

# Compliant Clinical Trial Coding & Billing

A White Paper Provided by Coding Strategies Inc.



Clinical trials are carefully designed research studies that test promising new cancer treatments, and help researchers determine the overall efficacy and therapeutic value of a new drug or treatment method compared with conventional treatment. They are crucial to determining the safety of medical interventions and the ability to achieve particular health outcomes and represent a significant investment from all involved — patients and others who volunteer to participate, organizations that sponsor trials, and the researchers who conduct a study and analyze the data. In general patients participate in clinical trials to:

- Gain access to a new treatment not available outside of the study;
- Potentially improve their treatment outcomes; and
- Contribute to the advancement of medical science and the improvement of available therapies.

Both governmental payors and traditional health insurers are considering the use of evidence-based healthcare

when determining the medical necessity of covered services. One definition of evidence-based medicine is “the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients.” Definitive clinical trial data and analysis contributes to the understanding of disease processes and responses to treatments. For example, the strongest evidence for a therapeutic intervention may be provided by the systematic review of randomized, double-blind clinical trials.

On June 7, 2000, the President of the United States issued an executive memorandum directing the Secretary of Health and Human Services to “explicitly authorize [Medicare] payment for routine patient care costs... and costs due to medical complications associated with participation in clinical trials.”<sup>1</sup> As a result, the Centers for Medicare & Medicaid Services (CMS) began reimbursing for routine services performed in connection with clinical trials; however, CMS suspects that they have been reimbursing for services that are not “routine” care.

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## Qualified Clinical Trials

In an effort to provide detailed information on clinical trial coverage, CMS published a National Coverage Determination (NCD) for Routine Costs in Clinical Trials.<sup>ii</sup> CMS has further instructed Medicare contractors to *not* develop Local Coverage Determinations (LCDs) for clinical trial services; if the trial meets the criteria in the NCD it is considered to be reasonable and necessary. Clinical trials that meet the qualifying criteria will receive Medicare coverage of routine costs after the trial's lead principal investigator enrolls the trial and certifies that the trial meets the criteria.

Any clinical trial receiving Medicare coverage of routine costs must meet the following three requirements:

- The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (e.g., physicians' service, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).
- The trial must not be designed exclusively to test toxicity or disease pathophysiology; it must have therapeutic intent.
- Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.

However, the three requirements above are insufficient by themselves to qualify a clinical trial for Medicare coverage of routine costs. Clinical trials should also have the following desirable characteristics:

1. The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes;
2. The trial is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use;
3. The trial does not unjustifiably duplicate existing studies;
4. The trial design is appropriate to answer the research question being asked in the trial;
5. The trial is sponsored by a credible organization

or individual capable of executing the proposed trial successfully;

6. The trial is in compliance with Federal regulations relating to the protection of human subjects; and
7. All aspects of the trial are conducted according to the appropriate standards of scientific integrity.

Effective September 19, 2000, some trials, as described below, are presumed to meet these characteristics and are automatically qualified to receive Medicare coverage:

The billing provider must include in the beneficiary's medical record the following information:

- Trial name,
- Sponsor, and
- Sponsor-assigned protocol number.

This information does not need to be submitted with the claim but must be provided if requested for medical review.

1. Trials funded by the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Agency for Healthcare Research & Quality (AHRQ), Centers for Medicare & Medicaid Services (CMS), United States Department of Defense (DOD), and the US Department of Veterans Affairs (VA);

2. Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD and VA;

3. Trials conducted under an investigational new drug application (IND) reviewed by the Food and Drug Administration (FDA); and

4. Drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1) will be deemed automatically qualified until the qualifying criteria are developed and the certification process is in place.

In addition, all clinical trials have a written protocol and this protocol must discuss how the results are to be generalized to the Medicare population. Clinical trials covered by Medicare are registered on [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov)

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## Routine Costs

Deciding which services represent “routine care” and which services are considered to be investigational is one of the biggest challenges when billing for clinical trial services. For example, if a non-trial patient would receive a single pre-treatment CT scan, this same imaging study would be reimbursed by Medicare for a clinical trial patient. However, if the trial protocol includes monthly CT scans while the patient is under treatment to obtain more data on treatment response, these additional scans would be part of the “investigational” charges.

According to CMS, routine costs of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial. As a result, it will be necessary to review the individual trial information to determine the extent of services to be performed in compliance with the trial protocol; then segment those services into routine costs and investigational costs.

Routine costs include, but may not be limited to:

- Items or services that are typically provided for direct patient care absent a clinical trial (e.g., medically necessary conventional care);
- Items or services required solely for the provision of the investigational item or service (e.g., administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and

- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service in particular, for the diagnosis or treatment of complications.

## Investigational Costs

Investigational clinical services are defined as those items and services that are being investigated as an objective within the study. Investigational clinical services may include items or services that are approved, unapproved, or otherwise covered (or not covered) under Medicare. Investigational costs also include administrative services; defined as all non-clinical services, such as investigator or coordinator salaries; protocol development; participant recruiting costs; data quality assurance activities; statistical analyses; dissemination of findings; and study management.

Investigational costs include, but may not be limited to:

- The investigational item or service, itself unless otherwise covered outside of the clinical trial;
- Items and services for which there is no Medicare benefit category;
- Items and services provided solely to determine trial eligibility;
- Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and
- Items and services customarily provided by the

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## Sample Clinical Trial Coverage Analysis

Procedures	Pre-Study Screening	Baseline	Visit 1	Visit 2	Visit 3
Patient visit/examination	R	R	T	R	T
Administration of study drug			T	T	T
Imaging studies (CT, MR, PET, etc.)	R	R	R	T	R
Hematology (CBC, platelets, etc.)		R	T	T	T
Chemistry		R		R	
Specimen collection		R	T	T	T
Miscellaneous Expenses (parking, etc.)	R	R	R	R	R

R = Research (sponsor funded)  
T = Third-Party Payor  
P = Trial Participant  
N = Not Billable to sponsor or insurer

research sponsors free of charge for any enrollee in the trial.

Providers are not required to submit charges for items and services provided free-of-charge by research sponsors, since these things are typically not separately reimbursed. If it is necessary for a provider to show the items and services that are provided free-of-charge in order to receive payment for the covered routine costs (e.g. administration of a non-covered chemotherapeutic agent), hospitals are instructed to submit such charges as non-covered on the UB04 claim form at the time of entry.<sup>iv</sup>

In addition, under Outpatient Prospective Payment System (OPPS) claims submitted to Medicare by the hospital must include a token charge for a “no cost” item in the covered charge field along with the applicable HCPCS modifier (i.e., modifier FB, item provided without cost to supplier or practitioner) appended to the procedure code that reports the service provided to furnish the “no cost” item.

Remember that there is no reimbursement “double dipping” – services cannot be charged both to the patient’s insurance and to the trial sponsor. If the research budget includes payment for a necessary service also considered routine care, and the clinical trial sponsor is paying for it, the provider cannot also bill this service to the insurance payor.

## Deductible and Coinsurance

Medicare patients participating in a qualified clinical trial must continue to pay deductible and coinsurance amounts.<sup>v</sup> Thus, the provider of service should bill the beneficiary for co-payments and deductible, and may only waive these patient cost-sharing payments for beneficiaries who have a valid financial hardship.<sup>vi</sup>

There is nothing in the CMS regulations or instruction that prohibits a hospital or freestanding cancer center from waiving collection of charges if it is done as part of the provider’s indigency policy. By “indigency policy” CMS means a written policy developed and utilized by a hospital to determine patients’ financial ability to pay for services. CMS further defines “medically indigent” as patients whose health insurance coverage, if any, does not provide full coverage for all of their medical expenses and that their medical expenses, in relationship to their income, would make them indigent if they were forced to pay full charges for their medical expenses.

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A question answered by CMS in the same document states:

Question: May a research sponsor pay Medicare copays for beneficiaries in a clinical trial?

Answer: If a research sponsor offers to pay cost-sharing amounts owed by the beneficiary, this could be a fraud and abuse problem. In addition to CMS' policy, the Office of Inspector General (OIG) advises that nothing in OIG rules or regulations under the Federal anti-kickback statute prohibits hospitals from waiving collection of charges to uninsured patients of limited means, so long as the waiver is not linked in any manner to the generation of business payable by a Federal health care program.

The citations include 42 U.S.C. 1320a-7(a)(i)(6); OIG Special Advisory Bulletin on Offering Gifts to Beneficiaries:

<http://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf>

And the OIG Special Fraud Alert on Routine Waivers of Copayments and Deductibles:

<http://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html>

## Required Diagnosis Code

All claims submitted for a patient treated under a clinical trial protocol must include ICD-10-CM diagnosis code Z00.6 (Encounter for examination for normal comparison and control in clinical research program) as a secondary or subsequent diagnosis code. Remember that this diagnosis code is reported on all treatments, imaging studies, laboratory tests and other procedures performed during the time period that the patient participates in the clinical trial. As described on the prior page, each clinical trial may have a different participation time frame; some trials may include only the time the patient is actively treated, while others may include the duration of treatment and a specified follow-up period.

## Modifiers

Medicare requires, and other payors may utilize, modifiers for clinical trial services on outpatient hospital and freestanding center claims for *all* services provided to a clinical trial patient.<sup>viii</sup> Each procedure or service billed for a patient participating in a clinical trial must include one of these modifiers.<sup>ix</sup>

Investigational clinical services are defined as those items

and services that are being investigated as an objective within the study. Investigational clinical services may include items or services that are approved, unapproved, or otherwise covered (or not covered) under Medicare. Even though the charges for investigational services will not be reimbursed, they still must be billed with modifier QØ.

QØ Investigational clinical service provided in a clinical research study that is in an approved clinical research study.

For example, a patient receiving standard treatment for a specified condition would have an order for a single CT scan prior to treatment. If the clinical research patient will receive weekly CT scans during the treatment portion of the trial, these scans will be reported with the QØ modifier to indicate that they are performed for data analysis rather than for patient treatment.

Routine clinical services are defined as those items and services that are covered for Medicare beneficiaries outside of the clinical research study; are used for the direct patient management within the study; and do not meet the definition of investigational clinical services. Routine clinical services may include items or services required solely for the provision of the investigational clinical services; clinically appropriate monitoring, whether or not required by the investigational clinical service; and items or services required for the prevention, diagnosis, or treatment of research related adverse events.

Q1 Routine clinical service provided in a clinical research study that is in an approved clinical research study.

For example, drug administration services for a patient participating in a clinical trial that will test an investigational monoclonal antibody would be considered a routine cost reported with modifier Q1.

It is important to recognize that if the cancer center or program is managing a clinical trial patient, it falls to the staff in this department to notify the laboratory, imaging center and any other medical entity that interacts with the patient of the patient's clinical trial status. In addition, these ancillary providers must be alerted regarding correct modifier reporting (e.g., modifier QØ or modifier Q1). For example, if the imaging center will perform a data analysis CT scan for the patient that will be reported with modifier QØ, the individual or facility coordinating patient care must have a process to pay directly for this service and include the charges on the bill to the trial sponsor.

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## Clinical Trial Number

Effective April 1, 2008, CMS allowed the *voluntary* submission of the 8-digit clinical trial number on both the hospital and physician claim forms. The number that CMS requested is the number assigned by the National Library of Medicine (NLM) Clinical Trials Data Bank when a sponsor or investigator registers a new study. CMS has been using this number to identify all items and services provided to beneficiaries during their participation in a clinical trial.<sup>x</sup> This identifier also permitted CMS to meet the recommendations from the White House Executive Memorandum to increase Medicare participation in clinical trials by tracking Medicare payments for trial services, using the information gathered to make informed coverage decisions and ensuring that research focuses on issues that are important to the Medicare population.

Effective January 1, 2014 CMS will no longer consider the inclusion of the clinical trial number to be voluntary; instead, healthcare providers will be required to report the 8-digit trial number on all claims during the time period the beneficiary participates in the trial. MLN Matters MM8401, dated August 9, 2013, includes detailed claim submission requirements and states:<sup>xi</sup>

Medicare Part B clinical trial/registry/study claims with dates of service on and after January 1, 2014, not containing an 8-digit clinical trial number will be returned as unprocessable to the provider for inclusion of the trial number.

Accompanying Transmittal 2758, also dated August 9, 2013 adds:

The clinical trial number that the Centers for Medicare & Medicaid Services (CMS) is making mandatory is the same number that has been reported voluntarily since the implementation of CR5790, TR310, dated January 18, 2008, the number assigned by the National Library of Medicine (NLM) ClinicalTrials.gov website when a new study appears in the NLM Clinical Trials data base.

All hospitals, freestanding centers and physicians should keep in mind that once the clinical trial number has been captured by the CMS Common Working File (CWF), *any* subsequent claim for that patient without the mandatory NLM study number could be rejected. As a result, it is essential that internal tracking of clinical trial patients, manually or electronically, be maintained to ensure that all services, including but not limited to, treatment, imaging, laboratory, professional charges, surgery and other related diagnostic and/or therapeutic procedures include the appropriate clinical trial number to prevent claim rejection. In addition, all physicians and facilities providing any part of the trial patient's care must coordinate to appropriately report investigational and routine services performed as part of the trial protocol.

MLN Matters SE1344 was released in early January and includes an update regarding the mandatory submission of the 8-digit clinical trial number on all claims for Medicare patients participating in an approved clinical trial.<sup>xii</sup> Subsequent to the requirement for inclusion of the clinical trial number, CMS learned that some physicians, hospitals or

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## Claim Form Submission

Clinical trial claims are identified through the presence of the following elements; remember that either modifier Q1 or modifier Q0 will be appended to each claim line.

### Modifier Q1

- Routine clinical service provided in a clinical research study that is an approved clinical research study

### Modifier Q0

- Investigational clinical service provided in a clinical research study that is an approved clinical research study

### Z00.6

- Encounter for examination for normal comparison and control in clinical research program

### Mandatory

- 8-digit clinical trial number

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other healthcare providers did not have the ability to submit this identifier. As a result, CMS provided an option to submit a generic number in place of the actual National Clinical Trials (NCT) number.

Beginning January 1, 2014 and continuing no later than December 31, 2014, those physicians, providers and suppliers *who do not have the capability of submitting the actual clinical trial number* may instead report an 8-digit generic number of 99999999 using the same submission instructions previously published. CMS reiterated that trial-related claims will be returned if they do not contain either the actual clinical trial identifier number or the 8-digit generic number 99999999 – the field cannot be left blank. CMS stresses that if providers can report the actual clinical trial number, that is the number that should be included on the claim; the generic number is *only* to be reported by those healthcare providers who do not have the ability to report the actual number.

And remember, the clinical trial identification number is required for all items and services provided in relation to participation in a clinical trial, clinical study or registry that may result from coverage with evidence development (CED), the Medicare Clinical Trial Policy, or a CMS-approved investigational device exemption (IDE) study.

### Medicare Managed Care

The Balanced Budget Act of 1997 (BBA) established a new Part C of the Medicare program, known then as the Medicare+Choice (M+C), effective January 1999. As part of the M+C program, the BBA authorized CMS to contract with public or private organizations to offer a variety of health plan options for beneficiaries, including both traditional managed care plans and new options that were not previously authorized.

The M+C program in Part C of Medicare was renamed the Medicare Advantage (MA) Program pursuant to Title II of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), which was enacted on December 8, 2003. The MMA updated and improved the choice of plans for beneficiaries under Part C, and changed the way benefits are established and payments are made. Under the MMA, beneficiaries may choose from

additional plan options, including regional PPO (RPPO) plans and special needs plans (SNPs).

Original Medicare pays for the costs of routine services provided to an MA enrollee who joins a qualifying clinical trial. MA plans pay the enrollee the difference between Original Medicare cost-sharing incurred for qualifying clinical trial items and services and the MA plan’s in-network cost-sharing for the same category of items and services.

To be eligible for reimbursement, beneficiaries (or providers acting on their behalf) must notify their plan that they have received qualified clinical trial services and provide documentation of the cost-sharing incurred, such as a Medicare Summary Notice (MSN). Medicare Advantage organizations (MAOs) are also permitted to seek MA member Original Medicare cost-sharing information directly from clinical trial providers.

However, for beneficiaries enrolled in a managed care plan, hospital providers must not bill outpatient clinical trial services and non-clinical trial services on the same claim. If covered outpatient services unrelated to the clinical trial are rendered during the same day/stay, the provider must split-bill so that **ONLY** the clinical trial services are contained on a single claim and billed as fee-for-service (this allows the Medicare claims processing system to not apply deductible when the patient is found to be in a managed care plan). Any outpatient services unrelated to the clinical trial should be billed to the managed care plan.

### Other Payors

Section 10103(c) of the Patient Protection and Affordable Care Act (PPACA or ACA) added a new provision to the federal Public Health Service Act which imposes requirements on group health plans and health insurance issuers offering individual or group health insurance products to provide for coverage of routine patient costs associated with approved clinical trials. This is the first federal law mandating group health plans (including new self-funded arrangements) and state-licensed health insurance issuers to cover the standard of care costs associated with participation in clinical trials.

The provision, new section 2709 of the Public Health Service Act, states in part:

Prohibition on denials of coverage or on discrimination. With respect to plan years beginning on or after January 1, 2014, if a group health plan or health insurance issuer offering group or individual coverage provides coverage to a qualified individual, then the plan or issuer is prohibited, under federal law, from doing any of the following:

1. Denying the individual participation in an approved clinical trial.
2. Denying or limiting, or imposing additional conditions on, the coverage of routine patient costs for items or services furnished in connection with participation in the approved clinical trial.
3. Discriminating against the individual on the basis of the individual's participation in the approved clinical trial.

A qualified individual is defined under law as an individual who is enrolled or participating in a health plan or coverage and who is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of cancer or another life-threatening disease or condition. There is an additional requirement that a determination be made that the individual's participation in the approved clinical trial is appropriate to treat the disease or condition.

There is also a definition of "routine patient costs" for purposes of these new federal requirements. In general, routine patient costs include all items and services consistent with the coverage provided by the plan for a qualified individual who is not enrolled in a clinical trial. The plan or issuer is not required under federal law to pay for the following:

- The cost of the investigational item, device or service.
- The cost of items and services provided solely to satisfy data collection and analysis needs and that are not used in direct clinical management.
- The cost for a service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis.

The statute also has a slightly different definition of "approved clinical trial" than that established for Medicare patients. For non-Medicare patients an approved clinical trial is a Phase I, Phase II, Phase III or Phase IV clinical trial that is conducted in relation to the prevention, detection or treatment of cancer or other life-threatening disease or condition and is one of the following:

1. A federally funded or approved trial (funded

or approved by the NIH, CDC, AHRQ, CMS DOD or Department of Veteran's Affairs).

2. A clinical trial conducted under an FDA [Food & Drug Administration] investigational new drug application.
3. A drug trial that is exempt from the requirement of an FDA investigational new drug application.

Of importance, a plan or issuer may require the individual to participate in the approved clinical trial through a participating provider if the provider will accept the individual as a participant in the trial. An additional clarification is that these new requirements are not intended to require a plan or issuer to provide benefits for routine patient services out-of-network unless out-of-network benefits are otherwise provided under the plan or coverage. Last, payors are only required to provide coverage of services and items delivered by out-of-network providers if the approved clinical trial is only offered outside the patient's state of residence.

Remember, these new federal requirements will not apply to grandfathered health plans. Section 1251 of the ACA states that a grandfathered health plan is a group plan or health insurance coverage in which an individual was enrolled on the date of enactment (March 23, 2010) and, unless otherwise specified, is exempt from the requirements of Title I of the Act. According to the Association of Community Cancer Centers (ACCC):<sup>xiii</sup>

Given that initially the vast majority of group health plans and health insurance coverage will be grandfathered, the impact of the application of these new federal requirements is far from sweeping.

Section 2709 of the Public Health Service Act (the section imposing these new federal requirements for coverage of approved clinical trials) makes it clear that it does not preempt any state laws that require a clinical trials policy for state regulated plans that is in addition to the policy required under this section. As a result, the federal requirements are minimums; states may impose additional requirements.

Those commercial third-party payors that are not impacted by the ACA and do not accept the same guidelines as Medicare with respect to clinical trial services, may classify clinical trial services as "investigational" or "experimental." As a result, providers should obtain individual insurance payor guidelines in writing to ensure they correctly bill services associated with a clinical trial. Thirty-four states and the District of Columbia have enacted laws regarding clinical trials, which are listed at:

<http://www.cancer.gov/clinicaltrials/learningabout/payingfor/laws>

## Billing Research Services

A clinical study coordinator (CSC), also called a clinical trial coordinator (CTC) or clinical research coordinator (CRC), is a health-care professional who works under the direct supervision of a physician investigator or a clinical trial associate. This individual is responsible for organizing all aspects of a medical or pharmaceutical research project and duties may include recruiting participants, collecting research data and managing all calendars as they relate to the project.

The health and safety of the human subjects used in the trials is the main concern of a clinical trial coordinator. He extensively studies and reviews the guidelines for the experiments and monitors the test subjects throughout the processes. In addition, many facilities that participate in clinical research employ a clinical trial management system (CTMS) to track trial patients and study outcomes.

A Clinical Trial Management System (CTMS) is a customizable software system used by some clinical research institutions, including hospitals, physician practices, academic medical centers and cancer centers, to manage the large amounts of data involved with the operation of a clinical trial. The CTMS maintains and manages the planning, preparation, performance, and reporting of clinical trials, with emphasis on keeping up-to-date contact information for participants and tracking deadlines and milestones such as those for regulatory approval or the issue of progress reports. Often, a clinical trial management system provides data to a business intelligence system, which acts as a digital dashboard for trial managers.

In the early phases of clinical trials, when the number of patients and tests are small, many trial managers use an in-house or home-grown program to handle their data. As the amount of data grows, organizations increasingly look to replace their systems with more stable, enhanced software provided by specialized vendors.

Each sponsor has different requirements that the CTMS must satisfy; it would be impossible to create a complete list of CTMS requirements. Despite differences, common requirements include: project management, budgeting and financials, patient management and recruitment, investigator management, Ethics Committee and/or Institutional Review Board approvals, compliance with US Food and Drug Administration (FDA) regulations, and compatibility with other systems such as data management systems, electronic data capture, and adverse event reporting systems.

Sites performing clinical trials can also benefit from having

their own CTMS to support their day-to-day operations in areas such as conducting study feasibility, streamlining the workflow of the trial coordinators and investigators, providing a centralized place to house all trial-related information, and making clinical data management more efficient by equipping staff with the time-saving tools necessary to optimize productivity.

Regardless of the method employed to manage the clinical trial process, consider the following:

1. Create a detailed list of all patient services and procedures that are required to meet the protocol requirements. Include patient visits, laboratory, imaging studies, drug administration, radiation therapy, surgical procedures and any other item or service.
2. Designate all services and procedures that will be paid by the sponsor (or be reimbursed from the dollar pool) as reported with modifier QØ (investigational; not separately reimbursed).
3. Designate all services performed for data-gathering or analysis as reported with modifier QØ; these services should also be paid by the sponsor or from the dollar pool.
4. Determine the medical necessity of all remaining items on the list.
5. Reimbursable services should then be reviewed to provide the patient with an estimate of their resulting liability for coinsurance and deductibles.
6. The final aspect of the billing analysis may be negotiation with the sponsor to ensure that there is sufficient reimbursement for services and procedures that will not be reimbursed by insurance.

Trained staff should negotiate contract terms, including payment policies. Successful contract negotiations are based on a full understanding of the costs and operational requirements for performing the study. Generally, an individual trained to conduct clinical research negotiations works closely with the principal investigator to secure an optimal contract.<sup>xiv</sup>

For example, the sponsor should reimburse for non-billable staff time, including extended patient visit services and the completion of reports (data coordination, completion of case report forms, copy charges, print services), investigator involvement (travel, telephone conferences, meetings, etc.), costs of creating or copying electronic information, pharmacy recordkeeping, costs of separate drug storage, documentation of trial drug destruction, maintaining a

separate laboratory preparation area, marketing costs, patient recruitment time, purchase of computer equipment and software programs.

## What Does It All Mean?

Coding and billing for clinical trial services is complex and error-prone in many departments, physician practices and facilities. There have been a total of eleven False Claims Act settlements relating to incorrect billing for clinical trial services since 2003, totaling nearly \$45 million.<sup>xv</sup>

Billing for clinical services provided to patients enrolled in research studies is problematic because often more than one provider of service is responsible for the costs incurred in the trial. It is the responsibility of the cancer center to notify all physician groups, hospitals, laboratories, imaging centers or other entities that may provide services to a patient enrolled in a clinical trial of the patient's trial status. Make certain to avoid reimbursement penalties by maintaining detailed medical records, ensuring accurate modifier and diagnosis code assignment and tracking of all medical care provided to the trial patient. □



- i. <http://www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies/index.html>
- ii. <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&fromdb=true>
- iii. <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c32.pdf>
- iv. <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c32.pdf>
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- xiv. [http://acc-cancer.org/oncology\\_issues/articles/marapr08/turgon.pdf](http://acc-cancer.org/oncology_issues/articles/marapr08/turgon.pdf)
- xv. <http://www.oig.hhs.gov/>