performed by the provider’s Medicare Administrative Contractor. Every Medicare Administrative Contractor has unique rules and processes for approving a device study and their websites should be consulted.

(For specific rules on qualifying clinical trials, see Medicare NCD 310.1)
Routine costs are the items and services which are covered by Medicare during a qualifying clinical trial. The Medicare program has a fairly complete definition for routine costs in NCD 310.1 and it is worth quoting it in full:

- “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
- “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”
Managing CRB requires that all studies be analyzed to determine if they are qualifying clinical trials, or whether they are the type of device study that must be approved by the Medicare Administrative Contractor. Every study will have a unique answer. The answers for the questions for the qualifying clinical trial analysis should be documented.

Once a study is established as a qualifying clinical trial, then every service required by the protocol must be analyzed against the Medicare definition of “routine costs.” This will require working through the schedule of events as well as any other services required by the study that are not listed in the schedule of events. A study with a thorough schedule of events will make this process easier.

When a service required by the study meets the definition of a routine cost (and is not paid for by the sponsor or promised free in the informed consent), the research site or provider should document its reasoning and why the service meets the definitions of a routine cost.

Deciding whether something meets the definition of a routine cost can be a difficult process. When a provider is uncertain, then it is important that the decision be a good faith application of the rules (not an application that is self-serving) and that the application or interpretation be applied consistently.
Clearly, there is quite a bit of information which must be coordinated and many decisions must be documented. The results of those decisions should be shared between the research site that originates the study and the hospital and physician billing offices. The best way to do this is with a Coverage Analysis.

A Coverage Analysis is a tool to coordinate the study information for CRB and document the reasoning. It puts everyone “on the same page” so that the hospital and physician practice billing offices know which items and services can be billed to the subject’s insurance and which should be billed to the study. It also allows the providers to do this consistently within a study so that subjects are not treated differently.

A Coverage Analysis has many benefits aside from the very important one of making sure CRB occurs accurately and consistently for all subjects. Some of the benefits of a Coverage Analysis include:

- Assists in the budgeting process at the start of a study by helping the budgeters know what is or is not billable
- Allows the billing offices to make accurate and consistent decisions about where to direct charges during the study
- Provides a tool for the Compliance Officer to perform auditing and monitoring of CRB compliance
- Offers assistance later in the study to assess whether budgeting was accurate, and if not, then to learn more about the billing process for better future budgets.

A Coverage Analysis looks a lot like the schedule of events in the protocol and is built from the study calendar. Using tools that build a Coverage Analysis from a study calendar saves considerable time.
How to begin a CRB initiative is a challenge. The steps will be unique for each research enterprise, but here are some suggestions of what to think about:

1. **Understand your research enterprise.**
   What are the legal entities or divisions impacted by CRB? For example, the School, the hospital, the physician practices, etc.

2. **Who are the stakeholders in the CRB process?**
   Examine which departments and people within a department must hand off information in order to get CRB correct. Make sure that the analysis includes both the hospital charge capture and billing process, as well as the physician practice billing process.

3. **Where are the study documents?**
   If the organization is not using a CTMS yet, then make sure an accounting is done of where the principal documents are being housed. Among the most important documents for CRB are the protocol, the clinical trial agreement and budget (or any other funding document), the IRB-approved informed consent, and miscellaneous FDA documents and information depending upon whether it is a device or drug study.

4. **Are research teams using study calendars?**
   A study calendar is important for managing CRB claims. When a billing office has claims associated with a research subject, the staff will not know what services the claims are associated with in the Coverage Analysis unless there is access to a study calendar identifying which dates the protocol services occurred on.

5. **Who will be responsible for developing a Coverage Analysis?**
   This is different for every organization and will depend on operational structure and budget considerations. Some organizations have established specific offices to develop Coverage Analyses and others have identified teams with representatives from many offices. Still others have assigned Coverage Analysis development to research study teams but with another office doing quality reviews. The important task is to make sure a process for Coverage Analysis development is plotted out and there is an accountable office overseeing the process.
There are technology solutions, commonly referred to as clinical trial management systems (CTMS) or enterprise research systems, that are available to support clinical research billing processes.

Some systems offer basic functionality for tracking charge determinations, which supports accuracy of billing between insurance and the sponsor. Other systems may include more comprehensive functionality for easing the CRB process, providing a centralized tool around which an organization’s processes can be developed. Functionality in these systems may include:

- Billing designations, such as routine costs and sponsor reimbursement, which can be defined during protocol creation.
- A centralized repository of documentation of billing decisions.
- The ability to store and report information for determining if a protocol meets requirements for insurance reimbursements.
- A billing grid that mirrors the protocol calendar and documents billing decisions, including assessment of “routine cost.” It may also provide mechanisms to document why a provider believes the study is “qualifying.”
- Multiple versions of the Coverage Analysis for a protocol that allows for changes as regulations and protocols evolve.

Your institution may not need all the functionality offered in different systems, so when selecting a CTMS, it’s important to choose one that fits the needs and goals of your institution.

To learn more about the systems offered by Forte Research Systems, please visit http://forteresearch.com/clinical-trial-management-systems.
There are several commonly asked questions about CRB. We answer the top three.
Legacy studies are studies which were opened prior to beginning a particular clinical research operations initiative. For CRB compliance there is no difference between a “new” study and a “legacy” study — both must have accurate claims.

Institutions should develop a strategy for legacy studies. There is a considerable risk if an organization only develops Coverage Analyses for “new studies.”

Some organizations have linked the “catch-up” phase to continuing review. That is, requiring a Coverage Analysis to be completed at time of continuing review (usually annually). This allows for a one-year “catch-up” process. Organizations also often give priority status to some legacy studies which have high enrollment or studies with no enrollees become priority when they have their first subject enroll.

**Question #1:**

**What do we do about “legacy studies”?**
Coverage Analysis skills are still new for many research staff and organizations. Most organizations have needed to recruit people inside their organization and then train them to do Coverage Analyses. A team approach usually works the best.

We have found that this tends to be the most successful skill sets, but there could be many more:

- Familiarity with research terms
- Ability to read a protocol
- Knowledge of clinical services
- Conversant with contract terms and interpretation
- Objectivity: Ability to read an Informed Consent form from the perspective of the subject
- Basic understanding of billing rules
- Comfortable with exploring unknowns and willingness to learn
The CRB rules are set out in many different places. The two most important rules are (1) the Medicare Clinical Trial Policy (NCD 310.1), and (2) the local rules for the provider’s Medicare Administrative Contractor.

The following is a list of some (but not all) of the CRB rules and resources:

- Medicare Clinical Trial Policy (National Coverage Determination 310.1)
- Medicare Claims Processing Manual, Ch. 32
- 42 CFR 405.201-405.215, 411.15, and 411.406 (for device trials)
- CMS MLN Matters SE0822 (Jan 7, 2009)
- CMS National Coverage Analysis Memos from 2007 relating to examination of CTP and proposed changes
- State legislative efforts
Conclusion

Clinical research billing is one of the most challenging compliance initiatives an organization can undertake. It takes patience, time, and a willingness to coordinate with many different people.

While this eBook cannot cover all the regulatory and operational detail needed for a CRB initiative, we hope that it has provided an introduction to the importance of CRB and given you some starting points to begin to develop an effective CRB initiative.
About Aegis Compliance & Ethics Center, LLP

Aegis provides expert compliance and ethics advice and support that keeps pace with today’s increasing regulatory scrutiny. Our team of professionals offers clients a customized, hands-on experience, drawing from decades of leadership across diverse organizations.

We understand tight budgets in an era of declining reimbursement. We approach all of our engagements with an eye towards improving operational efficiencies and, when possible, “teaching” the client how to handle their issues internally.

Our core services are Clinical Research Compliance, Corporate Compliance Effectiveness, HIPAA Privacy & Security, Medicare/Medicaid Reimbursement Issues, and Corporate Integrity Assistance. Many of these issues are interrelated and we keep an eye on the ever-changing global regulatory landscape for you.

The world of health care regulation and compliance is constantly changing. We continue to identify and develop new service offerings that complement our initial core services based upon our experiences and anticipated areas of increased government scrutiny.

Aegis is proud to offer innovative products for the health care industry in our core service areas.
About Forte Research Systems, Inc.

We have been providing systems that support excellence in clinical research operations for over a decade. In this time, it has been our good fortune to work collaboratively with our customers as we developed new products and enhanced product functionality to meet the challenges that they face every day. We strive to be the recognized thought leader and preferred provider of innovative solutions that help improve operational efficiency, patient safety, regulatory compliance, and financial viability.

A comprehensive clinical research management system, OnCore® Enterprise Research supports centralized operations at academic medical centers, cancer centers, and health care systems.

A cloud-based clinical trial management system, Allegro® CTMS efficiently manages the operational data of clinical trials for dedicated research sites, physician practices, and community hospitals.
References

This eBook was based off the webinar, “Coverage Analysis: Best Practices for Clinical Research Billing Compliance,” which was presented by Ryan Meade, JD, and Julie Colasacco of Aegis Compliance & Ethics Center, LLP.