Clinical Research: What it Takes for Physician Practice Billing Compliance

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Executive Summary

Physicians conducting clinical research increase their risk of billing noncompliance because of complex and evolving research-specific regulations. Mitigating that risk requires interpretation of regulations and the implementation of a billing compliance assurance process that ensures:

1. Coverage analysis prior to contract and consent-form finalization to determine what may and may not be billed as conventional care
2. Routing of non-covered research-related services to the research sponsor to avoid billing errors
3. Modification of conventional care charges before billing to Medicare, to comply with federal billing requirements. Conducting a self-audit is the first step in developing that process and remains a good check for process improvement.

Clinical research is crucial to the future of healthcare, but it increases risk for physician investigators, especially Medicare providers. Federal regulations governing clinical research billing are complex, evolving and sometimes ambiguous. A compliance assurance process is required to ensure the risks of billing for clinical research are mitigated. An effective compliance assurance process consists of:

- Consistent interpretation of the relevant regulations
- Orderly finalization of financial study documents
- Segregation of conventional care and research only charges
- Modification of conventional care charges to be billed to Medicare
- Appropriate invoicing of the study sponsor

To facilitate this process, conducting a self-audit to identify risk and the education of staff for risk mitigation action are key ingredients.

Overview of Clinical Trials Policy (CPT)

The primary document governing clinical research billing is the CTP, which was issued in 2000 and updated in 2007. The policy confirms that all other laws apply and routine costs associated with clinical research must follow Medicare's non-research billing requirements. Therefore, these items:

- Must fall within a Medicare benefit category
- Must not be statutorily excluded
- Must not be prohibited by a National Coverage Decision (NCD) or Local Coverage Decision (LCD)

Federal regulations governing clinical research billing are complex, evolving and sometimes ambiguous.

Because Medicare providers must meet these requirements for all billing, the routine costs of clinical research should pose no special challenges to physician practice billing.

The CTP further clarifies that all items considered "reasonable and necessary," in the absence of research participation, fall within routine care. Physicians should note that, similar to non-research clinical services, Medicare's understanding of "reasonable and necessary" is not the same as "medical necessity."

Many items a physician might perceive as being medically necessary would not be allowable by Medicare, such as hearing aids, which are excluded by the Social Security Act. Medicare also extends the concept to frequency of services or diagnosis-related service limitations, such as monthly echocardiograms or an MRI when an x-ray would be the clinically indicated image modality.

The policy also defines what may not be billed to Medicare. For instance, the investigational item itself may not be billed, unless it is an item that would be provided to a patient in the absence of research. Also, any item that is not necessary for the clinical care of the participant, but is provided solely for data collection and analysis, cannot be billed to Medicare. Lastly, items "customarily" provided by the trial's sponsor may not be billed to Medicare.

Finally, the policy addresses research-specific items that are defined as "routine." These include items required solely for the provision of the investigational item, or for clinical monitoring of the effects of the item, or for the prevention, diagnosis, or treatment of complications related to the provision of the investigational item. By policy these items are billable to Medicare.

When routine services qualify to be billed to Medicare

In order to charge Medicare for routine services, three fundamental requirements are necessary:

- The service under evaluation must fall within a Medicare benefit category and not be statutorily excluded.
- The trial must have therapeutic intention.
- The trial must enroll patients with a diagnosed disorder; diagnostic studies that enroll healthy participants in a control group do apply.

These three requirements, when coupled with seven other "desirable characteristics," appear to be sufficient to charge Medicare for the routine services as defined by the CTP.

However, the CTP does not indicate clearly whether or not all studies meeting the 10 requirements and desirable characteristics are "qualified" to bill Medicare for routine services. Instead, the CTP indicates a federal panel will convene to develop a self-certification process aimed at determining whether or not a study meets the seven desirable characteristics that appear in the CTP. Once the future self-certification process is in place, studies will be able to qualify.

Until then, the studies having the following characteristics are considered "deemed" or "automatically qualifying" because they are likely to meet the seven desirable characteristics:

- Funding from one of six federal agencies including NIH, CDC, AHRQ, CMS, DOD and VA
- Support from cooperative groups that are funded by one of those same six federal agencies
- Investigational New Drug (IND) assignment by the FDA
- IND exemption as specified by the Code of Federal Regulation

The CTP is a complex document and MACs around the country interpret it in different ways.

The CTP is silent about device studies, except to indicate that device studies must follow pre-existing regulations. These regulations allow the potential for services related to provision of an IDE device, and in some cases, the device itself, to be covered by Medicare. Approval by the Medicare Administrative Contractor (MAC) is required for coverage. Note that approval requirements differ by MAC region.

CTP interpretation and cancer treatment trials

The CTP is a complex document and MACs around the country interpret it in different ways. Not only do studies face different rules on IDE devices, but "Phase I" cancer-treatment trials may be covered or not, depending upon MAC interpretation of the "therapeutic intention" requirement.

The typical Phase I trial enrolls only healthy participants for the first human studies of an experimental drug to collect data on safety. However, Phase I cancer-treatment trials typically do not allow the participation of healthy individuals because the drugs are so inherently dangerous. Moreover, many Phase I cancer treatment trials include an analysis of the efficacy of the drug—they are not limited to toxicity analysis. Thus some Phase I trials include therapeutic intention but may range in the degree of that intention. Because MAC interpretations of that intention vary, a Phase I study may or may not include "routine services."

The CTP clearly mentions that the chemotherapeutic administration of an investigational drug can be billed to Medicare. The investigational drug itself does not have to be routine. Principal investigators should note that greater complexity arises when the infusion, for example, is billed and the drug is not.

Some investigators may decide not to charge for the administration of the drug to a third party, but to negotiate with the sponsor to pay for this CTP-stipulated "routine" care. If the infusion will be

The most relevant federal clinical research billing rules

1. The Centers for Medicare and Medicaid Services (CMS) provide a National Coverage Determination (NCD) governing clinical research billing. Known as the "Clinical Trials Policy" (CTP), NCD 310.1 appears simple but it has been interpreted in many ways. In this article we review policy highlights, beginning with CMS reaffirmation that the CTP follows statutory law governing (non-research) clinical billing. See www.cms.gov/clinicaltrialpolicies/.
2. The Medicare Claims Processing Manual, transmittal 1418, provides the required billing modification for research-related routine care. See www.cms.gov/transmittals/downloads/R1418CP.pdf.
3. The Medicare Benefit Policy Manual, (chapter 14), provides the conditions for billing charges related to devices assigned an Investigational Device Exemption (IDE) by the Food and Drug Administration (FDA). See www.cms.gov/manuals/downloads/bp102c14.pdf.
4. The Medicare Advantage (MA) Payment Guide for Out-of-Network Payments, updated on June 1, 2011, confirms that Medicare Part A and Part B will cover the routine costs of clinical research, while MA Plans will pay the difference between Medicare and MA copayments, leaving the MA patient to pay only the MA copayment. See www.cms.gov/medicareadvtgspecratestats/downloads/oon-payments.pdf.
5. The Medicare Managed Care Manual (chapter 8, section 40.4.3) denotes that the routine costs of care for MA research participants must be billed to Medicare. Section 40.4.4 specifies that MA Plans are responsible for routine charges associated with a Category B IDE device if the Medicare contractor has approved those charges. (See 4, above, for details on Category B devices.) The MA Plans may initiate authorization requirements. See www.cms.gov/manuals/downloads/mc86c08.pdf.
6. Numerous other federal laws or regulations are also relevant for compliant research billing, including the False Claims Act, the Stark Law and the Anti-Kickback Statute. Providers should be compliant with these regulations with respect to their non-research billing. Also of note is that investigators should avoid collecting more than fair market value (FMV) for services provided to a study sponsor.

billed and the drug itself is not billable, due to its FDA status, then best practice dictates including the drug on the bill in the "non-covered" column and applying the modifier Q0 to that line item. See below for more on Q modifiers.

Medicare Advantage billing rules

Another intricacy of Medicare research coverage involves the rules for billing CMS managed-care plans, known as Medicare Advantage Plans (MAPs).

Be cautious about "reasonable and necessary" because, by Medicare definition, it is not identical to "medical necessity."

A MAP patient can be billed for routine services, but most studies' charges will have to be routed to Medicare Plan A or Plan B, because the MAPs have not (yet) received funding to provide research-specified routine services. Therefore, physician office billers must work out a method by which they identify this exception and route the qualifying study charges to Medicare Plans A and B.

To make billing more complicated, there's an exception to the exception involving MAC-approved IDE-related charges. If the device is designated as a Category B, it should be billed directly to the MAPs, because MAPs are funded for Category B IDE charges.

Just to add a further MAP complexity, when qualifying charges are routed to Medicare's fee-for-service administrators, a difference in copayment requirement kicks in. Often the fee-for-service copayments are higher than MAP copayments. Thus CMS clarified in June 2011 that the patient is responsible for only the copay amount. Any difference between the fee-for-service and MAP copayment is to be paid by the MAP.

We have not found a billing system that provides program logic to meet these MAP clinical research exceptions. So you need to be careful.

Develop a compliant billing process

After the intricacies of the regulations have been digested, a billing compliance assurance process can (and should) be developed to address them. The remainder of this article outlines the steps to develop a billing compliance process.

The first set of tasks occurs before any participant is enrolled in a study. The principal investigator (PI) needs to ensure that all finance-related study documents are *consistent and accurate*. The documents involved are listed chronologically:

- The protocol
- The protocol billing plan including coverage analysis
- The internal budget
- The sponsor contract, including sponsor budget
- The informed consent form (ICF)

The informed consent

The informed consent, and the last document in chronological order of production, is the primary document that directs billing compliance because it acts as a contract between the principle investigator and the participant-patient. The informed consent is required by regulation to include a financial disclosure—meaning the costs to and compensations of the participant. Clarity is crucial.

Best practice dictates that the items the study sponsor is providing should be clearly distinguished from the items that will be billed as routine care to the participant or their insurer. Depending on the study, the sponsors may pay for items that are routine, but they are only required to pay for items that are research only. Included in this requirement are all items that are protocol-specified for data collection rather than patient care.

Before the participant costs and compensations can be finalized in the prospectively obtained informed consent form, it is incumbent on the principle investigator to differentiate what is to be billed to insurance from what must be billed to the sponsor. The principle investigator then must ensure the sponsor will pay for those items. Informed consent is not viable until the principle investigator includes financial responsibility as part of human subject protection requirements that include financial planning and negotiation.

The protocol, billing plan, and coverage analysis

Study document consistency begins by identifying all clinical procedures, services and other items required by the protocol and listing those items. For this, most principle investigators use a grid, widely referred to as a Protocol Billing Grid (PBG), which is a schedule of the study's clinical events, including the bill routing (i.e. routine care or study-provided). All clinical events are listed along the y-axis and all study visits are listed on the x-axis, as in Exhibit 1.

To indicate an item as routine, a coverage analysis is required. Typically, this is done by analyzing the Medicare non-allowable costs, using the CTP. Any clinical event identified as non-allowable should be marked as study-provided on the billing grid.

Best practice consists of seeking positive evidence for medical necessity through the use of drug and device manufacturers' brochures, national practice guidelines and reference to evidence-based guidelines that might be appropriate (e.g. the National Comprehensive Cancer Network's). When the allowable and non-allowable study clinical events have been determined, they should be listed on the billing grid. The clinical events should be double-checked to be sure they are consistent across the study documents.

Principle investigators should be cautious about "reasonable and necessary" because, by Medicare definition, it is not identical to "medical necessity." Coverage analyses are always interpretive, except when a

Exhibit 1 – Protocol Billing Grid

	Visit One	Visit Two	Visit Three	Visit Four
Clinic visit	Routine	Study	Study	Routine
ECG	Routine	Study	Study	Study
Study drug	Study	Study	Study	
CBC	Routine	Routine	Routine	Routine
CT scan	Study			Study

clinical event is found to be explicitly non-allowable. Therefore, taking the extra step to find national-level evidence for need shows good faith diligence, caution and awareness of billing compliance. These are good qualities to exhibit in financial planning—and in the event of an audit.

Coverage analysis efforts to comply with Medicare law is a great start in conducting commercial coverage determinations, because commercial carriers often follow Medicare billing rules. However, it is not entirely sufficient because individual coverage plans may exclude routine care charges if they occur in a research study.

About two-thirds of states require routine charges to be covered by insurance. However, many states restrict that coverage to cancer-treatment trials. When you have determined what your state law provides for, review your organization's contracts with insurers, beginning with the biggest insurers. Some contracts can limit charges, as long as they are not in violation of applicable law.

The sponsor must pay for everything that is non-allowable, including all items that are for data collection only. The allowables may be billed to insurance or they may be paid by the sponsor, depending how this was negotiated. Opinions differ on whether or not it is best to have a sponsor pay for everything, or if it is better to charge all routine care to the participant to avoid participation "incentivization."

Physicians working with the National Institutes of Health (NIH) cannot simply attempt to have the sponsor pay for everything. The NIH explicitly requires that the hospital/provider costs of routine care should be billed to insurance, except in special circumstances, including cases in which the participant is uninsured or underinsured (http://grants.nih.gov/grants/policy/nihgps_2010/nihgps_ch19.htm).

Budget development

When the coverage analysis is complete, the next step is to develop a comprehensive internal budget. This is done by gathering any other study-related costs, including per-participant and project-wide costs. An internal budget, also known as a "cost budget," projects every anticipated cost of the study.

Common per-participant items are the costs of time and effort for obtaining informed consent, randomization, data collection, study questionnaires and all other administrative items that are never billable to insurance. Project-wide items that are commonly included are Institutional Review Board (IRB) and/or pharmacy administrative costs, time for IRB application, budgeting and contract negotiation.

Some items may incur costs in time and in individual service—for instance, reimbursement may be a flat $100 per participant visit, but also requires managing time, which could dictate a budget cost of $185 per visit, if the cost of accounting and administrative time totals $85.

Only when the all-inclusive internal budget is projected can the budget for the clinical trials agreement (contract) or grant be finalized. Typically, grants funding does not allow negotiations, but non-grant contractual funding usually does, even when it is a subcontract for the NIH. You cannot charge the NIH more than your costs, but if they are offering less than your costs, it is permissible to request an increase in contractual funding.

Commercial agreements allow the most room for negotiation, but limits are still in place. If your physician practice is nonprofit, then tax-exempt resources cannot be provided to a commercial entity.

Best practice is to spell out the individual items rather than taking a flat per participant rate, per visit rate or completion of milestones. If individual items are not delineated, it will not be possible to document what the sponsor was providing, thereby making it riskier to bill any service or item to participants or their insurance. You may find it necessary to educate the sponsor on billing compliance in order to finalize the contract satisfactorily.

Summary of document consistency

The informed consent disclosure of study costs is ready for finalization when the contract budget has been signed by the sponsor. The informed consent disclosure should mirror the contractual terms. To ensure it does, there must be accurate alignment between the protocol, the billing grid and budget. Each of these, of course, should have been the subject of coverage analysis.

The dependent relation of one document upon another does not prohibit simultaneous production of document drafts. However, it does restrict finalization of documents to the necessary order of dependence to achieve the best chance for billing compliance.

Segregating charges

On a typical patient encounter, charges will be generated. For compliance purposes, these charges will need to be identified and placed into the proper category for billing. Some principle investigators use a manual process to do this, while others use an automated computer application or a combination of automation and a manual process.

Regardless of the segregating process employed, the goal is the same—correctly identify which charge is which so billing is consistently accurate with respect to correctly segregating study related charges from insurance charges. The process must be designed to be auditable.

Research modifications of Medicare bills

Correct charging of Medicare is not achieved by compliant charge segregation alone. Research modifications must be appended to any qualified research-related claim sent to Medicare. Transmittal 1418 provides the full details. Key highlights of the transmittal include:

1. A "Q1" is appended to outpatient line items that are routine and protocol-specified and are not the investigational object.
2. A "Q0" is appended to the line item referencing the investigational object, if that item is provided in an outpatient setting. By definition the object must be protocol-specified.
3. If the investigational object is itself routine, then the object is reimbursable and the Q0 is appended.
4. If the investigational object is not routine, but the object is added to the claim in the noncovered service, the Q0 should be appended in the "non-covered service" column.

   The transmittal is not clear whether to add the noncovered object and hence its Q0 to the claim. However, it is best practice to do so whenever the object is provided by the study, but the administration of the investigational object is being billed to Medicare. In this case, the Q0 indicates to the MAC that the drug-administration charge is not an error.

> You may find it necessary to educate the sponsor on billing compliance.

In addition to the Q-modifiers, Medicare requires both the v70.7 diagnosis code, from the International Classification of Diseases, edition 9 (ICD-9), to be placed in a secondary diagnosis position, and for Part A billing, the Condition Code 30. The v70.7 indicates participation in clinical research; the Condition Code 30 indicates that the participation occurs in a qualifying clinical trial. They are to be appended to outpatient and inpatient claims.

Electronic healthcare billing systems and clinical research management systems are developing automated processes that segregate and modify charges—and document that the segregation and modification occurred. At least one clinical research management system is also able to document that routing and modification occurred in relation to a finalized PBG and to allow electronic payment of claims routed to the study. Other software developers will likely be developing similar capabilities.

Billing the sponsor

Correct billing of the sponsor is important. Sponsors should be billed for only those items and services in accordance to the contract and the informed consent. Control monitoring should be in place to ensure the sponsor is not billed for items that are not included in the contract and that the participant or Medicare is not billed for anything that has been billed to the sponsor.

Increase compliance assurance

Establishing a billing compliance assurance process necessitates awareness of the regulations and the limitations of your present system to process transactions in accordance with those regulations.

A two-pronged self-audit can help assure compliance. First, appoint a compliance officer or assign a savvy biller(s) to conduct research on the applicable regulations and to review the processes your organization has in place. Secondly, match the process in place to the regulations to identify where improvements may need to be made to the organization's processes.

If the processes have been carefully developed, it may only be necessary to make a simple change or two that can be done quickly and easily. If a number of changes are identified, it will likely be necessary to prioritize the tasks to be undertaken. Here, careful consideration of noncompliant activity can be helpful in prioritizing which work needs to be done first.

For example, if you find that charges are not being properly segregated or modified, work on the segregation issue first. Failing to segregate charges results in mis-billing and potentially double billing, and carries much more dire consequences. Q-modification, however, is utilized by Medicare for collecting data on clinical research, and doesn't affect reimbursement.

Using another example, let's say that the consent forms are not consistent with the rest of the financial study documents. Trying to correct everything at once would be huge as well as disruptive. Your best plan is to take on new contracts that are not yet finalized and/or research projects that exhibit the most egregious issues first. Always be sure to involve legal counsel if the self-audit identifies mis-billing.

When a compliance assurance process has been established, documenting what has been put in place is an important step to undertake. Documenting the consistent application of federal regulation throughout the research billing process is paramount, in part because the relevant regulations are frequently challenging to interpret.

> Maintaining a consistent, documented compliance practice evidences your organizations' due diligence efforts.

Maintaining a consistent, documented compliance practice evidences your organization's due diligence efforts. If there is a change in the interpretation of a regulation, and thus in the process, document the change and the reason for the change. Then—importantly—apply the new interpretation consistently.

Conclusion

Effective billing compliance involves educating everyone involved in both the initial self-audit effort and the resulting changes to the process. But good compliance assurance doesn't end with the launch of a billing compliance assurance process. It requires that you continue to monitor and audit the processes, as well as providing education to those involved. It also involves keeping current with evolving federal research billing requirements.

This is really complex billing and compliance assurance. Never assume that you are on top of it all because the federal regulations, internal systems and sponsor contracts are always changing. Lastly, education is an important element because of staff turnover and changes in responsibilities. **NP**

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A sign on the lawn at a drug rehab center said: 'Keep off the Grass.'
~Anon.