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## CMS Opens 30-Day Comment Period on Revised Clinical Trial Coverage Policy

### Proposed CMS Changes Restrict Rather than Expand Coverage

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The Centers for Medicare & Medicaid Services (CMS) issued its Proposed Decision Memo for Clinical Trial Policy (to be renamed the “Clinical Research Policy (CRP)”) on April 10, 2007. The Proposed Decision is posted at:

<http://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=186>

The Proposed Decision signals a potentially significant impact on manufacturers, providers, and patients with respect to coverage, reimbursement, billing compliance, and patient access to new treatment options. The Proposed Decision would afford Medicare coverage for a smaller subset of qualifying clinical trials than the original National Coverage Decision did, and its implementation may constrict access of Medicare beneficiaries to these studies. Further, coverage and billing uncertainty will continue for providers, manufacturers, and patients.

**The comment period for this Proposed Decision closes on May 9, 2007.** CMS expects to issue its final decision by July 9, 2007.

The Proposed Decision follows a December 13, 2006 Medicare Coverage Advisory Committee meeting. King & Spalding’s Client Alert of December 20, 2006 provides a detailed discussion of that meeting and the history of the CMS Clinical Trial Policy. Please see <http://www.kslaw.com/Library/publication/ca122006.pdf>.

Since CMS announced it would reconsider its clinical trial policy, nearly all of the fifty-three (53) commenters, including eleven (11) medical device and pharmaceutical manufacturers, expressed opposition to any policy revision that would constrict Medicare coverage. CMS responded with a statement that it remains committed to the goals of the 2000 Executive Memorandum directing Medicare coverage of routine care costs associated with clinical trials for all diseases, and that it would direct policy changes at removing barriers to



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beneficiary participation in clinical studies. However, we do not believe that CMS has fulfilled this commitment.

The 30-day comment period might be the last meaningful opportunity for stakeholders to provide the Agency with information and public policy considerations to guide formulation of the final National Coverage Decision.

### Summary of the Proposed Decision Memo

**“Approved Research Studies”:** CMS reliance on Section 1862(a)(1)(e) of the Social Security Act as the basis for Medicare payments associated with clinical research imposes significant limits on the studies qualifying for coverage to those “conducted with AHRQ support pursuant to section 1142 of the Act.” According to CMS, AHRQ will support studies that meet general standards for technically sound clinical research. The following studies will be “deemed” to meet this requirement:

- ✓ Studies of health outcomes reviewed and funded by a program component of DHHS, the VA, or DOD;
- ✓ Studies reviewed and approved by health care research centers or cooperative health care research groups that are funded by one of the above Federal Agencies, if the Agency reviews and approves:
  - o subcontract and sub-grant funding requirements;
  - o selection procedures;
  - o oversight methods; and
  - o determines that the processes afford the level of review that would be provided by the supporting Agency.
- ✓ Investigational New Drug (IND) studies when FDA has reviewed the protocol and the IND is not on hold;
- ✓ Post-approval studies required and approved by FDA;
- ✓ Studies required by a Coverage with Evidence Development (CED) National Coverage Decision (NCD).

***Significantly, under the Proposed Decision IND-exempt studies will no longer be covered, and the self-certification process for coverage in connection with non-deemed trials will not be implemented.***

As with the current National Coverage Decision on Clinical Trials, the revised policy would not impact the existing Medicare coverage regulations published in the September 19, 1995 Federal Register with respect to the coverage of the clinical costs of trials involving a device with an FDA-approved investigational device exemption.

**General and Medicare-Specific Standards Must Be Met:** The above-listed “deemed” studies are presumed to meet the general standards for technically sound clinical research studies. Although the



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Proposed Decision authorizes Medicare Contractors to determine whether Medicare-specific standards are met, there is no discussion of approval processes to ensure compliance with the general standards and the self-certification process will not be implemented. It is, therefore, unclear whether any non-deemed trial will qualify for coverage. The general standards are:

- ✓ Principal purpose is to evaluate an intervention's improvement on participant's health outcomes;
- ✓ Study is grounded in available scientific and medical information or is intended to clarify or establish commonly used intervention's impact on health outcomes;
- ✓ No unjustifiable duplication of existing studies;
- ✓ Study is designed to answer the research question;
- ✓ Sponsor is capable of executing the study successfully;
- ✓ Compliance with Federal regulations at 45 C.F.R. Part 46 concerning protection of human subjects and, if FDA-regulated, 21 C.F.R. Parts 50 and 56;
- ✓ Adhere to appropriate standards of scientific integrity;
- ✓ Conducted under a written protocol.

The Medicare-specific standards clearly add a layer of requirements to clinical trials for which Medicare coverage is secured. Sponsors need to appreciate that these standards require meticulous attention to public disclosure of the existence of the study prior to first patient enrollment and explicit written plans for public disclosure of study results. According to these standards, an approved clinical research study must:

- ✓ Not be designed exclusively to test toxicity or disease pathophysiology. *Phase I trials that measure therapeutic outcomes meet this standard only if the studied disease or condition is chronic, life-threatening, or debilitating;*
- ✓ Be registered on [ClinicalTrials.gov](http://ClinicalTrials.gov) prior to enrolling subjects;
- ✓ Be conducted under a protocol that specifies and fulfills the method and timing of public release of all specified outcomes measured, regardless of whether the outcomes are negative or the study is terminated early;
- ✓ Contain, in the study protocol, an explicit discussion of inclusion criteria and consideration of relevant subpopulations;
- ✓ Discuss, in the study protocol, the impact of age-specific and other factors on outcomes and whether the study is sufficiently powered to draw Medicare-specific conclusions.

**Clinical Research Studies Consisting Exclusively of Data Collection:** Clinical studies that consist exclusively of data collection processes that do not introduce an intervention that may influence health outcomes or patient management do not have to comply with the standards or approval process contained in the Proposed Decision. Items and services provided to study subjects in connection with such research are covered if they meet the general Medicare standard of reasonable and necessary.



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**CMS Oversight and Potential Fraud and Abuse Concerns:** The CMS Chief Medical Officer, with or without the advisory opinion of the MedCAC, has discretionary authority to determine that a research study for which Medicare payments are made does not meet (or no longer meets) the criteria for coverage or that it jeopardizes the safety or welfare of beneficiaries.

- ✓ In such a situation, participating beneficiaries would not be liable for costs.
- ✓ Billing providers, however, may be held liable and find themselves (and the principal investigator) subject to fraud investigation for billing for services that they should have known were not covered. The most obvious application of this provision is to clinical trials for which negative results are not publicly reported. The knowing submission of claims for trial-related costs for trials CMS deems not to be eligible for coverage could subject the provider to liability under federal and state healthcare fraud laws.

**Covered and Non-Covered Items and Services:** CMS proposes to retain the set of covered items and services contained in the current policy and to also cover the item or service that is the subject of the study if it is available to Medicare beneficiaries outside the clinical study. Non-covered administrative services include clinical services provided solely for data collection and analysis and all non-clinical services, including investigator salaries.

### Key Issues for Pharmaceutical, Biologics, and Medical Device Manufacturers:

- Although commenters requested clarification on the interface between Medicare Secondary Payor (MSP) provisions and clinical trial coverage, CMS has declined to include guidance within the National Coverage Decision process.
- Trials employing devices that FDA has approved for marketing under the Humanitarian Device Exemption (“HDE”) are not specifically included in the Proposed Decision as anticipated. CMS has stated that the appropriate means for determining coverage of FDA-required studies for HDEs is through the CED process as part of an NCD. It is not clear whether the Agency would look at these devices broadly or on a device-specific basis.
- Medicare generally covers reasonable and necessary medical care for treatment of complications arising from non-covered items or services, including investigational services. For example, Medicare does not cover purely cosmetic surgery, but would cover the costs of treating any complications arising from such non-covered surgery (subject to MSP provisions). **The Proposed Decision lends itself to confusion and a misinterpretation of the Medicare statute that coverage for complications is limited to approved clinical research, when coverage of complications arising from non-covered procedures is allowed under existing law.**



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- Medicare contractors may be inconsistent and may vary in their determinations of whether studies meet the Medicare-specific standards and in their follow-up on adherence to those requirements.
- Clinical trial costs are eligible for coverage only if the investigated item or service falls within a Part A or Part B benefit category. Studies related to Part D drugs are not within the Proposed Decision.

If you have a questions about CMS' Proposed Decision, or would like more information about King & Spalding's coverage and reimbursement capabilities, please contact:

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