The Healthcare Compliance Professional's Guide to Clinical Trials

F. Lisa Murtha, JD, CHC • Leah Guidry, JD • Huron Consulting Group

The Healthcare Compliance Professional's Guide to Clinical Trials

F. Lisa Murtha, JD, CHC
Leah Guidry, JD
Huron Consulting Group

HCPro

The Healthcare Compliance Professional's Guide to Clinical Trials is published by HCPro, Inc.

ISBN 978-1-60146-224-4

F. Lisa Murtha, JD, CHC, Editor
Leah Guidry, JD, Editor
Melissa J. Varnavas, CPC-A, Senior Managing Editor
Melissa Osborn, Executive Editor
Lauren McLeod, Group Publisher
Susan Darbyshire, Art Director
Janell Lukac, Graphic Artist
Leah Tracosas, Copyeditor
Sada Preisch, Proofreader
Darren Kelly, Books Production Supervisor
Jean St. Pierre, Director of Operations

Arrangements can be made for quantity discounts. For more information, contact:

HCPro, Inc.
P.O. Box 1168
Marblehead, MA 01945
Telephone: 800/650-6787 or 781/639-1872
Fax: 781/639-2982
E-mail: *customerservice@hcpro.com*

Visit HCPro at its World Wide Web sites:
www.hcpro.com* and *www.hcmarketplace.com

7/2008
21483

Contents

About Huron Consulting Group

Huron Consulting Group helps clients effectively address complex challenges that arise in litigation, disputes, investigations, regulatory compliance, procurement, financial distress, and other sources of significant conflict or change. The company also helps clients deliver superior customer and capital market performance through integrated strategic, operational, and organizational change. Huron provides services to a wide variety of both financially sound and distressed organizations, including Fortune 500 companies, medium-sized businesses, leading academic institutions, healthcare organizations, and the law firms that represent these various organizations.

About the Authors

Christina Davis, CHC

Christina, a manager with Huron Consulting Group, in Washington DC, has more than 12 years of research experience. Her specific areas of concentration include the management of engagements focused on building operational efficiency and infrastructure, research project management, Institutional Review Board (IRB) operations structure and function, regulatory compliance evaluation, and Medicare coverage analysis.

Christina earned a bachelor degree in psychology from Randolph-Macon College in Ashland, VA, and has a certification in healthcare compliance from the Health Care Compliance Association (HCCA). She is also a member of Public Responsibility in Medicine and Research and the HCCA.

Contact her at cdavis@huronconsultinggroup.com.

Kevin R. Eskew, MBA, CHC

Kevin, a director with Huron Consulting Group, in Chicago, has 12 years of experience serving the healthcare and education marketplace as both an administrator and a management consultant.

He regularly works with organizations to improve their operational effectiveness by identifying risks, taking actions to limit risk impact, and designing strategies to protect clients' compliance management interests while enhancing performance.

Kevin has an MBA from Indiana University in Bloomington and a bachelor's degree from DePauw University in Greencastle, IN. He is also certified in healthcare compliance.

Contact him at keskew@huronconsultinggroup.com.

Beau S. Gostomsky, RN, BSN, MBA

Beau is a manager for Huron Consulting Group, in New York City. He has experience in the strategic, financial, and operational aspects of clinical research programs and has provided a broad prospective for the development, planning, implementation, and review of various types of research operations.

Beau has an MBA from the University of Phoenix, and a bachelor of science in nursing degree from Wright State University in Dayton, OH. He is also a member of the Association of Clinical Research Professionals and the Health Care Compliance Association.

Contact him at bgostomsky@huronconsultinggroup.com.

Leah Guidry, JD

Leah is a director at Huron Consulting Group, in Washington, DC, and has 20 years of experience working with various healthcare entities, including healthcare systems, hospitals, academic medical centers, physician groups, group purchasing organizations, and pharmaceutical and device manufacturers.

She advises academic medical centers and other research sites on a variety of compliance-related matters. Her particular expertise is in working with clients on government disclosure determinations, development and implementation of the infrastructure necessary to appropriately bill Medicare for research-related items and services, and staff training.

Leah has a juris doctorate from the Jacob D. Fuchsberg Law Center at Touro College in New York City, a master of arts in counseling from Chapman University in Tucson, AZ, and a bachelor of science in psychology from Louisiana State University in Shreveport.

Leah is also a member of the American Health Lawyers Association, the Health Care Compliance Association, and the District of Columbia Bar Association.

Contact her at lguidry@huronconsultinggroup.com.

Stuart Horowitz, PhD, MBA

Stuart serves as a director for Huron Consulting Group, in Chicago and has more than 20 years of experience establishing and managing research operations in the biomedical and clinical sciences. Stuart is a frequent speaker at national and regional industry conferences on a variety of topics related to clinical research operations and compliance for executives of pharmaceutical and medical device companies and contract research organizations, as well as administrators of universities, hospitals, and academic medical centers.

Stuart holds a doctorate of philosophy and cell and molecular biology and a master of science in biology degree from the University of Rochester in New York, an MBA from Bellarmine University in Louisville, KY, and a bachelor degree in biology from State University of New York in Binghamton.

Stuart is a member of the Health Care Compliance Association, the Association of Clinical Research, and the Perinatal Research Society.

Contact him at shorowitz@huronconsultinggroup.com.

Janice Jacobs, CPA, CPC, CCS

Janice, a director for Huron Consulting Group, in New York City, has experience working with clients on various clinical research billing compliance projects, interim compliance work, and coding and revenue cycle projects including medical record chart audits, coding assessments, and revenue cycle redesign.

Janice graduated magna cum laude with a bachelor of science degree from Marywood University in Scranton, PA. She also is a Certified Public Accountant, a Certified Professional Coder, and a Certified Coding Specialist.

Janice is also a member of the Pennsylvania Institute of Certified Public Accountants, the Healthcare Financial Management Association, the American Academy of Professional Coders, and the Health Care Compliance Association.

Contact her at jjacobs@huronconsultinggroup.com.

Matthew J. Lester, MBA, MHA

Matthew serves as a director for Huron Consulting Group, and has more than eight years of consulting experience in research management issues, particularly in the operations and financial management of clinical research. His diverse experience spans all aspects of research administration from federally funded laboratory research to industry-sponsored clinical trials.

Matthew has master of business administration and master of healthcare administration degrees from Pennsylvania State University and a bachelor of arts in business administration from the University of Washington in Seattle.

Contact him at mlester@huronconsultinggroup.com.

F. Lisa Murtha, JD, CHC

Lisa, a managing director for Huron Consulting Group, in New York City, has 22 years of experience in the healthcare industry. She leads the Huron Clinical Research Solutions and Healthcare Compliance Practice.

Lisa has written numerous articles and books on research, healthcare, compliance, and fraud and abuse topics in professional publications, including *The Journal of Health Care Compliance, Widener University Law Journal, The Philadelphia Business Journal, Aspen Publishers Compliance Handbook, Medical Research Law and Policy Report (BNA)*, *The HCCA Compliance Newsletter* and *Patient Safety Meets Corporate Compliance (HCPro, Inc.)*.

Lisa received her juris doctorate from the Dickinson School of Law in Carlisle, PA. She also has a BA in speech communication from Pennsylvania State University in University Park and is certified in healthcare compliance. In addition, Lisa is a founding board member of the Health Care Compliance Association and serves on the Board of Directors of the Society of Corporate Compliance and Ethics..

Contact her at lmurtha@huronconsultinggroup.com.

Judy Ringholz, RN, JD, CHC

Judy has 30 years of experience in the healthcare and medical-legal industries and currently works as a manager for Huron Consulting Group, in Washington DC. Her expertise is in assisting healthcare organizations to identify and manage internal risks, assess the effectiveness of their compliance programs, and identify opportunities for strengthening their efforts to promote a culture of compliance.

Judy received her juris doctorate from the University of Houston Law Center. She also holds a diploma in registered nursing from St. Vincent's Medical Center of Richmond in Staten Island, New York and a bachelor of science degree in nursing from the University of Texas Medical Branch in Galveston. She is Certified in Healthcare Compliance through the Compliance Certification Board of the Health Care Compliance Association.

Judy serves as chairperson for the Health Law and Compliance Section and is also a member of the American Association of Nurse Attorneys, the American Health Lawyers Association, and the Health Care Compliance Association.

Contact her at jringholz@huronconsultinggroup.com.

Rebekah M. Stewart, JD, MBA, CPC, CHC

Rebekah serves as an associate for Huron Consulting Group, in Washington DC, and has expertise in regulatory compliance assessments, policy and procedure management, and training development.

Rebekah received her juris doctorate from Oklahoma City University School of Law, a master of business administration degree from Oklahoma Christian University in Oklahoma City, and a bachelor of arts in communication studies from James Madison University in Harrisonburg, VA.

Rebekah is also certified in healthcare compliance and is a certified professional coder. She is a member of the American Academy of Professional Coders, the American Health Lawyers Association, and the Health Care Compliance Association, and a board member of the Virginia chapter of the National Association of Health Service Executives.

Contact her at rstewart@huronconsultinggroup.com.

Madeleine A. Williams, CIP, CHC

Madeleine is a manager for Huron Consulting Group, in Washington DC, and has more than 10 years of experience in clinical research and healthcare compliance. Her specific areas of focus include Institutional Review Board (IRB) structure and function, regulatory compliance evaluation, human research protection program evaluation and accreditation, and Medicare coverage analysis.

Madeleine has a master of arts in clinical psychology degree from Towson University in Towson, MD, and a bachelor of science in psychology degree from Pennsylvania State University. She is also a certified Institutional Review Board professional and is certified in healthcare compliance.

Madeleine is also a member of Public Responsibility in Research and Medicine and the Health Care Compliance Association.

Contact her at mwilliams@huronconsultinggroup.com.

Chapter 1

Introduction to Clinical Research

By Stuart Horowitz, PhD, MBA

Most people think of clinical research as clinical trials—studies in which new treatments, typically drugs or medical devices, are tested by physicians on patients who volunteer to become participants, or subjects, in research studies. Indeed, this working definition of clinical research remains the most widely applicable, but the relationship between physicians and their patients is often confused with the relationship between the investigator and the research subject, a phenomenon termed the *therapeutic misconception*.[1]

Likewise, confusion between clinical treatment and experimental or investigational procedures often leads to misconceptions about bills resulting from items and services provided to patients who also happen to be clinical research subjects. When such misconceptions lead to billing errors, and especially when the errors involve bills submitted to Medicare, TriCare, or Medicaid, the doctor or hospital submitting the erroneous charges may be subject to prosecution for billing fraud.

This chapter describes clinical research activities and the major players involved in these activities, including healthcare providers, investigators, and sponsors. It also sets the stage for the challenge and importance of bringing clarity to the process of clinical research billing.

Definitions of Clinical Research

Some of the confusion about clinical research stems from the definitions used to describe related and largely overlapping activities. It may be helpful to first consider the broadest category—human subject

1. Moss, RW. Clinical trials and the "Therapeutic Misconception"—The War on Cancer. Townsend Letter for Doctors and Patients, February–March 2002.

research—and then focus more narrowly on a subset of human subject research—clinical trials. Broadly speaking, human subject research consists of two components:

1. Human subjects
2. Research

According to the Common Rule[2] for the protection of human subjects in research, the definition found in Chapter 45 of the *Code of Federal Regulations* (CFR) Part 46 applies:

> *"Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information. Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."*

Even if the otherwise ambiguous definition of research were crystal clear, the universe of human subject research is much larger than the typical clinical trials that occur in the healthcare setting and includes social and behavioral research, as well as some surveys.

Because clinical research or clinical trials often involve testing for drugs, medical devices, and biologics regulated by the Food and Drug Administration (FDA), it is important to understand the FDA's regulations that define the term *clinical investigation,* as follows:

> *"Clinical investigation means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration . . . or need not meet the requirements for prior submission to the Food and Drug Administration . . . but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit . . . "*

The terms *research, clinical research, clinical study, study*, and *clinical investigation* are deemed synonymous. Note, this list of terms does not include the term clinical trial, yet for the purposes of this overview you should also consider it a synonym.

The Centers for Medicare & Medicaid Services (CMS) developed a set of policies and billing requirements for investigational items and services and what it terms *investigational drugs and biologics, experimental medical devices,* and *investigational medical devices* (which are considered nonexperimental).

2. *Federal Register,* Vol. 56, No. 117. June 18, 1991.

Although these policies have brought some clarity to healthcare providers conducting clinical trials in the 21st century, they have not resulted in harmony among terms and definitions.

Types of Clinical Research

There are several categories of clinical research typically encountered in healthcare settings. The actual conduct of research in any of the categories requires resources and entails considerable costs to the individuals and organizations involved. As will be described in Chapter 2, Medicare reimburses only some of these activities.[3]

Drugs and biological products

The term *drug* is defined at 21 USC 321 (g)(1), which states in part:

> *"Drug means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals . . . "*

Note that a drug is not necessarily new, experimental, or investigational. A clinical research study may thus involve not only new drugs, but also drugs already approved and commercially available, or a combination of the two.

As will be described in Chapters 2 and 3, this can be important not only for determining whether a clinical research study qualifies for Medicare reimbursement, but also for how to notify Medicare that a patient is a participant in the study.

Biological products, also known as biologics, are regulated in a manner somewhat similar to drugs. According to the FDA, biologics include a wide range of products such as:

- Vaccines
- Blood and blood components
- Allergenics
- Somatic cells

3. The chapters in this book focus attention on the Medicare clinical research billing rules. The reasons for this are numerous: The Medicare rules are the most developed in the industry to date; Medicaid and private insurance plans tend to follow Medicare billing rules; and failure to comply with Medicare billing rules carry significant penalties.

- Gene therapy
- Tissues
- Recombinant therapeutic proteins[4]

Biologics can be composed of sugars, proteins, nucleic acids, or complex combinations of these substances. Additionally, biologics may be living entities such as cells and tissues. Clinical trials of some biologics are similar to trials of drugs but are often more complex. For example, gene therapy involves biologics and requires much greater scrutiny, follow-up, and cost than most drugs.

Clinical research studies with drugs and biologics can occur in either the inpatient or outpatient settings. Today, the majority of outpatient research in the United States is conducted in the private practice setting, although academic medical centers also conduct a significant volume of clinical research. It should be noted, however, that many inpatient trials do require that certain items and services be provided in a hospital.

Today, the majority of outpatient research in the United States is conducted in the private practice setting, although academic medical centers also conduct a significant volume of clinical research.

Also, it is not unusual for physicians with private practices operating from space leased by a hospital or who are located in facilities near a hospital to send patients to that hospital for research-related services. Therefore, it is important to identify such patients to ensure that their bills are not treated as routine care.

Medical devices

Most people tend to think of medical devices in terms of prostheses or implantable devices, such as pacemakers. But the definition is actually much broader. According to the Food, Drug and Cosmetic Act, Section 201, a medical device is:

> *" . . . an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar article that is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease."*[5]

4. 21 *CFR* Part 600 Chapter I, Subpart F.
5. 21 *CFR* Part 814 Chapter I, Subpart H.

This definition includes a broad range of possibilities, from an artificial heart to home HIV-testing kits, from magnetic resonance imaging scanners to medical adhesives or cements. Medical devices are categorized as approved, investigational, or experimental. Investigational devices are further categorized as having either significant or nonsignificant risk.

As will be discussed in detail in Chapter 2, the rules for billing Medicare in clinical trials of medical devices are different than billing for drugs, biologics, and other investigational items and services. This billing issue can become further confused when the research involves a combination of a medical device and a new drug or biologic, such as in a gene therapy study in which an experimental virus is administered with a new injection device.

Registries

Registries are databases of patient information and encompass a broad range of activities. For example, many registries involve databases for research endeavors to track the safety of drugs and medical devices after they are approved for marketing and during a period in which they are being used in a much larger population than was used for clinical trials.

For example, the FDA often requires that device safety is tracked in postmarketing surveillance studies. As with clinical trials, participation in a registry incurs costs in addition to those required for the provision of healthcare alone. The costs of participation are generally not billable to Medicare, however, with the notable exception of registries under *Coverage with Evidence Development* (discussed later).

Registries are not necessarily related to FDA-approved technologies and can also involve the collection of tissue samples or biological specimens. Such registries are also referred to as *biorepositories or biobanks* and include the collection and long-term storage of biological specimens (which may or may not include identifiers) for specified or unspecified future research.

Another type of registry might involve patients with a particular disease, in which long-term outcome data are collected and tracked and used to understand the natural progression of a disorder. Not all registries exist for research purposes; some registries are required as part of public health surveillance, including tumor registries that are mandated by states and the collection of data on sexually transmitted diseases.

Outcomes Research

Evidence-based medicine is the application of clinical research results to the practice of medicine. But clinical research is not limited to development or use of new therapeutic and diagnostic technologies. Clinical research often involves comparisons of existing treatment modalities, nursing care, surgical techniques, clinical monitoring, etc., to determine which modality yields superior clinical outcomes, such as faster recovery.

So-called outcomes research is the cornerstone of evidence-based medicine and occurs throughout academic medical centers and many community hospitals. Outcomes research can be either prospective or retrospective. The costs associated with the collection and analysis of this research are generally not reimbursable by Medicare.

Coverage with evidence development

The process of obtaining approval from the FDA to market drugs and medical devices is separate from the process of approval for reimbursement from Medicare. It is not unusual for new medical technologies to be FDA-approved but not yet receive reimbursement from payers.

Similarly, expensive medical technologies may be approved for a narrow indication, yet also be used for more widespread indications—so-called off-label use. Although such use is permitted, Medicare may refuse reimbursement and, in some cases, specifically prohibit healthcare providers from submitting bills for off-label use.

A relatively new and important exception is a category of clinical research called *coverage with evidence development (CED)*. Under CED, coverage for specific tests or procedures may be contingent upon the prospective collection of data under a formal clinical research registry. Additional information about CED studies can be found in Chapter 2.

Clinical Research Investigators

The prototypical clinical research investigator (sometimes known as the *principal investigator* [*PI*] is a physician who, in addition to providing clinical care to his or her patients in the practice, clinic, or hospital setting, is also engaged in clinical trials involving a subset of patients.

Ideally, the physician investigator delegates some clinical responsibilities to others, including research professionals like certified clinical research coordinators. More often, these investigators delegate

responsibilities to members of the clinical care team, including nurses, physician extenders, and office assistants. Occasionally, investigators work alone, without assistance.

Not all clinical research investigators are physician investigators. Depending on the nature of the study, nurses, psychologists, pharmacists, or other nonphysician scientists may be principal investigators.

Clinical Research Sites

Generally, clinical research activities occur at sites where healthcare is also provided, leading to the challenges surrounding compliant billing. Inpatient studies occur in hospitals, where billing may often be most complicated.

Hospitals also conduct a fair amount of outpatient research through clinics or outpatient departments of the hospital. Most hospitals have developed efficient charge-capture systems to ensure timely payment for clinical services. As discussed in detail in Chapter 4, it is essential for hospitals to identify nonroutine care items and services to route the bills appropriately.

Most hospital bills involve technical fees that also have associated professional fees, such as an x-ray (technical fee) that is then interpreted by a radiologist (professional fee). As explained in greater detail in Chapter 4, the professional fees for nonroutine care must also be segregated from Medicare bills, whether the physician is in private practice or employed by the hospital.

Some hospitals engaged in clinical research may be part of a larger university system, and it is not unusual for the actual clinical research award to be held by the university, rather than the hospital. These awards come in the form of contracts by an outside entity, like a drug company or non-profit foundation, or in the form of a grant from a public agency like the National Institutes of Health (NIH). In such cases, it is imperative that the university and the hospital(s) share essential information to ensure proper billing.

This is even more important when the research project is funded by a governmental agency or department such as the NIH. In these cases, not only is the possibility of double-billing exacerbated by the fact that the payer is the federal government in both cases, but it is important to verify that the amounts paid by the federal grant or contract for items and services are not in excess of what the federal government has agreed to pay (discussed later).

Outpatient research conducted in the clinical or medical office settings must be managed in much the same way as inpatient research, though outpatient research tends to be less complicated, mostly because of study design.

Yet in both settings the same billing prohibitions apply—billing for items and services:

- Paid from another source
- Provided solely for research purposes
- Promised free to research participants in the informed consent form

As such, billing systems must be employed to segregate billable research (e.g., routine care) from nonbillable research services. Although some physicians have transformed their practices into full-time outpatient research operations, in some cases they also bill Medicare and other payers for routine care and therefore need the same set of controls in order to avoid billing anomalies.

Sponsors of Clinical Research

The term *sponsor* is generally used to describe any entity that provides funding or reimbursement for clinical research. For corporate studies, the sponsor is typically a pharmaceutical, medical device, or biotech company that contracts with the research site and investigator to carry out their research.

Among U.S. federal agencies, the NIH is most typically a sponsor of clinical research (through grants, contracts, or subcontracts). Other agencies sponsor research activity, including the U.S. Department of Defense. Private foundations can also be clinical research sponsors, such as the Juvenile Diabetes Research Foundation and the Cystic Fibrosis Foundation. A university or hospital itself can also be a sponsor of research, either at its own or other facilities, or in the community.

Finally, clinical research can be conducted without the allocation of specific funds—so-called *unfunded* or *unsponsored research*. However, this is a misnomer, because even in the absence of funds that are specifically earmarked for a study, the study itself always involves additional cost, and it is more accurate to refer to such research as self-funded or funded in-kind.

Self-funded research must be treated no differently from sponsored research, because with or without a sponsor, only certain routine care can be billed to payers. It is therefore necessary to segregate billable from nonbillable charges even when the costs are written off.

Clinical trial agreements

The garden-variety clinical trial is sponsored by a company through a contract or clinical trial agreement (CTA). The contract typically includes, among other provisions, the responsibilities of the site and the sponsor and an itemized budget, which generally includes the specifics of payment for the items and services required to collect the data. Sponsors sometimes agree to pay for all clinical services delivered during the course of a study, but more often expect third-party payers to be billed for routine care[6] of their subscribers.

The CTA also requires the site and investigator to promise not to bill the payers for any items and services for which the sponsor has agreed to pay. This serves as a reminder for all research and billing personnel that the providers must find the means to identify research costs on the bills of every research participant.

The site and the sponsor engage in an arms-length negotiation to determine the amounts to be reimbursed to the site. For items and services that the site might bill to Medicare in the absence of a clinical trial, the site is free to seek payments from sponsors that may be significantly higher than the Medicare reimbursement rate.

Yet the site must be careful to not accept payments that are so high as to be considered an enticement to use/purchase the sponsor's product. However, if the sponsor is the U.S. government, the provider cannot charge in excess of the Medicare rate unless it has an agreement with the Department of Health and Human Services allowing it to do so.

Investigators may choose to participate in a research protocol that was developed by others, as in the case of a multisite clinical trial designed and sponsored by a pharmaceutical company, or they may design their own studies, a category referred to as *investigator-initiated research*. The rules and regulations surrounding this type of research are essentially the same as for sponsor-designed research. However, sponsors often provide financial and regulatory support that may be unavailable to investigator-initiated research projects, which raises the risks of noncompliance for this category of research.

6. The term *routine care,* when used throughout the chapters in this book, is intended to mean the items and services that would have otherwise been provided to the research subject were they not participating in the clinical research. They are distinguished from the items and services that are provided over the course of the research solely to gather research data. Most, but not all, routine care is reimbursed by Medicare, and most, but not all, research services are not reimbursed by Medicare. The distinction between billable and nonbillable services is described and segregated more fully in Chapter 2.

Self-funded research must be treated no differently from sponsored research, because with or without a sponsor, only certain routine care can be billed to payers. It is therefore necessary to segregate billable from nonbillable charges, even when the costs are written off.

Research Activities

For the purposes of understanding clinical trial billing and budgeting, there are two broad categories of activities—the provision of:

1. Clinical items and services
2. Nonclinical items and services

The first category is the one that provides the greatest opportunity for errors. Clinical items and services are listed in the site's charge description master and typically involve professional fees, as well. These are the exact same items and services that healthcare providers render on a routine basis during the provision of treatment. These items invoke a risk of billing noncompliance precisely because they involve the same activities for a research study as they involve for routine clinical care.

For example, a computed tomography (CT) scan of the brain plus the professional interpretation can be billed either to a third-party payer as a clinical event, or it can be billed to the sponsor of a research study, depending on the budget for that particular study and the underlying reason for conducting the CT scan.

Moreover, the same CT scan might be billable to the payer the first and second time it is performed in a particular clinical research study, but not the third time, depending on what is accepted as routine care for a patient with that disease or condition. The details of which clinical item or service is billed to the payer versus the study sponsor should be planned and clearly noted in the study budget to make sure that only one party is billed for the same item or service, and also to ensure that the party that is billed is the correct party. Failure to segregate these charges appropriately is among the factors leading to the CMS Clinical Trial Policy, discussed later in this book.

The second category involves nonclinical items and services that are part of the study budget but are nonbillable, at least in terms of billing a third-party payer. There are two major subcategories in this group:

1. Data collection
2. Other services

Data collection refers to the time and effort spent to ensure that accurate data are reported to the sponsor. Typically, this includes the salary and benefits paid to study coordinators or other study support personnel, as well as the additional time spent by the PI.

Other research services might include quality assurance, travel, record retention, etc. These items should be paid for by the sponsor, but they do not involve risk of billing noncompliance because they are outside the realm of activities that could trigger a clinical bill.

Clinical Research Billing: Chaos and Control

The regulations governing Medicare billing have never been known for their clarity or inveteracy. In the absence of specific rules for clinical research, it might be imagined that practices vary widely, ranging from the comingling of bills for routine costs and research to their strict segregation. Although no one knows for sure, there are reasons to suspect that prior to 1994, the vast majority of research activity was billed as routine care.

Case study

Investigational impetus

In March 1994, a landmark qui tam, or whistleblower, case was filed by Kevin Cosens against 132 hospitals in 32 states.[7] Cosens, a former Medtronic salesman, alleged, among other things, that hospitals filed false claims with Medicare for cardiac devices that were investigational.

This caught the attention of healthcare compliance professionals because hundreds of millions of dollars were collected as hospitals settled with the government. Until that landmark case, much of this activity remained under the radar of hospital billing systems. The case caused hospitals to focus on medical device research and the associated billing risks.

In 1995, CMS published the device reimbursement regulations found at 42 *CFR* Part 405 addressing coverage for Category B devices as well as certain related services and subsequently expanded coverage (in part) to Category A device trials as part of the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

7. Wilcox, JD. Hospital whistle-blower could pocket $20 million. *Pittsburgh Tribune Review.* June 8, 2002.

In September of 2000, President Clinton attempted to bring additional clarity to the system by prompting CMS to draft the National Coverage Decision on Medicare Coverage Routine Costs of Beneficiaries in Clinical Trials (NCD).[8] Unfortunately, this well-intentioned effort added to the confusion because there was no clear or agreed-upon system for Medicare or for providers to implement it.

In June 2007, CMS brought some clarity to the issue of billing for trials with its final version of the NCD for Routine Costs in Clinical Trials, known as the Clinical Trials Policy (CTP).[9] As discussed in detail in Chapter 2, providers now have some rules to manage compliant billing for investigational studies. This, together with the discussion on billing in medical device studies, provides helpful road maps for managing clinical research billing risk.

8. The NCD published in September 2000 was updated in June 2006 and the name was changed to the Clinical Trials Policy. Thus, throughout this book, the term NCD/CTP will be used to refer to the rule. The rule has been incorporated into the *National Coverage Determinations Manual* and can be found at §310.1.

9. *www.cms.hhs.gov/Transmittals/downloads/R74NCD.pdf*

HCPro

Order your copy today!

Please fill in the title, price, order code and quantity, and add applicable shipping and tax. For price and order code, please visit *www.hcmarketplace.com*. If you received a special offer or discount source code, please enter it below.

Title	Price	Order Code	Quantity	Total
				$

Your order is fully covered by a 30-day, money-back guarantee.

Shipping* (see information below)	$
Sales Tax** (see information below)	$
Grand Total	$

➲ **Enter your special Source Code here:**

Name

Title

Organization

Street Address

City State ZIP

Telephone Fax

E-mail Address

***Shipping Information**
Please include applicable shipping. For books under $100, add $10. For books over $100, add $18. For shipping to AK, HI, or PR, add $21.95.

****Tax Information**
Please include applicable sales tax. States that tax products and shipping and handling: CA, CO, CT, FL, GA, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, NC, NJ, NM, NY, OH, OK, PA, RI, SC, TN, TX, VA, VT, WA, WI, WV.

State that taxes products only: AZ.

BILLING OPTIONS:

☐ Bill me ☐ Check enclosed (payable to HCPro, Inc.) ☐ Bill my facility with PO # _____

☐ Bill my (✓ one): ☐ VISA ☐ MasterCard ☐ AmEx ☐ Discover

Signature Account No. Exp. Date

(Required for authorization) (Your credit card bill will reflect a charge from HCPro, Inc.)

Order online at *www.hcmarketplace.com*

Or if you prefer:

MAIL THE COMPLETED ORDER FORM TO: HCPro, Inc. P.O. Box 1168, Marblehead, MA 01945

CALL OUR CUSTOMER SERVICE DEPARTMENT AT: 800/650-6787

FAX THE COMPLETED ORDER FORM TO: 800/639-8511

E-MAIL: *customerservice@hcpro.com*

 Code: EBKPDF