Developing an Effective and Compliant Plan for Billing Clinical Trials

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Medicare's financial coverage for clinical trial participants and potential overpayments for items and services provided to patients in clinical trials are significant issues that, if not addressed, could compromise the ability to conduct clinical research. As financial pressure on the Centers for Medicare & Medicaid Services (CMS) resources increases, there is greater scrutiny on payments made by CMS. Errors in billing Medicare for items or services rendered in clinical trials could trigger allegations under the False Claims Act (which provides for an action for presenting a false claim to the government. There are civil \$3730 and criminal components, all with fines; additionally, under the False Claims Act, private individuals may bring a civil action

for a violation of §3729 on behalf of both the private person and the US Government),¹ and improper billing to private insurers could trigger allegations of insurance fraud.

Types of billing errors include "double dipping," or billing Medicare or other third party payers for an item or service provided by the clinical trial's sponsor, or billing for an item or service that is being done purely for research purposes. Effective billing for clinical trials is a "hot" topic due to the Medicare's National Coverage Decision (NCD)² providing reimbursement for routine clinical trial costs; the Department of Health and Human Services Inspector General's 2002 and 2003 plans to monitor Medicare for clinical trials³ and the recent Rush University Medical Center's settlement agreement (news release available online-only).⁴

Determining how to bill third-party payers for clinical trial care is a complex task that requires collaboration of a wide range of individuals working closely to develop a process that will work in their practice setting. This article will review issues associated with this process.

Medicare's NCD for Routine Costs in Clinical Trials

Prior to Medicare's NCD, beneficiaries did not have guaranteed access to clinical trials. Effective September 19,

2000, Medicare ensured coverage for routine care rendered during clinical trials, providing that the care falls within a Medicare benefit category and is not statutorily excluded for coverage.² *Routine costs* are defined as items or services (1) typically provided absent a clinical trial; (2) required solely for the provision of an investigational item or service (such as administration of a noncovered chemotherapeutic agent, clinical monitoring of the effects of the item or service, or the prevention of complications); and (3) needed for reasonable and necessary care arising from the provision of an investigational item or service, particularly to diagnose and treat complications. Of importance is that the NCD does not withdraw coverage for items or services that may be covered by local medical review policies (LMRPs), now referred to as local coverage decisions (LCDs) or regulations on category B investigational device exemptions (IDE). LCDs are written by fiscal intermediaries or local carriers that represent CMS and are intended to determine coverage decisions regarding a particular service on an intermediary-wide or carrier-wide basis in accordance with Section 1862(a)(1)(A) of the Social Security Act (ie, a determination as to whether the service is reasonable and necessary). NCDs describe what specific services, procedures, or technologies Medicare will cover on a national basis. Additional information on LCDs and NCDs can be obtained from the CMS glossary at www.cms.hhs.gov/.

The NCD provides new opportunities to ensure that Medicare beneficiaries have access to clinical trials and novel new treatments. Due to the divergence among clinical investigators, compliance personnel, and attorneys regarding the definition of routine items and services, it is essential for stakeholders to agree on a lexicon to facilitate development of a practical and compliant research billing process. CMS is reconsidering the current NCD to address several issues that have arisen since its implementation. One of the issues CMS raised is clarification of the definitions of routine clinical care costs and investigational costs. CMS initiated reconsideration in July 2006, solicited public comments, and expects to issue a decision memo in January 2007.

Conditions for Qualifying and Deemed Trials

For Medicare to consider reimbursement under the NCD, a study must be a qualifying clinical trial. A *qualifying clinical trial* must (1) evaluate an item or service that falls within a Medicare benefit category and is not statutorily excluded from coverage; (2) have therapeutic intent; and (3) enroll patients with a diagnosed disease. Trials that are funded by certain federal agencies, conducted under an investigational new drug (IND) application, or are exempt from having an IND and meet the three requirements, are automatically

qualified to receive Medicare coverage under 21 CFR 312.2(b)(1).²

Working With Routine Care and Customarily Provided Care

Differentiating between *routine care* and *care customarily provided by the trial sponsor* is often challenging. Methods to determine routine care are to note if an item or service would be conducted outside a clinical trial, if there are specific practice guidelines for the conduct of such care, and/or if peer reviewed journal articles exist. Difficulties arise when different clinicians in the same practice use different methods to treat their patients. While the practice of medicine is an art and science, for billing purposes, it is easier to document routine care if there is consistency. Additionally, not all routine care is covered by Medicare. For example, a clinician may order a particular blood test as routine conventional care for a patient with a particular diagnosis. However, this same blood test may be excluded from coverage due to another NCD and therefore is not reimbursable by Medicare even if the blood test is a required component of care and must be done. (It is imperative that clinicians understand that even though Medicare may not cover an item or service, this noncoverage is not a judgment of the type of care they are providing, but rather an analysis of what can be billed and reimbursed.) Determining what is customarily provided by the sponsor can also be difficult as there are few, if any, benchmarks to check validity. While it may not be feasible to check with other institutions as to what the sponsor is providing, reviewing the study objectives and the IND letter from the US Food and Drug Administration may provide insight as to the requirements for the conduct of a particular study.

Device Clinical Trials

Device trials conducted under an IDE provide two options for billing; the NCD on Routine Costs for Clinical Trials or 42 CFR Parts 405 and 411.⁵ Medicare's coverage for device clinical trials is dependent on the designation of the device. Additionally, coverage is determined by the fiscal intermediary or local carrier on a case-by-case basis. Under the NCD on clinical trials, the device would not be covered; however, under the device regulations, Medicare could be billed for the device (as long as the sponsor is not providing the device).

Effective Billing Plan

Key components to a successful billing plan and program include communication, education, and a relationship with one's fiscal intermediary or local Medicare carrier. For hospitals, the fiscal intermediary administers Medicare Part A, and for physicians the local Medicare carrier administers Medicare Part B. One needs to determine the type of billing operation that exists at one's institution and either fine tune it or build a new system. If an institution or practice has discovered problems with its current billing operation, there

needs to be open communication with a wide variety of individuals to determine the scope of the problem and mechanisms to cure the problem.

Methodology to Determine Coverage of a Clinical Trial: Coverage Analysis

If all items and services are covered by the sponsor, the only applicable rule is not to bill a third-party payer. However, for clinical trials in which there is no sponsor or the sponsor is covering some items or services, the following should be considered:

- What are the items and services outlined in the protocol
- What is the investigational item or service
- What items or services has the sponsor offered to pay
- The cost to conduct the clinical trial
- If the trial is a qualifying clinical trial under the NCD
- What items or services can or cannot be billed to Medicare (The NCD specifically notes "all other Medicare rules" apply. Therefore, even if an item or service is routine/conventional care, it may not be covered by Medicare.)
- What items and services private insurers will cover (precertification)

One method used to determine the foregoing is a coverage analysis or billing plan. With this methodology, reviews of the protocol, proposed budget, informed consent, and sponsor contract, are required to determine all the items and services needed for the conduct of the clinical trial. Documenting these items on a spreadsheet provides a visual template which assists with this analysis. Review each item or service and note if the sponsor is providing funding or goods, such as the investigational agent. Under this methodology a line item budget is used. For the items in which there is no coverage, list out the items and note if they are conventional care or if they are being conducted for research purposes only (the NCD on Routine Costs associated with clinical trials excludes coverage for items or services conducted for research purposes only). For the conventional care items, review NCDs and LCDs to determine coverage. If the clinical trial involves "off-label" use of an agent or agents and a LCD does not exist for coverage, coverage may be granted by the local fiscal intermediary or local Medicare carrier if the use is determined to be medically accepted.⁶ For anticancer chemotherapeutic agents, coverage may occur if its use is supported in any of the three drug compendia or, if not, noted in specific peer-reviewed journal articles.⁷ For any questions pertaining to coverage or noncoverage of an item or service, it is prudent to contact the local fiscal intermediary or local Medicare carrier for a coverage determination. Finally, before starting the study, it is important to review the informed consent document, the negotiated study budget, and contract to ensure concordance regarding which party is financially responsible for the items and services required to conduct the clinical trial.

If the coverage analysis is conducted after the contract is executed and the study has commenced, the focus of the coverage analysis is what items and services the sponsor is covering. These items and services need to be noted and not billed to a third-party payer. It is important also to review the informed consent document to note what has been promised to the subjects at no charge and what items will be charged to the subject or a third-party payer. If the informed consent promises an item or service at no charge, neither the subject nor a third-party payer can be billed regardless of what the negotiated budget states.

Benefits of a Coverage Analysis

A coverage analysis used when billing for clinical trial services can prevent errors in billing. It can also be used as a template to negotiate a study budget, determine the financial gain or loss associated with a particular study, and can assist with writing an informed consent that adequately delineates potential financial liability of the subject.

Other Considerations

Developing a billing plan to work with cooperative group clinical trials presents other issues, as there may be no additional funding, and a line item budget may not be available. It is difficult for some clinicians to understand that while these clinical trials are supported by governmental agencies, not all of these studies meet the requirements for a qualifying clinical trial, or the items or services noted may not be reimbursable by Medicare.^{2,8,9} Applying the same coverage analysis for cooperative group clinical trials can prevent

billing errors. When the billing process for clinical trials is being developed or revamped, there may be delays in the processing of clinical trials agreements. These delays can be ameliorated by focusing on the specific issue and developing a plan of action to evaluate the progress and modify the billing program to meet the individual needs of the institution or practice.

Billing for clinical trial care raises many issues that may cause billing errors. While these issues may seem insurmountable, addressing them results in an effective and compliant billing plan that prevents billing errors, determines the cost to conduct a clinical trial, and provides patients with an accurate accounting of their financial liability.

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