CMS Issues Draft Revised National Coverage Determination For Clinical Research

On April 10, 2007, the Centers for Medicare & Medicaid Services ("CMS") released its much-anticipated draft guidance to revise Medicare coverage for services furnished to Medicare beneficiaries in research studies. The current Medicare coverage policy, issued in the form of a National Coverage Determination ("NCD") in September 2000, has profoundly affected participation in and funding for clinical trials but has also provoked confusion and controversy. With the draft revision, CMS has signaled not only that it seeks to clear up confusion and resolve controversy around billing for clinical research, but also that it has the goal of increasing beneficiary access to enrollment in clinical research studies.

The public has 30 days to comment on the draft revised NCD. CMS intends to release a final NCD 60 days therafter, *i.e.*, on or about July 9, 2007.

The proposed revisions keep intact the overall structure of the NCD. That is, for Medicare to cover certain items and services provided during a clinical study, the study must: (1) satisfy certain "general standards for a scientifically and technically sound clinical research study" (the 2000 NCD called them "highly desirable characteristics"); and (2) satisfy certain "Medicare-specific standards" (the 2000 NCD referred to them as requirements for a qualifying trial).

CMS has proposed the following revisions, among others:

- Rename the NCD the "Clinical Research Policy," rather than its current name, "Clinical Trial Policy."
- Clarify that the general standards are deemed satisfied as to studies that are: (1) approved by any DHHS agency, the Veterans Administration or the Department of Defense, or by research centers or cooperative groups funded by one of those agencies; (2) conducted under an Investigational New Drug application (IND) if the protocol has been reviewed by the FDA and the IND has not been put on hold; and (3) required and approved by FDA as a post-approval commitment.
- End the current policy that IND-exempt trials are deemed to satisfy the general standards.
- Add to the "Medicare-specific standards" the requirements that: (1) the research study must be registered on the ClinicalTrials.gov website before enrollment of the first study subject; (2) the written protocol must explain the method and timing of the public release of the research results; (3) the research study must have explicitly discussed inclusion criteria and considered relevant subpopulations in the research protocol; and (4) the protocol must discuss how the results will generalize to the Medicare population.
- Clarify the items and services provided in clinical trials covered by Medicare, including clarifying that Medicare will cover items and services used for patient management (aside from the investigational item or service itself).
- Clarify that the Medicare-specific standards allow coverage if the study is not designed exclusively to test toxicity or disease pathophysiology, revising the former requirement that therapeutic intent must be the primary objective of the study.

The draft revised NCD leaves some questions unanswered. For example, it does not address the application of the Medicare as Secondary Payor rules. Nor does it discuss whether the revised NCD will apply to open studies. CMS officials have orally stated that the revised NCD will not apply "retroactively," but it is not clear whether open studies or the documentation regarding open studies could be modified in some way in order to allow for Medicare coverage. Some have also expressed uncertainty regarding

the proposed provision that protocols discuss the method in which the research results will be publicly disclosed. It is likely that these and other questions will be addressed when CMS issues the final version of the revised NCD.

Organizations affected by the revised NCD should review the draft revisions to determine whether they wish to submit comments to CMS. As noted, the deadline to submit comments is May 9, 2007.

Given the anticipated July 2007 release of the revised NCD, providers should review their operations both to ensure compliance and to ensure that they are obtaining Medicare reimbursement for covered services. We recommend that providers take the preliminary step of taking an inventory of current research. Second, upon issuance of the final NCD, providers should undertake an operations review of the various components of each trial, to ensure that numerous different departments (admissions, nursing, laboratory, medical records, billing) are coordinated in their approach to identifying patients in clinical trials and that they are billing appropriately. Whatever standards the final NCD adopts, it will be necessary to review each study separately to determine the extent and limits of Medicare coverage.

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