Client Advisory: Clinical Trials Compliance

MEADE & ROACH LLP ATTORNEYS AT LAW

March 2006

CMS Answers Questions on Clinical Trial Billing Rule Ambiguities

On February 22, 2006, the Director of the Coverage and Analysis Group for the Centers for Medicare & Medicaid Services (CMS) released answers to questions regarding ambiguities in the Medicare Program's National Coverage Decision on Clinical Trials (the Clinical Trials NCD). Written clarifications were released in conjunction with an audioconference on the Clinical Trials NCD in which the CMS official, Dr. Steve Phurrough, provided a presentation with Ryan Meade, a partner in both Meade & Roach, LLP and Meade Roach Consulting, LLP. This release constituted the first written clarifications from CMS on the Clinical Trials NCD in five years. The audioconference was hosted by the American Health Lawyers Association.

The clarifications are reproduced in their entirety, beginning on page 4 of this newsletter.

The informal written clarifications are not legally binding, but serve as an important window into how CMS interprets the Clinical Trials NCD. Many of the questions that CMS responded to were originally issues that were clarified orally in the course of the recent Rush University Medical Center settlement of clinical trial services overpayments. Ryan Meade served as legal counsel to Rush in the voluntary disclosure and settlement. He represented Rush at meetings with the Department of Justice, the HHS-OIG and CMS.

The CMS questions and answers also include additional issues that were not raised by the Rush settlement but have long been a discussion within the health care industry.

Clarifications Were Needed

The Clinical Trials NCD is a complex billing rule that in some sections is not only ambiguous but is also internally inconsistent. Since its release in September 2000, providers who conduct research have struggled with how to interpret the rules and how to develop operations to comply with the NCD.

Many providers who conduct research have struggled over a number of questions related to the Clinical Trials NCD. For instance, what are the criteria for a qualifying clinical trial? When are FDA-approved drugs covered when they are being investigated for off-label use by the study? What constitutes therapeutic intent? And who determines that sufficient therapeutic intent exists in a research study in order to bill for its services?

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The Clinical Trials NCD allows Medicare to cover "routine costs" during "qualifying clinical trials." The "routine costs" must also meet ordinary Medicare rules. The investigational item or service is specifically excluded from the definition of routine cost.

The Clinical Trials NCD sets out examples of what is or is not a routine cost. For the most part, a routine cost includes services that are conventional care for the therapy or regimen investigated in the research study. Routine costs also includes items and services that are provided to detect, prevent or treat complications of the medical treatment.

Importantly, the Clinical Trials NCD excludes from routine costs any item or service which the sponsor provides for free to any enrollee in the study. This means that if the sponsor pays for a service, it cannot be billed to Medicare and therefore the compensation arrangement with the sponsor becomes critical in determining what is or is not billable to Medicare. The protocol's schedule of events cannot be reviewed for Medicare coverage outside of the context the contract with the sponsor.

Also important to the coverage process is the financial disclosure language of the informed consent. Every research study must have a specially designed informed consent approved by an IRB that includes a discussion of costs to the patient. An increasing line of cases treats these written research informed consents as contracts with the patient. Anything promised free in an informed consent should not be billed to Medicare.

Consequently, in order to comply with Medicare's billing rules for clinical trial services, all three of these documents (the protocol; the sponsorship contract; and the informed consent) must be coordinated in the context of ordinary billing rules. Many providers have chosen to coordinate this information into a usable tool that informs a provider's charge capture system whether an item or service is billable through the normal payor process or should be charged to an internal research fund.

Rule of Thumb Interpretation of the Clinical Trials NCD

One of the important clarifications in the February 22 document is CMS's agreement that a "a fair rule of thumb interpretation of the NCD" is that "anything covered outside a clinical trial is covered during a clinical trial if the item or service is being used for the same indication."

This interpretation is important when the investigational item or service is commonly used outside a trial. In order to publish research outcomes or to convince oversight bodies that a service or drug use is safe and effective, it is usually necessary for the item or service to be investigated in a research study. The medical community may have long been providing the service or drug, and in practice the service or item may be "medically accepted" so that even Medicare has determined that the item or service is "reasonable and necessary" under certain circumstances. But, if the item or service becomes the subject of a research study in order to formally establish its efficacy, then this medically accepted use could technically be excluded from coverage under the strictest reading of the Clinical Trials NCD. This would have a serious effect on medical research. It could discourage Medicare beneficiaries from enrolling in clinical trials if coverage for the item or service is lost, simply because the patient is receiving the same care under the controlled environment of a clinical trial.

CMS's clarification recognizes that if an item or service is paid for outside a trial and is provided during a clinical trial, then the item or service would still be covered. This is an important policy position to ensure that Medicare beneficiaries are encouraged to enroll in research studies without fear of additional cost.

Medicare Contractor LCDs are Central to Coverage Reviews

The CMS questions and answers also call attention to the importance of the local fiscal intermediary and carrier's Local Coverage Determinations. The CMS clarifications end the questions over the ambiguous note in the Clinical Trials NCD that "this

policy does not withdraw coverage for items and services that may be covered according to local medical review policies." Subsequent to the issuance of the Clinical Trials NCD, the Medicare Program has changed the title of local medical review policies (LMRPs) to Local Coverage Determinations (LCDs).

CMS clarifies that if an LCD exists that allows coverage of an item or service, then the item or service will remain covered by Medicare, even if the item or service is the investigational item or service.

LCDs are issued at the discretion of the local Medicare contractor and apply only to the jurisdiction covered by the Medicare contractor. LCDs cannot disagree with national CMS policy, but Medicare contractors are given wide latitude to issue LCDs allowing coverage for items and services that the local Medicare contractor believes are "reasonable and necessary."

Off-Label Use of Drugs as Investigational Item

The studies that will be most affected by these clarifications are studies investigating the off-label use of FDA-approved drugs. Many clinical trials study the efficacy of drugs in contexts other than as approved by the FDA or studying the benefits of different dosages than approved for marketing. Since Medicare, at base, only pays for drugs that are used as approved by the FDA, the question of coverage for off-label use of drugs has been a vexing issue for providers.

The Medicare Benefit Policy Manual specifically allows coverage for off-label use of drugs if the local Medicare contractor has determined that the off-label use is "reasonable and necessary" and has become "medically accepted" by the medical community. With respect to off-label use of drugs for anti-cancer purposes, Medicare does not require a local contractor's determination but allows physicians to look for "medical acceptance" of the off-label use in specifically cited drug compendia and peer-reviewed cancer journals.

Since coverage for off-label use of drugs for anti-cancer purposes is not necessarily dependent upon the existence of an LCD, the Clinical Trials NCD wording created a quandary as to whether this same off-label coverage rule would apply inside a clinical trial studying the off-label use.

The CMS questions and answers agreed that "since the rule for coverage of off-label use of drugs is different for non-cancer drugs…and anti-cancer drugs…, the NCD allow[s] coverage for investigational off-label use of an anti-cancer drug if the off-label use has been determined to be 'medically accepted' by drug compendia/ literature."

Defining a Qualifying Clinical Trial

Billing for routine costs under the Clinical Trials NCD is premised on the research study meeting the criteria of a "qualifying clinical trial." The Clinical Trials NCD lists 10 criteria for a qualifying clinical trial. Of the 10 criteria, 3 are noted as "requirements" and 9 are referred to as "desirable characteristics." Currently there is only one way to meet the desirable characteristics criteria, and that is if a study is "deemed" to meet the 7 desirable characteristics. The 3 additional requirements include: the study must investigate an item or service that represents a reimbursable Medicare benefit category; the study must enroll diagnosed patients; and the study must not be designed to test only the toxicity and safety of the item or service (i.e., the study must have therapeutic intent).

The Clinical Trials NCD lists out what types of trials are "deemed trials." Deemed trials include certain government and cooperative sponsored studies, along with drug studies that are being conducted under an approved investigational new drug (IND) application with the FDA and studies that are exempt from filing an IND.

There has been considerable confusion in the health care industry as to whether the deemed status of a trial resulted in the study being a qualifying clinical trial without needing to also demonstrate compliance with the three other criteria. *The CMS document clarifies that deemed trials are not automatically qualifying clinical trials.*

In order for a trial to be a qualifying clinical trial, the study must be a deemed trial *and* must also satisfy the three additional requirements.

What Should Providers Do?

The Rush settlement in December 2005 was a landmark for research billing enforcement as it was the first Medicare settlement involving drug clinical trials that was directly related to claims that did not conform with the Clinical Trials NCD. Rush's internal response, including an aggressive internal investigation, instituting a bill hold on cancer clinical trial services, voluntary disclosure to the U.S. Attorney's Office and establishment of a new centralized process to perform coverage reviews for all research studies, won Rush praise when the OIG called Rush's response and corrective action a "model" resolution to a compliance issue.

The Rush settlement is instructive of what the government is looking for from providers who do research. We suggest that any provider who conducts research undertake the following:

1. Conduct an assessment of whether a coverage review process exists to determine which clinical trial items and services are billable to Medicare.

2. Determine if coverage information for clinical trial items and services is being provided to the organization's charge capture system to ensure accurate billing.

3. Analyze the sponsorship contracting process and the informed consent development process to ensure that these processes are contemplating the Medicare coverage rules.

4. Develop an up-front process to review the coverage opportunities for a clinical trial's items and services before final execution of sponsorship agreements. This will allow better negotiations with the sponsor for appropriate compensation.

5. Establish a research compliance program if none exists. If a research compliance program exists, then test its effectiveness to manage compliance risk.

Reprint of CMS Clarifications

The following is a reprint of the question and answers provided by CMS in conjunction with the AHLA audioconference on February 22, 2006 entitled "Legal Issues in Medicare Reimbursement of Clinical Trial Services."

AHLA Audioconference: February 22, 2006

"Legal Issues in Medicare Reimbursement of Clinical Trial Services"

The following questions were prepared by Ryan Meade (Meade & Roach, LLP), Dennis Barry (Vinson & Elkins) and Holley Thames Lutz (Sonnenschein Nath & Rosenthal LLP) for CMS to consider discussing on the AHLA February 22, 2006 audioconference. CMS provided written responses to the questions. The questions and answers are reproduced below.

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QUESTION 1. What is the test for a Qualifying Clinical Trial? Is the test: a) the three "requirements" (benefit category; enrollment of diagnosed patients; therapeutic intent) plus the seven "desirable characteristics; or b) is presence of the seven desirable characteristics through a deemed trial sufficient to establish a qualifying clinical trial?

CMS RESPONSE 1. All qualifying clinical trials must be deemed and meet all 10 requirements.

QUESTION 2. Assuming that the three initial requirements (noted in #1) are required, what is sufficient level of therapeutic intent in order to meet this requirement? Is it sufficient for a trial to "observe for therapeutic benefit" to meet this requirement?

CMS RESPONSE 2. The phrase "therapeutic intent" is open to interpretation. The purpose of this requirement is to exclude clinical studies to evaluate the toxicity or adverse events solely.

QUESTION 3. If an LCD provides coverage of an item or service outside a clinical trial and the item or service is the investigational item or service during a clinical trial (e.g., the off-label use of commercially approved drug), does the provision of the NCD leaving intact "LMRPs" allow coverage for the investigational item or service?

CMS RESPONSE 3. Yes

QUESTION 4. Since the rule for coverage of off-label use of drugs is different for non-cancer drugs (must be a local coverage decision of some sort) and anti-cancer drugs (allowing use of drug compendia and literature if there is no LCD), does the NCD allow coverage for investigational off-label use of an anti-cancer drug if the off-label use has been determined to be "medically accepted" by drug compendia/literature?

CMS RESPONSE 4. Yes

QUESTION 5. Is a fair rule-of-thumb interpretation of the NCD, anything covered outside a clinical trial is covered during a clinical trial if the item or service is being used for the same indications?

CMS RESPONSE 5. Yes

QUESTION 6. Does the exclusion from routine costs of items and services provided free to any patient enrolled in the study refer to the entire enrollee population of the study (nationwide) or does it refer to the enrollees at the institution? In other words, is the contract negotiations and coverage of items and services for a particular institution influenced by other institution's studies/contracts?

CMS RESPONSE 6. A clinical trial may not provide free services to all non-Medicare participants and expect Medicare to pay for the same services. However, the institution may still receive Medicare payment if its decision to waive payment for non-Medicare participants is made on a case-by-case basis due to factors applied outside of the scope of the trial protocol. Payment waivers for non-Medicare participants must be offered only when the institution would have waived payment if the service were provided outside of a trial, e.g., general assistance programs for indigent patients, etc. The intent is to not have Medicare pay for services that are provided free to non-Medicare participants.

QUESTION 7. What is sufficient to establish that a service is being performed to detect or prevent a complication? If the results of the service would be used to determine whether to cease treatment, is that sufficient to meet the criteria for a "routine cost" associated with potential complications?

CMS RESPONSE 7. A service being used to determine whether to cease treatment would be a routine cost if it would have been paid outside of the trial.

QUESTION 8. How should ambiguous Medicaid rules related to clinical trials reimbursement be interpreted?

CMS RESPONSE 8. Medicare cannot answer questions about Medicaid.

QUESTION 9. If the provider offers an enrollee charity care for standard of care items and services (so the same types of services that would be Medicare reimbursable items and services), must the items and services provided free for charity care also be provided free to Medicare beneficiaries enrolled in the trial?

CMS RESPONSE 9. Same as answer to question #6.

QUESTION 10. If a sponsorship contract states that the sponsor will pay for a service only if the third-party does not pay for the service, does that immediately render the service non-reimbursable by Medicare? If so, is this because of Medicare Secondary Payor issues or some other rationale?

CMS RESPONSE 10. Same as answer to question #6.

QUESTION 11. Further clarification for therapeutic intent:

Q11A. Can CMS offer a workable definition of therapeutic intent?

CMS RESPONSE: No.

Q11B. If the objectives state a therapeutic intent, even one whereby there is an objective to "observe for therapeutic benefit", and it is in the Primary and Secondary Objectives, does it have to be in a particular placement within these objectives? Some protocols have 5 and 6 bullets under each objective, and is any bullet/position too low?

CMS RESPONSE: No.

Q11C. If the protocol states as an objective the observation for therapeutic benefit and articulates a theory of therapeutic benefit, but the IRB insists that the informed consent state that there will be NO BENEFIT to the patient, does the informed consent override the protocol's therapeutic objective?

CMS RESPONSE: It is the responsibility of the local contractor to determine whether or not a trial has therapeutic intent.

Q11D. Is it most appropriate for the PI to make the call as to whether there is therapeutic benefit intended by the trial? It's difficult for an HIM person to try to determine, from a coverage perspective, whether the protocol is designed with therapeutic intent which is an undefined regulatory term. We could see a provider's reasonable reliance on the PI to justify therapeutic intent, with reasonably supported data.

CMS RESPONSE: It is not the PI or HIM who may determine whether the protocol is designed with therapeutic intent. It is the responsibility of the local contractor to determine whether or not a trial has therapeutic intent.

QUESTION 12. Is the QV modifier required for UB-92 outpatient claims? Or, as we believe to be the case, is it only to be used with 1500s? Use of a QV modifier on UB-92 seems unduly burdensome given that some study patients have bills that are 4 pages long. If CMS contends that QV is required on a UB-92, please cite the authority for this proposition.

CMS RESPONSE 12. The QV modifier is not required for UB-92 claims.

Recent Publications

Meade, R., "IRB Members Should Know More About the Reimbursement Rules for Clinical Trial Services," *Medical Research Law & Policy*, 1/18/2006, pp 65-67.

Meade, R., "Compliance Aspects of the Medicare Part D Prescription Drug Benefit," *CCH Health Care Compliance Letter*, 1/9/2006, pp 4-6.

Upcoming Presentations by Meade & Roach, LLP

March 28: "New Approaches for Clinical Trial Billing Under Medicare." Audioconference sponsored by Melamedia, publisher of *Drug & Biologic Guidance Watch*.

March 31: "Research Billing Issues – Recent Developments & CMS Clarifications." Florida Hospital Association's Research & Clinical Trials Conference; Orlando, Florida.

April 11: "Clinical Trial Billing." Audioconference sponsored by Huron Consulting Group and Meade & Roach, LLP

April 25: "Avoiding Compliance Quicksand – Clinical Trials and Claims to Third-Party Payors: A Compliance Case Study." Panel discussion with representatives from Rush University Medical Center and the U.S. Attorney's Office for the Northern District of Illinois. Health Care Compliance Association Annual Compliance Institute; Las Vegas, Nevada.

April 28: "Managing Compliance Risks for Physician Practices." American Academy of Medical Management; Chicago, Illinois.

May 18: "Recent Developments in Research Billing Compliance." ABA National Institute on Health Care Fraud; Fort Lauderdale, Florida.

May 22: "A Legal Overview: Medicare's National Coverage Decision on Clinical Trials." Chicagoland Symposium on Clinical Trial Billing Compliance sponsored by Rush Medical College; Chicago, Illinois.

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Meade & Roach, LLP and Meade Roach Consulting, LLP's Clinical Trials Compliance Services

Every client's needs are unique and services and solutions are crafted for the unique client setting. However, the following are a selection of the most common services Meade & Roach, LLP and Meade Roach Consulting, LLP provide to clients to address their clinical trials compliance needs.

- Education Sessions on Medicare Clinical Trial Billing Rules
- Training on Medicare Coverage Review Process
- Coverage Reviews of Clinical Trials
- Gap Analysis/Process Assessment of Clinical Trials Billing
- Operational Consulting to Manage Compliance Risks and Establish Efficient Clinical Trial Operations
- Sponsorship Contracting Process Improvement
- Coding Reviews

Follow-Up Information

If you would like more information about clinical trials billing compliance or would like to learn more about Meade & Roach's compliance services, please contact **Michael Roach at (312) 255-1773** or **Ryan Meade at (312) 498-7004**.

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