Medicare Calls for Revised Clinical Trials Policy

BY MARK S. LESNEY

Senior Editor

I tuture clinical trials may have to conform to several new procedural and reporting requirements in order for Medicare beneficiary participants to be eligible for reimbursement, if revisions to the Clinical Trial Policy national coverage determination are implemented.

Changes proposed by the Centers for

Medicare and Medicaid Services would include:

- ► Requiring all trials to be registered on the National Institutes of Health ClinicalTrials.gov Web site before enrollment begins.
- ► Requiring study investigators to publish their results.
- ▶ Adding Food and Drug Administration postapproval studies and coverage with evidence development (CED) to studies that would qualify under this policy.
- ▶ Paying for investigational clinical services if they are covered by Medicare outside the trial or required under CED through the national coverage determination (NCD) process.
- ▶ Expanding the agencies that can deem whether a trial has met the general policy standards to include all Department of Health and Human Services agencies, the Veterans Administration, and the Department of Defense.

The 30-day public commentary period began in April. The CMS will review all public comments and suggestions and incorporate them into the final published NCD no later than 60 days after the end of the comment period, and the revised policy will be effective with that publication.

Further details are available from the CMS coverage Web site at www.cms.hhs. gov/mcd/viewdraftdecisionmemo.asp?id =186

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