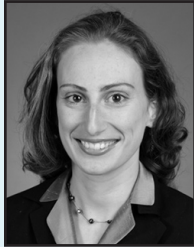


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COMPLIANCE PERSPECTIVES



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Two Steps Forward, One Step Back: A Review Of Proposed Clinical Trial Policy

On April 10, 2007, the Centers for Medicare and Medicaid Services (CMS) released proposed revisions to the existing national coverage decision setting forth the circumstances under which Medicare would pay for routine care costs provided during the course of a clinical trial. The coverage decision was issued on Sept. 19, 2000, in response to then President Clinton's June 7, 2000, executive memorandum promoting the participation of Medicare beneficiaries in clinical trials. Participation in clinical trials affords subjects access to emerging medical technologies and treatment protocols and is an important medical opportunity for the nation's Medicare community.

The goals of the proposed revisions were to clarify a) the attributes of clinical trials eligible for Medicare beneficiary participation; and b) the types of costs eligible for reimbursement. The proposed "Clinical Research Policy" (CRP) provides greater specificity and clarity—a significant step forward. The

proposed CRP, however, in a concerning step backward, may also inadvertently restrict the types of clinical trials eligible for reimbursement—particularly in the areas

of cancer research—thereby running counter to the philosophical underpinnings of the rule. The public has 30 days to comment and the agency is expected to issue a final rule approximately 60 days thereafter, or around July 9, 2007.

Background

The linchpin of Medicare coverage is that it pays for "medically necessary" services. Beyond all of the specific exclusions, coverage clarifications, and reimbursement rates, medically necessary means, essentially, those items and services that the medical community provides as part of the day-in, day-out standard of care that are reasonably required to diagnose or treat a specific health condition. As a result, items and services provided during the course of a clinical trial—which, by definition, involve something investigational in nature—could systematically fall outside of the realm of medically necessary without further statement by the Medicare program.

Uncertainty as to whether Medicare would cover routine costs incurred during a clinical trial functioned as a financial barrier to the participation of Medicare enrollees in the research arena.¹ The systematic under-representation of Medicare beneficiaries in clinical trials has at least two significant negative effects. First, the Medicare population is a distinct demographic population—generally,

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¹ Prior to 2000 Only about 1% of elderly Americans participated in clinical trials of drugs and treatments even though the elderly are more severely affected by disease than are younger people. Further, 73 percent of cancer patients are older than 65 but people that age make up only 33% of those enrolled in clinical trials. Medicare to Expand Clinical Trial Coverage, (2000), www.archives.cnn.com/2000/ALL-POLITICS/stories/06/07/clinton.medicare/index.html (last visited April 30, 2007).

people over the age of sixty-five. Given the much-touted “baby boomer” generation, the scientific community needs to understand how medical interventions work (and don’t work) in older people. Researchers have long been concerned about the chronic absence of certain medically relevant communities—women, children, etc.—from research data.²

Although there may be many reasons why the over 65-population might not consistently participate in clinical research, financial barriers only compound disincentives for research participation. If the particular effects of a treatment protocol, drug, or drug regimen on older patients are not well documented, physicians are left with an incomplete data picture on which to base their medical decision-making. If there are poorly understood and anticipated negative outcomes for older Americans, the over 65-population may experience more adverse events, poorer response rates, and an overall diminished prognosis, necessitating more medical interventions, and thereby increasing Medicare claims in the process. To put it differently, a nickel of prevention may be worth a dollar of cure.

Second, in certain cases, patients who decide not to, or cannot, participate in research are not meaningfully disadvantaged because participation or lack thereof in the particular research study does not significantly affect health outcomes (for example, a trial in which two different dosing regimens are being compared to improve patient convenience). In these situations, the individual can still receive medically appropriate and effective care outside of a clinical trial.

In many other situations, however, the most promising medical approach

may be investigational. In those cases, financial barriers to participation have a material and deleterious impact on a patient’s health. For example, in the oncology arena, individuals frequently participate in clinical trials because they have not responded to standard of care treatments or are otherwise medically unable to undergo the standard of care treatment approach. Since cancer rates increase as we age, the need to participate in clinical research is compounded in the Medicare population.³

If those individuals decide against participating in clinical trials because a significant portion of the care would not be covered by Medicare and they cannot afford to pay for the care themselves, they may not have access to the one or two experimental treatments that offer the best chance for extended survival or recovery. For these patients, the investigational intervention is the “medically necessary” care, and thus, a comprehensive national commitment to underwriting the costs of the Medicare population’s participation is critically important.

2000 NCD

The 2000 Medicare National Coverage Decision (NCD) dealt primarily with drug trials. As a practical matter, coverage for investigational devices was principally determined by the Food and Drug Administration’s (FDA) designation of so-called Part A and Part B devices, with routine care costs covered for Part B devices. For the qualifying clinical trials, Medicare would cover “routine” costs. This translated, generally, into Medicare not paying for the specific investigational test article, but paying for those items and services that would have been provided regardless if the patient would have received standard of care.

² See, e.g., National Institutes of Health, NIH Policy on the Inclusion of Women and Minorities as Subjects in Clinical Research, PHS Grant Application (PHS 398), http://grants.nih.gov/grants/funding/phs398/instructions2/p3_nih_policy_women_and_minorities.htm (last visited April 30, 2007).

³ Advancing age is a high-risk factor for cancer, with persons over-65 accounting for 60% of newly diagnosed malignancies and 70% of all cancer deaths. Nathan A Berger, M.D., et. al., Cancer in the Elderly, 117 *Trans. Am. Clin. Climatological Assoc.* 147 (2006) (The age-adjusted cancer incidence rate is 2151/100,000 population for those over 65 compared to 208/100,000 for those under 65.)

The 2000 NCD was criticized, for among other reasons, because: a) the self-certification standards were never announced; b) there was confusion about what costs constituted “routine” costs; and c) the 2000 NCD included an ambiguous provision disqualifying services paid for by sponsors and did not address the Medicare Secondary Payor Rule’s applicability to clinical research, which was seen as a barrier to industry sponsors agreeing to cover costs that were denied by insurance. On July 10, 2006, CMS announced that it would revisit the 2000 NCD, and the proposed policy is the result of that process.⁴

CMS identified 10 issues that it would address in revising the 2000 NCD:

1 Clarify the payment criteria for clinical costs in research studies other than clinical trials;

2 Devise a strategy to ensure that Medicare covered clinical studies are enrolled in the NIH clinical trials registry website;

3 Develop criteria to assure that any Medicare covered clinical research study include a representative sample of Medicare beneficiaries by demographic and clinical characteristics;

4 Clarify the definitions of routine clinical care costs and investigational costs in clinical research studies including clinical trials;

5 Remove the self-certification process that was never implemented;

6 Clarify the scientific and technical roles of federal agencies in overseeing IND exempt trials;

7 Determine if coverage of routine clinical care costs is warranted for studies beyond those covered by the current policy;

8 Clarify how items/services that do not meet the requirements of 1862(a)(1)(A) but are of potential benefit can be covered in clinical research studies as an outcome of the NCD process;

9 Clarify whether and under what circumstances an item/service non-covered nationally may be covered in the context of clinical research to elucidate the impact of the item or service on health outcomes in Medicare beneficiaries; and

10 Discuss Medicare policy for payment of Humanitarian Use Device (HUD) costs.

Proposed CRP

The Proposed CRP is designed to continue the governmental commitment to enabling Medicare enrollees to participate in clinical trials while clarifying those situations in which Medicare will foot the bill for routine costs and services. Although the Proposed CRP makes a number of changes, certain features deserve particularly close attention, including:

❖ The proposal changes the name of the policy to the “Clinical Research Policy” order to “signal [CMS’s] continued support of beneficiaries’ participation in the full range of qualified, scientifically sound research projects.”

❖ The proposed CRP provides a definition of research. Of interesting note, it does not incorporate the definition of “research” found in the primary federal regulation governing clinical research known as the “Common Rule.”

❖ The proposed CRP seeks to clarify “routine costs,” which were covered under the 2000 NCD by replacing it with the term “routine clinical services,” “investigative clinical services,” and “administrative services.”

❖ The proposed CRP continues the two-part approach of the 2000 NCD, dividing such standards into “scientifically and technically sound general study standards” and “Medicare-specific standards.” The former are the characteristics of a well-designed, scientifically bona fide study. The latter are the particular stan-

⁴ Centers for Medicare and Medicaid Services, NCA Tracking Sheet for Clinical Trial Policy (CAG-00071R), www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=186 (last visited April 30, 2007).

dards to qualify for Medicare reimbursement. In other words, a study may be bona fide and scientifically appropriate, but still not eligible for Medicare reimbursement if the study does not further the specific funding goals of the CRP.

❖ As in the 2000 NCD, the proposed rule seeks to identify a mechanism by which CMS can guarantee that the standards just described are met. The proposed CRP, therefore, continues to identify those clinical trials with sufficient federal supervision that CMS can feel reasonably confident that the standards are met. Such trials are deemed to qualify for Medicare reimbursement (“approved studies”). In a significant departure from the 2000 NCD, however, the proposed rule eliminates any other mechanism for interested parties to demonstrate the scientific bona fides of a proposed research study in order to qualify it for Medicare reimbursement.

Understandably, CMS did not embrace continuing the self-qualifying mechanism under the 2000 NCD, fearing that it was subject to ambiguity and/or abuse. But, consistent with the public policy intent to make clinical trial partici-

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ation opportunities available to Medicare beneficiaries, CMS should consider providing for another route whereby interested parties (for example, the research site,

sponsor, and/or investigator) can request that an objective, independent body review the study to determine whether it meets the scientifically and technically sound general study standards or otherwise presents an important, therapeutic opportunity for Medicare beneficiaries, and therefore should qualify for reim-

bursement. If CMS declines to provide for this alternative pathway, CMS may limit considerably the universe of qualifying trials.

❖ Further narrowing the range of clinical research eligible for Medicare reimbursement, the proposed CRP proposes to exclude investigational new drug application- (IND) exempt studies from the deemed approved studies. Under the 2000 NCD, clinical trials that were ruled IND-exempt by the FDA were still deemed as qualifying trials. The proposed CRP eliminates this category.

Thus, if the FDA determines that a clinical trial does not require an IND, the trial becomes ineligible for Medicare reimbursement. This is particularly ironic since one of the requirements for obtaining an FDA IND-exemption is a demonstration that the investigation “does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the product.”⁶ In other words, the less “investigational” a study is (i.e., the more akin to standard of care), the less likelihood of coverage. Such a result seems inconsistent with the goals of the policy.

❖ The proposed CRP states that “Medicare does not cover routine clinical services when they are provided free to the Medicare beneficiary or when the study sponsor agreement with investigator sites or the informed consent documents provided to the patient specify that the clinical service will be provided free to all enrollees.”

❖ The proposed CRP appropriately does not require that the research study be specifically designed to assist Medicare beneficiaries or enroll a certain proportion of Medicare beneficiaries.

❖ The proposed CRP clarifies that the Medicare-specific standards would permit coverage if the study is not designed

⁶ 21 C.F.R. § 312.2(b)(1)

“exclusively” to test toxicity or disease pathophysiology. This revises the 2000 NCD, which required that therapeutic intent be the primary objective of the clinical trial. Thus, the proposed CRP appears to cover certain Phase 1 studies. It also appears to extend coverage for observational clinical studies that some feared were not covered under the NCD 2000.

❖ As stated above, the proposed CRP requires the clinical trial to be registered to qualify on clinicaltrials.gov and requires that the investigators and/or sponsors periodically make the data publicly avail-

Although the proposed CRP may undergo further refinement, it is likely that the final rule will maintain several important features that influence how institutions craft clinical trial billing policies and procedures.

able. It is not certain how this data availability provision will work. For example, in certain cases, it is important to withhold results to avoid creating the

Hawthorne Effect—namely, where information affects the experiences of the enrolled subjects. In addition, it is not clear how this periodic reporting obligation will work with mandated securities filings or with industry needs to protect intellectual property.

❖ The proposed CRP declines to comment on the impact of the Medicare Secondary Payor (MSP) Rule on claims relating to subject injury or claims not covered by insurance. Research sponsors, IRBs, investigators, and sites understandably want to minimize the financial burden on subjects associated with medical injuries out of a sense of fairness and concern that individuals may be reluctant to participate if they would face unexpected medical bills. It is reasonable for sponsors to volunteer to be the back-up quarterback, picking up the ball only if the primary coverage—Medicare or other third-party payers—deny claims.

Because the proposed rule does not squarely address whether and how an industry sponsor may cover either denied claims or costs of subject injuries, and because the MSP Rule has been interpreted by some to mean that Medicare will not pay for claims if another liability insurer—in this case, the sponsor—is in the wings and willing to pay, sponsors may feel that they must effectively agree to pay for all or none of classes of claims and expenses. All interested will benefit if the final rule provides more clarity.

❖ The proposed NCD states that one pathway for being deemed an approved study is to be reviewed and funded by specific federal agencies. It is not clear what type of “review” is necessary.

Conclusion

As under the 2000 NCD, institutions providing items and services during the course of a clinical trial need to be mindful not to submit claims for Medicare reimbursement that do not meet the coverage standards that CMS has announced. Institutions that improperly submit claims to the Medicare program face repayment obligations and potential false claims act repercussions. Industry entities, too, need to be mindful of reimbursement rules so that these sponsors can draft clinical research budgets that do not leave research sites in a financial hole.

Although the proposed CRP may undergo further refinement, it is likely that the final rule will maintain several important features that influence how institutions craft clinical trial billing policies and procedures. *G2 Compliance Report* will publish a second article following the issuance of the final rule describing its provisions and including implementation suggestions.

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