

Managing Billing Compliance During Clinical Research amid Changing Medicare Coverage

Health Care Providers Should Turn to Core Medicare Principles for Compliance Program Guidance

Ryan D. Meade / Andra M. Popa

Health care providers that undertake clinical research studies face an increasingly challenging task of developing and maintaining compliance safeguards and structures while the Medicare program revises its coverage rules for clinical research items and services. Throughout 2006 and 2007, the health care industry has waited for reform of the Medicare coverage rules for clinical research services, and the Centers for Medicare & Medicaid Services (CMS) has indicated that the final quarter of 2007 will finally see the much anticipated changes.

The principal Medicare coverage rule for clinical research services is in the form of a national coverage determination (NCD) that sets out when research studies qualify for coverage and then what items and services within those qualifying studies are covered.¹ This NCD was first issued in September 2000 and will have its latest revisions published October 17, 2007.²

On July 9, 2007, CMS published a revised NCD on clinical research services coverage. CMS refers to this clinical research coverage NCD as the Clinical Trial Policy (CTP). The July 2007 CTP made minor changes to the original 2000 CTP by clarifying that the investigational item or service is covered during the clinical trial if the investigational item or service is covered outside the trial.

This July 2007 revised CTP arrived after a year-long reconsideration of the CTP and the release of an extensive proposed revision in April 2007.³ The April proposal was not adopted by CMS as the deadline loomed for CMS to conclude the NCD reconsideration process. On July 19,



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Ryan D. Meade, JD, is an attorney in Chicago at Meade & Roach, LLP. He is an adjunct professor of law at Loyola University Chicago School of Law and is an assistant professor at Rush University in the College of Health Sciences.

Andra M. Popa, JD, LL.M., is a consultant with Meade & Roach, LLP and Aegis Compliance & Ethics Center, LLP.

2007, however, CMS issued the second reconsideration⁴ of the 2000 CTP that revives many of the April 2007 proposed changes and adds significant new process proposals for coverage of research services.

The second reconsideration removes the so-called deeming process and establishes a new self-certification process for study sponsors and principal investigators to certify to CMS that a research study meets certain Medicare-desired standards. When the research study is self-certified as meeting the Medicare standards, it will be a “qualifying clinical research study” and Medicare will cover “usual patient care” during the study, assuming the usual patient care would be covered by Medicare outside the research study.

Also significant in the proposal is a change in terminology from “clinical trial” to “clinical research study” in order for CMS to emphasize that this policy covers a broad range of clinical research. Accordingly, the proposed rule also changes the name of the NCD from the Clinical Trial Policy to the Clinical Research Policy (CRP).

Through formal rulemaking (*i.e.*, regulations that will be codified in the Code of Federal Regulations), CMS plans to resolve conflicts with other Medicare coverage rules that may be in conflict or not in harmony with the CRP. Significantly, device trials that have been granted an investigational device exemption by the Food & Drug Administration (FDA) have coverage set out in formal regulations and therefore are not part of the CTP or the proposed CRP.⁵

Although the state of the specifics for the coverage of clinical research services is in flux, health care providers can focus their compliance efforts on basic principles of clinical research compliance that will not be changing with the new CRP. Both the current CTP and the second reconsideration’s proposed CRP indicate that certain fundamental Medicare rules and compliance principles must be addressed no matter what the final CRP says.

Among the practical compliance considerations that must be addressed in clinical research compliance initiatives that will not change with the CRP include: the need for documentation of medical necessity for any item or service billed to Medicare, the requirement that providers not bill for items and services that are solely for research purposes or data collection, the obligation of providers not to bill for items and services during a clinical research study that have been paid by the sponsor, and the need to ensure that written informed consents accurately discuss the added costs to the enrollee and the provider does not bill for any items or services promised free in the informed consent. The compliance risks associated with not addressing clinical research compliance are as important under the CTP as they will be under the CRP.

ORGANIZING COMPLIANCE INITIATIVES AROUND CONSTANT MEDICARE COVERAGE PRINCIPLES

An important practical reason why providers should undertake thorough clinical research billing compliance initiatives is because certain compliance risks exist now that will continue to exist after issuance of the final CRP. CMS has indicated in its proposed CRP that studies that have begun enrollment by the effective date of the CRP will continue to use the current CTP as the coverage rule for the life of that study.⁶

If the final CRP maintains its currently proposed transition plan for “grandfathering” research studies that have begun enrollment before October 17, 2007, then two different NCDs on clinical research coverage will be active at the same time: the CTP and the CRP. Therefore, compliance programs will have the challenge of managing compliance safeguards for two different rules and finding the common process points. The constant Medicare principles discussed above are some of those common process points and can be used to anchor a health care provider’s research compliance billing compliance initiative.

THE JULY 2007 CLINICAL TRIAL POLICY: PRESERVATION OF STATUS QUO

Although CMS will be issuing new clinical research coverage rules before the close of 2007, health care providers will still need to apply the July 2007 CTP coverage rules for studies that begin enrollment prior to the effective date of the final CRP. The July 9, 2007 CTP reaffirmed that Medicare covers “routine costs” during “qualifying clinical trials.” Both the term “routine cost” and “qualifying clinical trial” are defined terms.

If a research study is not a qualifying clinical trial, then no items or services required by the study are covered by Medicare. The exception is treatment of complications. Medicare will cover treatment of complications from a research study.

A qualifying clinical trial is a research study that meets three criteria and is one of four types of studies that are “deemed” to have seven desirable characteristics. This involves a two-part test to determine if a research study is a qualifying clinical trial.

The following are the CTP’s three criteria as the first part of the qualifying clinical trial test:

- The study investigates an item or service that is covered by a Medicare benefit category;
- The study must have therapeutic intent; the study is not designed to exclusively test toxicity or research disease pathophysiology;
- The study enrolls subjects with diagnosed disease.

For the second part of the qualifying clinical trial test, the study must be one of four types of the following studies:

- Trials funded by the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Agency for Healthcare Research and Quality (AHRQ), Health Care Financing Administration (HCFA), U.S. Department of Defense (DOD), and U.S. Department of Veterans Affairs (VA);

- Trials supported by centers or cooperative groups that are funded by NIH, CDC, AHRQ, HCFA, DOD, and VA;
- Trials conducted under an investigational new drug (IND) application reviewed by the FDA; and
- Drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1).

The following continue to be excluded from coverage under the CTP:

- The sponsor or another party is providing the investigational item or service for free;⁷
- The item or service is excluded from coverage by statute, regulation, or a national noncoverage determination (*e.g.*, self-administered drugs in an outpatient setting that do not meet an exception);⁸
- The items and services are for research purposes only; and
- Preventive care therapy that does not meet a Medicare coverage exception.⁹

In addition, the July 2007 CTP preserves the authority of CMS to permit additional standards and criteria to be met during the Coverage with Evidence Development process. The Coverage with Evidence Development option has been used in several instances, particularly with positron emission tomography scans (PET scans).¹⁰ Items and services performed within a clinical research trial under the Coverage with Evidence Development process will be considered to be “reasonable and necessary” and be covered by Medicare.

The Coverage with Evidence Development process places an administrative burden on sponsors and principal investigators and, therefore, often is not used, though CMS continues to encourage its use.¹¹

The July 2007 CTP does not require that trial information be posted to the Internet or that the investigator self-certify as to whether all the standards of a qualifying clinical trial are met. The September 2000 clinical trial NCD indicated that self-certification of the seven desirable characteristics would be an option that CMS would offer at some point; however, CMS never operationalized the self-certification process.

SECOND RECONSIDERATION OF THE CTP: PROPOSED CHANGES

When CMS issued in mid-July 2007 a new proposed CRP in the form of a second reconsideration of the clinical trials NCD only 10 days after issuing an announcement that the status quo of the CTP would be maintained, this sent a signal to the industry that reform of the CTP was likely to happen for certain in the next round.

Overall, the proposed CRP has a coverage framework that is similar to the September 2000 CTP. For example, Medicare does not cover items and services that are not in a “qualifying clinical research study” (replacing the term “qualifying clinical trial”). As with the CTP, any items and services during a study that do not meet the standards of a qualifying clinical research study will not be covered by Medicare.

The most significant change in the proposed CRP is the removal of the deeming process and the establishment of the new self-certification process, along with an expansion of the standards that must be met for the study to be qualifying. Among the expanded standards is a broader definition of when a research study will be considered to have therapeutic intent.

Coverage under the CRP

The second reconsideration of the clinical trials NCD proposes that the sponsor or principal investigator self-certify compliance with certain Medicare-desired standards for a research study.

The seven “desirable characteristics” of the CTP will stay essentially the same and be known as “standards.” The following is the CRP’s formulation of these original standards:

- The principal purpose of the research study is to test whether a particular intervention potentially improves the participants’ health outcomes.
- The research study 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.

- The research study does not unjustifiably duplicate existing studies.
- The research study design is appropriate to answer the research question being asked in the study.
- The research study is sponsored by an organization or individual capable of executing the proposed study successfully.
- The research study is in compliance with all applicable federal regulations concerning the protection of human subjects found at 45 CFR Part 46. If a study is FDA-regulated, it also must be in compliance with 21 CFR Parts 50 and 56.
- All aspects of the research study are conducted according to the appropriate standards of scientific integrity.

The following additional standards are proposed to be added in order for a study to qualify for coverage:

- The study must have a written protocol that addresses the Medicare standards.
- The study must be registered on ClinicalTrials.gov prior to subject enrollment.
- The protocol must provide method and timing of public release of the outcomes of the study, whether positive or negative.
- The protocol must discuss how the study addresses subpopulations.
- The protocol must discuss “how the results are or are not expected to be generalizable to the Medicare population.”

An additional standard requires that the research study have therapeutic intent. The proposed CRP standard is a significant rewrite of the CTP therapeutic intent requirement. Under the proposed CRP, the therapeutic intent standard can be met if any of the objectives of the study is to measure health outcomes if the disease being studied is a life-threatening condition. The proposed CRP technically set out the therapeutic intent standard using the following draft language:

The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Studies of all medical

technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life-threatening as defined in 21 CFR 312.81(a) and the patient has no other viable treatment options.

This language is likely more technical than what the final CRP will set out. At the August 7, 2007, CRP Open Door Forum, CMS indicated that the final language of the standard is still being developed but that the general policy goal of the standard is to not require a distinction between whether therapeutic intent is evidenced in the primary or secondary objectives of the protocol as long as the disease being studied is life-threatening.

The implications of this revised therapeutic intent standard are significant because it will allow coverage for Phase I drug studies even if the secondary objectives include therapeutic benefit and not just the primary objective. Many Phase I cancer studies will be able to receive coverage as the result of this change. If the disease is not life-threatening, however, then presumably the protocol must identify therapeutic benefit in the primary objective in keeping with the first standard that requires that “the principal purpose of the research study is to test whether a particular intervention potentially improves the participants’ health outcomes.”

The proposed CRP states that CMS will review the self-certification paperwork only for completeness. CMS will provide notice that the sponsor or principal investigator has certified compliance by posting the research study title and a registration number on the CMS Web site, ClinicalTrials.gov, and in the *Federal Register*.

One of the most important points of the CRP (as it is conceptually with the CTP) is that the research study first must meet the standards that the CRP sets out before any items and services can be billed to Medicare. Once a study is self-certified as a qualifying

clinical research study, then Medicare will cover “usual patient care.” The term “usual patient care” replaces the term “routine costs” from the CTP. Usual patient care is made up of routine clinical services and investigational clinical services that would be covered outside the research study.

CONSTANT MEDICARE PRINCIPLES

The proposed CRP reinforces that certain constant Medicare principles remain in effect and are important considerations for providers that undertake clinical research services and desire to bill for any of those services. Chief among these are:

- Items and services paid for by the sponsor are not covered by Medicare.
- Items and services that are promised free in the informed consent are not covered by Medicare.
- Items and services that are for research purposes only are not covered by Medicare.

PRACTICAL IMPLICATIONS TO CLINICAL RESEARCH FROM MEDICARE COVERAGE RULES

There are two overarching practical implications for providers from both the CTP and CRP: 1) providers must identify research studies being conducted by the provider or at the provider’s site as well as the patients who are receiving those research services; and 2) providers need to review research studies in the context of the CTP or CRP and determine coverage for each item and service required by the research study. Compliance safeguards must be established to ensure that only items and services that meet the various standards and requirements set out in the CTP or CRP are billed to the Medicare program.

The research study protocol, the written informed consent document, and the clinical trial agreement with the sponsor (sometimes referred to as the “budget” within the medical research community) are frequently the basis for most of the information that is required to determine coverage for an item or service. Health care providers should pay careful attention to the creation

of these documents at the time a research study originates and spend time identifying departments and individuals who use the information within these documents as sources for their work.

The way the protocol is designed, the way the informed consent is written, and what is negotiated in the clinical trial agreement all have significant impact on whether items and services are covered. The information in these documents must be coordinated. A common mechanism to coordinate this information is known as a “coverage analysis” and takes its most popular form in a spreadsheet of items and services with coverage designations for each of the items and services.

Often these research study documents are managed by different people within the provider. Providers need to identify what persons and departments are responsible for the documents as well as what operational areas need to have access to the coverage analysis to ensure that proper billing occurs. The advent of the need for coverage analyses of research studies also has created a new position within providers known as the “coverage analyst.”

CLINICAL RESEARCH BILLING COMPLIANCE IMPLICATIONS FOR INFORMED CONSENT DOCUMENTS

The proposed CRP clarifies what has been a legal principal for some time on the role of the informed consent in Medicare coverage, namely that Medicare will not cover items and services that are promised free in the informed consent. The informed consent, although approved by an institutional review board (IRB), is usually initially prepared by the principal investigator or the principal investigator’s study coordinator.

The principal investigator should pay close attention to the informed consent document, particularly if it is based on a template document drafted by the sponsor or modeled after another institution’s informed consent. The following are specific matters that should receive careful attention:

- Template informed consent documents should be closely scrutinized to ensure that the discussion applies to how the study will be conducted by the investigator.
- The “added costs” section of the informed consent that discloses the patient’s financial responsibilities should be careful not to promise items and services that are otherwise billable to Medicare.
- The informed consent should reference the same items and services that are part of the care of the patient as set out in the protocol. Use of template documents may risk referencing services that are not being performed or not referencing services that are being performed.
- If the informed consent states that only research-related items and services are provided for free by the sponsor or department, best practice is to identify what those research-related items and services are so that the patient understands what is not his or her financial responsibility.

CLINICAL RESEARCH BILLING COMPLIANCE IMPLICATIONS FOR PROTOCOL IMPLICATIONS

The principal investigator and his or her research staff also should be concerned about the section of the research study protocol that discusses the study objectives. From a Medicare coverage perspective, the most important dimension to the study objectives is whether they reflect therapeutic intent. If the research study can legitimately state that therapeutic benefit is one of the primary objectives, then this will significantly increase the chances that the study will be a qualifying clinical trial under the CTP or a qualifying clinical research study under the proposed CRP.

While the protocol may be principally written from a scientific perspective, it also needs to be reviewed from the perspective of third-party payor reimbursement. An audit of billing for clinical research services by Medicare or other payors often will start with an examination of the protocol to determine the purposes of the study and what the study seeks to investigate, along with the items and ser-

vices required by the study. While the principal purpose of the clinical research trial protocol is to provide a scientific explanation of the study, providers can better analyze Medicare coverage of items and services in the trial and work with trial documents such as the informed consent and the clinical trial agreement if the protocol language also contemplates Medicare billing considerations.

Some of the practical points that are relevant for coverage that can be incorporated into protocol language include clearly stating the objectives of the study, identifying what items and services are for research purposes only and are not being used for the clinical management of the subject, and identifying with specificity why certain items and services are being administered or conducted for the detection or prevention of complications that may arise due to certain research items and services.

CONCLUSION

While the Medicare program considers significant changes to coverage of items and services during clinical research studies, health care providers should turn to core Medicare

principles for compliance program guidance. Frequently, the informed consent, protocol, and clinical trial agreement documents are the documents that are most significant in ensuring compliance with Medicare billing principles. These documents should be assessed at various operational stages to prevent improper Medicare billing.

Endnotes:

1. Medicare National Coverage Determination 310.1.
2. www.cms.hhs.gov/MCD/viewtrackingsheet.asp?id=210.
3. Proposed Decision Memorandum for Medicare National Clinical Trial Policy, April 10, 2007.
4. Proposed Decision Memorandum for Second Reconsideration of the Clinical Trial Policy, Renamed the Clinical Research Policy (CAG-00071R2), July 19, 2007.
5. See 42 CFR 405.201-405.215, 411.15, and 411.406.
6. CMS Oral Commentary made at CMS Open Door Forum on August 7, 2007.
7. *Medicare Benefit Policy Manual*, Ch. 16, Section 40.
8. *Medicare Benefit Policy Manual*, Ch. 15, Section 50.3, 50.5.
9. *Medicare Claims Processing Manual*, Ch. 18.
10. For example, NCD 220.6.
11. Guidance for the Public, Industry, and CMS Staff National Coverage Determinations with Data Collection as a Condition of Coverage: Coverage with Evidence Development Document, Issued on July 12, 2006.

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