CMS Publishes Proposed Revisions to Clinical Trial Coverage Policy

On April 10, 2007, the Centers for Medicare and Medicaid Services published its proposed revision to the current National Coverage Determination for costs associated with clinical trials, which was initially published in 2000 and appears in Section 310.1 of the Medicare National Coverage Determinations Manual. CMS will accept public comments on this draft through May 10, 2007. The revision retains the same basic framework as the original coverage policy, and includes several changes and clarifications that reflect some of the concerns raised by trial sponsors and recommendations from the Medicare Evidence Development and Coverage Advisory Committee (“MedCAC”). Nevertheless, the proposed revisions do not address all of the coverage and reimbursement issues already raised by both sponsors and sites during the public comment process.

The first major set of changes proposed by CMS is the addition of general and Medicare-specific standards. Under the existing policy, Medicare coverage requires that the study (1) evaluate an item or service within a covered benefit category, (2) have a therapeutic intent, (3) enrolls patients with a diagnosed disease, and (4) have “desirable characteristics” including a focus on whether the intervention improves health outcomes, whether its objective is based on available scientific information, whether the study design is appropriate, and whether the study is conducted in compliance with scientific and regulatory standards. The draft policy would add new requirements that the study have a written protocol that specifies (1) the method and timing for the release of study results, (2) relevant subpopulations within the inclusion criteria, and (3) how study results are expected to be generalized to the Medicare population. In addition, in order to receive reimbursement, sponsors would be obligated to register the study (regardless of the phase of the study) on the ClinicalTrials.gov website before enrolling any study subjects. Although many sponsors voluntarily follow some or all of the new elements in the draft policy, CMS favors a broader disclosure of information as a condition for Medicare reimbursement.

The draft clinical study policy also seeks to coordinate with the Coverage with Evidence Development (“CED”) policy published by CMS in July 2006. Under that policy, CMS can issue National Coverage Determinations that specify that an item is covered only when used as part of a research study with appropriate safeguards and monitoring. The draft CMS policy would allow coverage for studies that have been approved through the CED process if Medicare-specific standards are also satisfied.

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Under the present policy, studies conducted under an Investigational New Drug application have been deemed to meet the “desirable characteristics” for coverage. CMS has proposed to clarify that the scope of coverage for IND drugs does not include applications where the FDA has placed a hold on the protocol review. In addition, CMS has proposed to scale back the current deemed status for studies involving drug trials that are exempt from the IND process under 21 C.F.R. § 312.2(b)(1). CMS raised this concern because these studies are not subject to FDA oversight, and “thus have no external process for ensuring that the standards of this Medicare policy are being met.” As a result, CMS has proposed to delete this exception and require that an IND-exempt study satisfy the other criteria in the policy in order to be covered. However, in its discussion CMS made no mention of the role of IRBs, data safety monitoring boards, or institutional policies as safeguards.

The proposed revisions provide some clarification of the scope of Medicare coverage for clinical research. It acknowledged that its current definition of covered routine costs has been confusing, and would redefine the term to include items and services available to Medicare beneficiaries outside of the study, items and services required for providing and monitoring the investigational item or service, and services required to prevent or treat any complications. The investigational item or service, along with nonclinical administrative services, would still be excluded from coverage.

Along with this clarification, CMS also addressed the situation in which an item or service currently covered by Medicare outside of a clinical research study is furnished to a Medicare beneficiary as part of a research protocol. In the past, this had caused confusion among sponsors and carriers. In this situation, CMS explained that an item or service that is reasonable and necessary in the absence of a clinical study does not become experimental or investigational simply because it is being furnished to a Medicare beneficiary through a research study protocol.

Finally, CMS has proposed several technical clarifications. First, CMS would replace the term “clinical trial” with the broader term “clinical research”. The agency would redefine the term “clinical research” to include “the observation of events in groups of individuals who share a particular characteristic, such as a symptom or illness; or who have the same treatment or diagnostic test provided for a symptom or illness.” The new definition also would recognize the obligations to comply with regulations and procedures intended to protect human subjects and privacy. Nevertheless, this would still leave sponsors to reconcile the differences between the CMS definition and the definitions of research in the Common Rule and in FDA regulations.3

* * *

CMS’s clinical trial policy has had a significant impact on research sponsors, institutions conducting research, and investigators. All entities involved in clinical research should review carefully the draft revisions and CMS’s decision memorandum to gauge the full impact of the proposed changes. As a reminder, public comments can be submitted through May 10, 2007.

3 See 45 C.F.R. §46.102(d) (Common Rule), and 21 C.F.R. §§ 50.3(c), 56.103(c), 312.3(b), and 812.3(h) (FDA Regulations).

If you would like additional information regarding this topic, please contact Robert E. Wanerman at 202/861-1885 or rwanerman@ebglaw.com in the firm’s Washington, DC office or the Epstein Becker & Green attorney who regularly handles your legal matters. For further information about Epstein Becker & Green’s Health Care & Life Sciences Practice, or to see back issues of Special Alerts, please visit our website at www.ebglaw.com.
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Amy Simmons
Marketing & Recruitment Manager
Health Care & Life Sciences Practice
Epstein Becker & Green, P.C.
1227 25th St., NW, Suite 700
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