CONTINUING EDUCATION

EDUCATIONAL OBJECTIVES

After participating in this activity, clinicians should be better able to

- Define coverage analysis and the role it plays in the determination of costs
- Describe the five common miscommunications in billing
- Recognize the criteria for a qualifying trial and a nonqualifying trial

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Meeting the billing challenges inherent with clinical trials

Kelly M. Willenberg, MBA, BSN, CHC, CHRC

STATEMENT OF NEED/PROGRAM OVERVIEW

The integration of billing procedures into medical records introduces the need for nurses to understand billing systems and medical payors. In addition, their role on research teams presents a need to understand the billing processes and laws applicable to clinical trials. Billing in clinical trials is complex and is changing. The need for nurses to stay appraised of billing codes and procedures, of changes in the laws, and in how to implement billing systems to ensure compliance is as essential to their role in the continuum of care as their medical knolwedge.

CE INFORMATION

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Meeting the billing challenges inherent with clinical trials

The integration of billing procedures into nursing care has mandated that nurses understand how patient care is billed in a clinical trial.

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As a clinical trial study coordinator and the director of a large clinical trials office, I know that nurses have to deal with many more regulations and compliance issues than ever before to provide nursing care. In addition, nurses must know more today than they have ever had to know in regards to billing for care and services, especially when a patient is participating in a clinical trial. Clinical trials have evolved from a lightly regulated part of clinical practice to a complex and strictly regulated environment. Informed consent for clinical trials were simple, three-to-four-page documents that required a patient's signature. Nurses did not have to worry about who covered the costs for items and services provided to participants. Nor was ethical scrutiny needed as a critical part of the decision regarding a patient's participation in a particular study. I have seen all that change in the more than 30 years since I began my career as an oncology nurse.

The need for communication is paramount. In this context, communication means sharing the

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clinical trial information with all parties involved in the care of the patient, including the facility conducting the trial; the primary care provider; and any hospital, clinic, laboratory, clinician, or technician that may provide services. This article explores the terms used in clinical trials and some of the hidden challenges faced when communicating clinical trial information throughout the continuum of patient care.

COVERAGE ANALYSIS AND INFORMED CONSENT

Understanding the terms used in the billing process is the first step. (The italicized terms in this article are defined in Table 1.) The *coverage analysis* is the document that identifies who the appropriate payor is for each item and service provided to participants in a clinical trial, as stated in the protocol and schedule of events. It does not guarantee payment from a provider but documents the intent to bill for items and services not supported by established regulations and guidelines for the treatment of the patient's cancer.

The coverage analysis can also be used by facilities to determine budgetary needs, contract negotiations (for example, between the facility conducting the trial and the clinical trial sponsor), and consent-form wording. This documentation is necessary for all studies, in particular cooperative group trials in which all usual routine costs are billed to a private insurance or Medicare payor.

The *informed consent* designed by the facility conducting the clinical trial, often a document modified from a template provided by the trial sponsor, states the items and services that are the patient's financial responsibility, and is an important guide for billing. It is carefully worded and informs patients of their true costs; promised services must match budgeted allocations and the coverage analysis. Clinical trial nurses and principal investigators should discuss the items and services that are the participants' financial responsibility with the patient and also document the discussion in the consent note. (Preauthorization and certification from the patient's insurance company should be obtained prior to registration.) The discussion should answer the following questions for the patient.

- What are my costs to participate in the clinical trial?
- What are my co-payments for the treatment?
- Why will my bills be sent to Medicare instead of my Medicare Advantage Plan?
- Could I be financially responsible for anything that is billed to my insurance company in the trial?

ROUTINE COSTS

What constitutes *routine costs*? This is an important question to ask with each clinical trial. Understanding what constitutes routine costs prevents providing erroneous information

TABLE 1. Terms to know

Coverage analysis	A document that identifies the appropriate payor (eg, the clinical trial sponsor, Medicare, or third-party payor such as an insurance company) for each item and service provided to clinical trial participants reviewed against regulations and guidelines
Informed consent	A document that provides a summary of a clinical trial, including the purpose of the trial, treatment procedure and schedule, risks and benefits, and participants' responsibilities (ie, items and services not covered by the sponsor or third-party payor)
National coverage determination (NCD)	National policies on coverage for specific medical services for patients on the Medicare program
Qualifying clinical trial	Clinical trial that meets specific criteria, including (1) the trial outcome has a therapeutic intent, (2) treatment is for a disease or condition covered under a Medicare benefit category, and (3) the trial enrolls patients with a diagnosed disease as participants.
Routine care (also known as conventional care)	Care typically provided to patients based on established recommendations and guidelines
Research costs	Those costs associated with conducting the trial such as data collection and management, research physician and nurse time, analysis of results, and tests performed solely for research purposes
Research only	Items and services provided solely for the purpose of measuring participants' clinical status at specific points during a clinical trial
Routine costs (also known as conventional costs)	Items or services that are (1) typically provided absent a clinical trial (eg, medically necessary conventional care), (2) required solely for the provision of an investigational item or service (eg, administration of a noncovered chemotherapeutic agent), (3) required for the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications (eg, additional blood tests to ensure no adverse reaction), (4) medically necessary for diagnosis or treatment of complications arising from the provision of an investigational item or service (eg, hospitalization to treat infection resulting from experimental surgical procedure)
Schedule of events	Calendared list of events taken from the clinical trial protocol, often used by insurance companies in the preauthorization process.

31 USC §3729—False claims

(a) **Liability for Certain Acts.—**

(1) **In general.**—Subject to paragraph (2), any person who—

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);

(D) has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property;

(E) is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(F) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge property; or

(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government, is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104–410[1]), plus 3 times the amount of damages which the Government sustains because of the act of that person.

Source: 31 USC §3729—False Claims. Cornell University Law School Web site. http://www.law.cornell.edu/uscode/text/31/3729. Accessed December 3, 2012.

to the patient, or even inadvertently to a payor, about the services the clinical trial sponsor is providing. Routine costs include the following items.

- Items and services typically provided absent a clinical trial (ie, *routine care*)
- Items and services required solely for the provision of the investigational item or service (ie, agents, equipment, and clinic time used in the administration of the investigational drug)
- Items and services used for the clinically appropriate monitoring of the effects of the item or service, or to prevent complications
- Items and services needed for the reasonable and necessary care arising from the provision of the investigational item or service, in particular diagnosis or treatment of complications.

For example, if administration of an investigational drug causes liver toxicities, all laboratory tests performed to monitor that toxicity are considered routine care and are billable to Medicare or other third-party payor under the *national coverage determination* (NCD). The tests are coded for billing as routine care. However, if the trial sponsor promises to pay for all laboratory tests performed in a clinical trial, Medicare or other third-party payor should not be billed for the laboratory tests.

BILLING ISSUES

Coordination of medical bills is sometimes very cumbersome. In many institutions, hospital and clinic billing is based on who ordered the item or service. Physician practices bill for the professional fees, while the hospital bills for the facility or technical portion. This is a crucial point in billing, as billing errors within clinical trials often occur at this point. An innocent error can result in an investigation of the facility or practice by the Office of Inspector General or the Department of Justice.

The CMS NCD for clinical trials clearly delineates what can be billed to Medicare within a clinical trial schedule of events.

The clinical staff is charged with identifying what constitutes routine care and what is for the purposes of *research only* when ordering or scheduling items and services for clinical trial participants. The coverage analysis is essential to make this determination accurately. Separating the charges for routine care from the charges for research-only items and services is

significant and must not be ignored. Further complicating the coordination and monitoring of billing, professional billing and facility billing do not always occur concurrently; invoices may be sent to payors upon the reporting of test results or later after a long hospital admission.

Billing issues are also complicated by statutory laws. The sponsor of a clinical trial does not pay for every item and service provided to participants, especially in the case of clinical trials for cancer treatment. *Research costs* associated with conducting clinical trials are covered by the trial sponsor, such as the National Cancer Institute (NCI) or a pharmaceutical company. Thirty-six states have statutes that require health plans to cover certain clinical trial costs, but these statutes vary by state. Alarmingly, health insurance companies are not required to cover the routine costs for patients participating in a clinical trial in 14 states.[1] However, the laws are in transition to comply with the Affordable Care Act (ACA). Oncology nurses should prepare to keep appraised of potential changes to clinical trial coverage laws. Based on what is known when this article went to press, the ACA will prohibit insurance companies from denying coverage for routine costs in a *qualifying clinical trial*.

The Centers for Medicare and Medicaid Services (CMS) NCD for clinical trials clearly delineates what can be billed to Medicare within a clinical trial *schedule of events*. CMS ensures Medicare will cover costs for routine care rendered during qualifying clinical trials provided the care falls within a Medicare benefit category and is not statutorily excluded for coverage. Many large commercial payors follow the practices of Medicare when determining coverage. However, there are so many variations in insurance policies that the determined coverage may vary.

Another concerning area is noncoverage of drug trials. Patients who participate in Medicare Advantage Plans have contracted their care to a managed care organization. These plans do not pay for routine costs in drug trials. Billing must go to a Medicare fee-for-service plan for payment.

COMMON MISCOMMUNICATIONS

Communication errors between the health care team members can result in problematic third-party billing. Five scenarios commonly lead to billing the wrong payor for care or services provided to clinical trial participants.

Sponsor-provided services Clinical trial sponsors provide money for and contract for participants' care to include particular tests or procedures (eg, CT scans, radiographs, laboratory tests). Although these services may be part of routine care, in this case, these services should be billed to the sponsor not a third-party payer. Orders and scheduling

31 USC §3730—Civil actions for false claims

(a) **Responsibilities of the Attorney General.**—The Attorney General diligently shall investigate a violation under section 3729. If the Attorney General finds that a person has violated or is violating section 3729, the Attorney General may bring a civil action under this section against the person.

(b) **Actions by Private Persons.—**

(1) A person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name of the Government. The action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting.

(2) A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the Government pursuant to Rule 4(d)(4) of the Federal Rules of Civil Procedure. The complaint shall be filed in camera, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders. The Government may elect to intervene and proceed with the action within 60 days after it receives both the complaint and the material evidence and information.

(3) The Government may, for good cause shown, move the court for extensions of the time during which the complaint remains under seal under paragraph (2). Any such motions may be supported by affidavits or other submissions in camera. The defendant shall not be required to respond to any complaint filed under this section until 20 days after the complaint is unsealed and served upon the defendant pursuant to Rule 4 of the Federal Rules of Civil Procedure.

(4) Before the expiration of the 60-day period or any extensions obtained under paragraph (3), the Government shall—

(A) proceed with the action, in which case the action shall be conducted by the Government; or

(B) notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the action.

(5) When a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action.

Source: 31 USC §3730—Civil Actions for False Claims. Cornell University Law School Web site. http://www.law.cornell.edu/uscode/text/31/3730. Accessed December 3, 2012.

of these items and services should be coded as sponsor-provided so they can be removed from a bill or submitted as a noncovered service to Medicare or a private payor.

Services promised in the informed consent The language in the consent form tells the participant that all clinical-trial services are being provided at no cost to them, but the facility allows an invoice to be submitted to a payor. Nurses and principal investigators involved in providing care in a clinical trial should familiarize themselves with the information presented in the consent form and be clear on the clinical trial services.

Research-only purposes The study protocol will state which services are needed for research purposes. For example, a clinical trial may require participants to undergo echocardiography for measurement as part of the objectives. This echocardiography is outside the routine care for the participant. The order for this procedure needs to indicate that the sponsor is to be billed, as the procedure is for research only.

Clinical trials are essential to the continued advancement of patient care; however, clinical trials also entail extra concerns for nurses.

Nonqualifying clinical trial A nonqualifying clinical trial is one that does not meet the minimum standards of the NCD. Prevention or healthy-volunteer studies, trials of elected cosmetic surgery, and some phase I studies are examples of nonqualifying trials. Medicare or any government payor cannot be billed for any services provided to patients participating in a nonqualifying trial.

Medicare Advantage Plans (Medicare Part C) Medicare Advantage Plans do not cover clinical trials involving drugs. Therefore, billing for drug trial participants should be submitted to regular Medicare fee-for-service plan. Medicare Advantage Plans, however, allow payment for device studies that have FDA exemptions.

LEGAL IMPLICATIONS

Care of clinical trial participants is part of an oncology nurse's daily routine; therefore, communication in regard to the clinical trial billing intent is important. Communication includes sharing information relative to the patient's care among everyone who may touch that clinical trial participant throughout the continuum of care. The documents that provide this communication are the coverage analysis, informed consent, and schedule of events.

Incorrectly billing Medicare for items or services rendered in clinical trials can trigger an investigation under the False Claims Act (FCA). Both criminal (31 USC §3729) and civil (31 USC §3730) components of the FCA include monetary fines. Civil actions for violations of the FCA can be brought up by private citizens, as well as the US Attorney General, on behalf of both the person and the US government.[2] Improper billing to private insurers can lead to allegations of insurance fraud.

CONCLUSION

Today's medical environment is very complex. The financial aspect of a patient's care often involves multiple payors. The billing for services is tied into the day-to-day administration of care. This places some of the burden for accurate billing on nurses and billers in a variety of settings that provide care. The sponsor of a clinical trial does not pay for everything that is provided to patients participating in the trial, especially in the case of clinical trials for patients with cancer. Efforts to clarify financial responsibility, using coverage analysis, informed consent, and schedule of events, still allow for billing errors. Billing issues are further complicated by statutory laws. With additional provisions of the Affordable Care Act on the horizon, who pays for health care provided in clinical trials will be again altered.

Clinical trials are essential to the continued advancement of patient care, and patients, especially those with cancer, are encouraged to participate in them. However, clinical trials also entail extra concerns for nurses. Using the tools of communication to identify who the payor is for each item or service provided to patients participating in a clinical trial will help when scheduling care and prevent billing errors. ■

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REFERENCES

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