Compliance Advisory:

MEADE & ROACH LLP

The CMS Final Clinical Trial Policy

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CMS Maintains Clinical Trial Policy & Defers Certain Coverage Decisions to Local Contractors

The Centers for Medicare & Medicaid Services (CMS) announced on October 17, 2007 that it will not be issuing its long-awaited Clinical Research Policy, but rather will maintain the current Clinical Trial Policy (CTP) as is. In making this announcement, CMS also published seven FAQs that could prove more significant than the announcement itself. The FAQs actively encourage providers to seek clarification from their local Medicare contractors for research studies that may not meet the CTP's qualifying clinical trial criteria.

In an important statement for providers with early phase drug trials and investigator-initiated studies, FAQ #4 states that a provider with "trials that do not meet the existing criteria for deemed trials should contact their local Medicare contractors to determine whether items and services will be covered in that geographic area." This statement arguably allows local Medicare contractors to permit coverage for items and services in studies that do not fit into the CTP's qualifying clinical trial criteria.

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In order to obtain coverage under the CTP, a research study must meet all 10 criteria of a "qualifying clinical trial." Seven of these criteria are met by being a type of study that is "deemed" to have those seven criteria. The other three criteria focus on standards that have their foundations in the legal structure of Medicare: investigating an item or service that falls within a Medicare benefit category; enrolling patients with diagnosed disease; and, the study must be designed with therapeutic intent.

The CTP only allows coverage of "routine costs" during a "qualifying clinical trial" and CMS has not allowed coverage of items and services that are required during a non-qualifying clinical trial unless the item or service is used to treat complications. The FAQs open up the possibility that a local Medicare contractor could establish its own criteria for assessing coverage of items and services during non-qualifying clinical trials.

The Open Question of Therapeutic Intent

The CMS announcement did not answer one of the industry's long-awaited questions: what constitutes sufficient therapeutic intent to be a qualifying clinical trial?

The current CTP requires that a qualifying clinical trial "not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent." Various oral statements from CMS have indicated that in order for a study to meet the therapeutic intent criterion in the CTP, one of the primary objectives in the protocol must be therapeutic benefit. CMS officials have even commented at the December 2006 Medicare Evidence Development and Coverage Advisory Committee Meeting that "there is in general the assumption that many Phase Ones, if not most Phase Ones, currently aren't covered in the Clinical Trial Policy."

The CTP criterion does not imply on its face that the primary objective must be therapeutic benefit and many early phase studies have therapeutic benefit as a secondary objective rather than as a primary objective, particular cancer studies. The fact that a study has therapeutic benefit as a secondary objective rather than a primary objective does not lessen the intent of the study to help individual patients; the sorting of the protocol objectives relates to the design of the study and not necessarily to the intention of the physician in providing therapy to a patient.

The Clinical Research Policy was expected to clarify

Medicare policy on therapeutic intent in research studies – but this issue remains unanswered and leaving many providers still wondering about coverage for Phase I drug studies that have therapeutic benefit as a secondary objective.

What Should Providers Do?

It is now more important than ever for providers to establish a relationship with the local Medicare medical director. With CMS issuing direction to refer non-qualifying clinical trial services to local Medicare contractors, providers that do not know their Medicare medical director or who do not ask their local Medicare medical director to review studies, could find themselves billing for services that the local contractor does not consider reasonable and necessary.

The role of the local Medicare contractor is broad under the structure of the Medicare Program. Medicare is a federal program that is administered regionally through private companies that have contracts with CMS. The local Medicare contractors are given wide berth to determine whether items and services are "reasonable and necessary" as long as the items and services are not excluded from coverage by statute or CMS has not already determined that an item or service is not covered. The local Medicare contractors in different regions do not always agree with each other and the structure is specifically designed this way to accommodate regional differences and practices.

Each of these local Medicare contractors has a medical director who oversees the clinical review of whether items and services are "reasonable and necessary." The Medicare medical directors issue local coverage determinations (LCDs), articles, clarifications and answer individual provider questions on coverage policy. The Medicare medical directors are often more accessible than providers think.

The following are some of the issues that providers should consider discussing with their local Medicare medical directors:

1. If a research study does not meet CMS criteria of a non-qualifying clinical trial, will the local Medicare contractor still cover the items and services that are for the clinical management of the patients enrolled in the study?
2. What test will the Medicare contractor use to determine whether the study is designed to have therapeutic intent? Will the Medicare contractor require that one of the studies' "primary objectives" or primary purposes be to assess the therapeutic benefit of the patient or will any objective evidencing therapeutic benefit be sufficient?
3. Will the contractor make a special consideration for studies that enroll patients with life-threatening illnesses such as cancer?
4. Does the Medicare contractor have a stance with respect to studies which are purely observational of conventional care treatment? Are the medically necessary services during observation studies assumed to be covered under normal billing processes?
5. Does the Medicare contractor want to review and approve each and every research study that does not strictly fit within CMS criteria of a non-qualifying clinical trial?

Moving Forward

The announcement by CMS that it is not adopting the Clinical Research Policy does not lessen a provider's need to develop clinical research billing compliance measures or conduct Medicare Coverage Analyses as tools to safeguard against inappropriate billing. If a provider has not coordinated its study document information into a process to manage billing, then the same risks still exist of billing for items and services that are already paid for by the sponsor in the clinical trial agreement or award, billing for items and services promised free in the informed consent, or billing for services that are purely for research purposes only.

Meanwhile, CMS is not closing shop on reforming its clinical research coverage policy. The announcement indicated that CMS still believes that the standards it set out in the proposed Clinical Research Policy are important standards that research studies should meet for coverage, but CMS will be considering the appropriate legal vehicle to revise its policy. CMS stated in the FAQs that it will be considering revising its policy through formal "rulemaking," which is to say through formal regulations set out in the Code of Federal Regulations and not through the National Coverage Determination process. Formal rulemaking would allow CMS to establish new processes and standards for coverage but provide a transition period, rather than imposing a new schema immediately through the NCD reconsideration process.

For more discussion and material on clinical research billing compliance, please visit www.meaderoach.com.

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