

Medicare Reimbursement for “Standard of Care” in Flux

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Medicare has proposed new rules as to when reimbursement is available for standard of care treatment furnished to clinical research subjects. “Standard of care” services are generally understood to be those services that would be furnished even if the individual receiving those services were not a subject in a clinical trial. Since standard of care services are thus medically necessary independent of the clinical trial, most professionals involved in clinical trials usually seek payment for those services from Medicare and other insurers. Currently, Medicare’s policy regarding standard of care services is in a state of flux. In recent unofficial statements, staff from the Centers for Medicare and Medicaid Services (CMS) purportedly “clarified” that standard of care services furnished to clinical trial participants are not payable under Medicare. Yet, in response to a number of comments received from the industry, CMS has given further thought to its policy, leading to new proposed standards under which reimbursement for these services would be allowed. If finalized substantially as is, these standards could significantly increase the regulatory burdens and the legal exposure associated with seeking Medicare reimbursement for medically appropriate care when patients happen to be in clinical trials. All parties involved in clinical trials should carefully consider CMS’s proposal and decide whether the submission of comments is appropriate.

Background on the Clinical Trial National Coverage Decision

CMS’s recent proposal was issued in conjunction with revisions to its clinical trial national coverage decision. Although many decisions regarding the scope of items and services covered under Medicare are made by local Medicare carriers, sometimes the decision is of such great importance that it requires promulgating a national coverage decision (NCD). NCDs apply uniformly across the nation and are binding on all local Medicare carriers.

In 2000, CMS issued an NCD relating specifically to certain services furnished to clinical trial subjects. When care is considered experimental by the Medicare program, as is the case for unapproved drugs and devices being tested in clinical trials, coverage is generally not available. Yet, without Medicare coverage and payment for treatment within a clinical trial, Medicare beneficiaries tend to have disproportionately low participation rates in clinical studies. Accordingly, the 2000 NCD aimed at increasing opportunities for Medicare beneficiaries to participate in clinical trials.

The 2000 NCD, however, offers only limited opportunities for reimbursement in the clinical trial setting. First, it covers only the “routine costs” of a clinical trial, as such costs are defined in the NCD.

Second, a trial could only qualify under the NCD if it exhibited certain traits, such as having a “therapeutic intent,” an ambiguous phrase that was not defined anywhere in the 2000 NCD. Third, perhaps the most significant limitation of the 2000 NCD is that it applied only to research funded by specified government agencies, research conducted under an investigational new drug application (IND), or research that is exempt from IND requirements. Because of these limitations, only a small fraction of studies of unapproved drugs and devices have ever involved any Medicare reimbursement.

Further Refinements and Clarifications to CMS’s Coverage Policy

CMS began a reassessment of its policy in 2006 after enough time had passed to allow CMS to observe how its policy was being implemented. This reassessment resulted in the publication of a proposed revised policy in April 2007. Many clarifications were proposed; however, none were likely to significantly expand the limited utility of the policy or the breadth of its scope. It was CMS’s intent to publish the policy in final form after reviewing the comments it received, which were to be submitted within 30 days of the date of publication of the proposed revised policy.

Yet, after the close of the comment period, various exchanges between CMS staff and industry representatives indicated that there were vast differences in terms of how CMS’s policy was being interpreted by these respective parties. Hospitals and others affected by the policy had widely believed that the policy only applied to clinical trials involving unapproved drugs and devices, which would otherwise be deemed experimental and therefore not covered under Medicare. For studies not involving unapproved products, the general presumption has been that care is covered whenever the care is of the sort that would ordinarily be furnished to Medicare beneficiaries outside of the study. CMS staff, however, stated that they believed that, unless qualified under the NCD, there is no coverage applicable to items and services furnished to a Medicare beneficiary whose care is the subject of *any research whatsoever*. The breadth of the scope of the application of CMS’s clinical trial NCD, as perceived by CMS staff, caused great stir among members of the industry.

CMS’s Further Reconsideration of Its Position

Upon learning that its interpretation was out of step with the widely held views of hospitals and other stakeholders, CMS reconsidered its informal policy. On July 9, 2007, CMS issued an interim final revised NCD, which implemented only modest changes to the 2000 NCD. In that issuance, CMS also committed to revisiting the rest of its policy, in light of its recent exchanges with various private sector representatives. Following quickly thereafter, CMS reopened the NCD on July 19 and included proposed changes potentially of far greater substance.¹ Some of these provisions look similar to the proposals set forth in April 2007. However, the proposal also contains much that is unprecedented, including statements implying that there is no coverage for any items or services furnished to Medicare beneficiaries if their care happens to be the subject of research.

Presumably in recognition of the potential for its policies to have a chilling effect on research, CMS has sought to facilitate coming under the purview of the clinical trial NCD through its proposed revisions. Specifically, CMS no longer limits qualifying studies to those that are funded by one of the specified agencies, those conducted under an IND, or those exempt from IND requirements. Rather, to fall within

1. Proposed Decision Memo for Clinical Trial Policy (CAG-00071R2), dated July 19, 2007 (located at: <http://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=210>).

the NCD, the proposal would allow the research sponsor or the principal investigator to certify to CMS that the research adheres to certain standards. Yet, upon close examination of the current wording of these standards, it becomes apparent that (1) for some of the standards, it will ordinarily be impossible to determine if the standard has been met, and (2) for other standards, where the meaning is discernible, it is clear that they will disqualify many studies beneficial to the Medicare population. Research sponsors seeking coverage under the NCD will likely want to review these standards closely because, if the NCD is finalized in its current form, such coverage could result in unanticipated exposure to claims of “false” certification.

Areas Requiring Comment

While CMS clearly is seeking to find some middle ground acceptable to the parties affected by this policy, the proposal is still not workable in its current form. In seeking to remove coverage for studies of even approved drugs and devices, CMS ignores the plain meaning of the governing statute indicating that the NCD is only permitted to *supplement*, not *supplant*, existing coverage. Furthermore, even for the studies that should benefit from qualification under the NCD because coverage would not be available otherwise, CMS’s proposed standards are too vague and unduly restrictive to be capable of being implemented as currently drafted.

For parties for which continued Medicare reimbursement for standard of care services furnished to research subjects is critical, a careful review of the proposed revised NCD is warranted, and substantive practical comments should be submitted. Conversely, for parties with unapproved products (and no government support) planning on engaging in clinical trials of their products, the proposal ushers in a new opportunity. Now, for the first time ever, there is the possibility that standard of care services may be reimbursable under Medicare for these trials through the self-certification process. These parties should carefully review the proposal, especially the proposed standards, and submit comments on any aspects that they believe will be problematic. Comments are due by **August 18, 2007**.

Members of Morgan Lewis’s FDA/Healthcare Regulation Practice have closely analyzed CMS’s proposed revised NCD and have identified numerous provisions that are in need of further modification before the policy can be successfully implemented. If you would like any further information regarding the issues raised in this Morgan Lewis LawFlash, please contact one of the following Morgan Lewis attorneys:

Washington, D.C.

Andrew Ruskin

202.739.5960

aruskin@morganlewis.com

Phoebe Mounts

202.739.5898

pmounts@morganlewis.com

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