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To Revise or Not to Revise, That is the Question: CMS's Vacillation on the Medicare Clinical Trial Policy

In September 2000, CMS released its National Coverage Decision ("the 2000 NCD") setting forth the Medicare reimbursement policy for clinical trials, in response to President Clinton's executive memorandum directing that Medicare pay for routine costs associated with participation in clinical trials.[1] In the last two years, CMS has promulgated draft modifications to the 2000 NCD, but it has not yet adopted any real substantive changes. This article provides a brief summary of the 2000 NCD and CMS's series of proposed, retracted, and final changes to the 2000 NCD.

The September 2000 Clinical Trial Policy NCD

The 2000 NCD, entitled "Clinical Trial Policy," [2] provides that Medicare will cover:

- "Routine costs" of items or services provided to Medicare beneficiaries participating in a "qualifying clinical trial"; and
- Reasonable and necessary items and services used to diagnose and treat complications arising from a Medicare beneficiary's participation in a clinical trial.

"Routine costs" is defined in the 2000 NCD as items and services provided to Medicare beneficiaries, in either the experimental or control group, that are:

- Typically provided absent a clinical trial (i.e., medically necessary, conventional care);
- Required solely for the provision of an investigational item or service (e.g., administration of a non-covered chemotherapeutic agent);
- Required for the clinically appropriate monitoring of the effects of an investigational item or service, or the prevention of complications; and
- Needed for reasonable and necessary care arising from the provision of an investigational item or service - - in particular, for the diagnosis or treatment of complications.

The NCD specifies that "routine costs" does not include:

- The investigational item or service itself;

1 Available at: http://clinton4.nara.gov/WH/new/html.20000607.html

2 Available at: http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=310.1&ncd_version=1&basket=ncd%3A310%2E1%3A1%3ARoutine+Costs+in+Clinical+Trials.

- Items or services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of a patient;
- Items or services customarily provided by the research sponsor free of charge; and
- Items or services provided solely to determine trial eligibility (e.g., screening to determine qualification for enrollment).

Furthermore, in order to be reimbursed for "routine costs," the clinical trial must be a "qualifying trial," which as the 2000 NCD explains, satisfies the following three criteria:

- Evaluates an item or service that falls within a Medicare benefit category and that is not statutorily excluded from coverage (cosmetic surgery being an example of an excluded service);
- Has a therapeutic interest (i.e., it is not designed exclusively to test toxicity or disease pathophysiology);
- Enrolls patients with a diagnosed disease (except that trials of diagnostic interventions may enroll healthy patients to ensure a proper control group).

In order to be a "qualifying trial," the research study must also have seven desirable characteristics described in the 2000 NCD.[3] Studies funded by certain agencies (e.g., National Institutes of Health, Veterans Administration) are deemed to meet the seven desirable characteristics, as are drug studies conducted under an IND or drug studies exempt from IND requirements. At the time, the 2000 NCD envisioned the future implementation of a self-certification process for principal investigators to certify compliance with the seven desired characteristics for non-deemed studies.

Intent to Revise

Following CMS's release of the 2000 NCD, commentators noted several ambiguities in the Clinical Trial Policy, and local contractors often interpreted the rules differently. Among other things, there was uncertainty over the scope of the reimbursement policy and over secondary payer issues. Also, CMS never implemented the self-certification option.

In July 2006, CMS announced an intent to revise the Clinical Trial Policy NCD, presenting ten different

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3 The seven desirable characteristics are: (1) The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes; (2) The trial is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use; (3) The trial does not unjustifiably duplicate existing studies; (4) The trial design is appropriate to answer the research question being asked in the trial; (5) The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully; (6) The trial is in compliance with federal regulations relating to the protection of human subjects; and (7) All aspects of the trail are conducted according to the appropriate standards of scientific integrity.

issues that it felt needed to be addressed.[4] Some of these issues concerned clarifications of the September 2000 NCD, including clarifying the definition of routine clinical care costs and investigational costs, clarifying the scientific and technical roles of federal agencies in overseeing IND exempt trials, and clarifying payment criteria for clinical costs in research studies other than clinical trials.

Several new initiatives included devising a strategy to ensure that Medicare-covered clinical studies are enrolled in the National Institute of Health clinical trial registry website, developing criteria to ensure that any Medicare-covered clinical research study includes a representative sample of Medicare beneficiaries, and determining if coverage outside routine clinical care costs is warranted.

CMS received comments from 53 different groups and individuals and convened meetings with the Medicare Evidence Development and Coverage Advisory Committee (MedCAC) and the Agency for Healthcare Research and Quality (AHRQ) to discuss these issues.

Proposal and Final Decision

Almost a year later, on April 10, 2007, CMS released a Proposed Decision Memorandum[5] introducing many changes to the Clinical Trial Policy NCD, including changing its title to "Clinical Research Policy." Significant proposed changes to the NCD included:

- Requiring research studies to be registered on the ClinicalTrials.gov website and the release of results to the public;
- Including a definition of "research";
- Adding as a new standard to the characteristics of a "qualified clinical trial" the requirement for research studies to have a written protocol; and
- Defining non-covered administrative services required to carry out studies.

However, after two rounds of public comments, CMS decided not to implement these changes and to preserve the status quo. In a July 9, 2007 Final Decision Memorandum [6], CMS explained that several commenters pointed out inconsistencies between the proposed changes and other Medicare policies and statements. Additionally, comments from hospitals and advocates asserted that local contractors were paying claims for hospital services for patients in clinical trials outside of the terms of the 2000 NCD. Noting the multitude of issues raised and the need for sufficient time to sort them out, CMS decided to make only two minor changes to the 2000 NCD.

First, CMS added language to clarify that Medicare coverage is provided for investigational items otherwise covered outside of the clinical trial. So long as

4 Available at: https://www.ms.hhs.gov/mcd/viewtrackingsheet.asp?id=186
5 Available at: https://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=186
6 Available at: https://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=186

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an item would be covered outside the clinical trial, it can be reimbursed within the clinical trial as well.

Second, CMS modified the NCD to reference CMS's 2006 Coverage with Evidence Development (CED) policy, which provides Medicare reimbursement for items or services in clinical trials that have shown evidence of significant medical benefit, but are not yet considered "reasonable and necessary," so long as certain requirements for collection of patient data are met. Specific requirements for CED items or services will be addressed in separate individual NCDs.

Re-Proposal and Final Decision

Ten days after releasing this much anticipated final decision, CMS proposed another round of changes in a July 19, 2007 Proposed Decision Memorandum.[7] These changes included many other previously proposed changes, but also included new standards for qualifying clinical trials. CMS also reintroduced the self-certification process, through which principal investigators can certify that their studies meet the standards for a "qualified clinical trial."

However, on October 17, 2007, CMS posted a Final Decision Memorandum[8] yet again declining to make final any of its proposed changes and instead merely reinstating the original 2000 NCD with the two minor clarifications described in the July 9, 2007 Final Decision Memorandum. CMS explained that this decision was fueled by both comments challenging CMS's authority to make these changes and the recent passage of the 2007 Food and Drug Administration Amendments Act of 2007, which established expanded clinical trial registration requirements. Not only did CMS state that it will make no changes to the existing policy, but CMS also stated that it will continue to "cover items and services in some trials that did not meet the standards of the 2000 policy but have been paid by some contractors."[9]

Conclusion

CMS's vacillation concerning changes to the Clinical Trial Policy has been frustrating for providers, researchers, and research institutions hoping for clarification on various aspects of Medicare clinical trial reimbursement. However, in the course of struggling with its Clinical Trial Policy, CMS has engaged in an important and advantageous dialogue with providers and researchers. Since CMS promises to "continue to work with other HHS components on resolving these issues,"[10] those seeking Medicare reimbursement for clinical trials should be familiar with CMS's series of proposed changes (since some may be proposed again) and should monitor future activity in this area.

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7 Available at: https://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=210
8 Available at: http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=210
9 Final Decision for Clinical Trial Policy Q's and A's, available at: http://www.cms.hhs.gov/determinationprocess/downloads/id210qa.pdf
10 Id.