

March 12, 2009

Charlene Frizzera
Acting Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., room 445-G
Washington, D.C. 20201

Also sent via email

Dear Ms. Frizzera:

The Association of American Medical Colleges is a not-for-profit association representing all 130 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 68 Department of Veterans Affairs medical centers; and nearly 90 academic and scientific societies. The AAMC's member medical schools and teaching hospitals collectively perform more than 60% of all extramural research sponsored by the NIH. Our member hospitals account for 19% of total Medicare discharges. I am writing to urge CMS to reconsider the Medicare's policy regarding coverage for beneficiaries enrolled in a clinical trial.

Currently, CMS policy resides in many places, including a National Coverage Decision (NCD) that was first issued in 2000, for category A and B devices in 42 CFR §405.201 *et seq.*, and in many manual sections and other subregulatory guidance documents. We supported the issuance of the policy in the NCD and provided testimony and comments. We also commented and testified during subsequent considerations of it. We strongly believe that Medicare beneficiaries should have the same access to the cutting edge care found in clinical trials as do other patients, and that research benefits when the Medicare population is adequately represented. However, our members continue to find the current policy confusing to implement, lacking consistency with other Medicare policies that affect clinical trials, and variable in its application due to differing interpretations by Medicare contractors.

The goal of a new effort by CMS should be two-fold: to increase the enrollment of Medicare beneficiaries in clinical trials and to give providers sufficient clarity about the requirements so that they can be followed with relative ease and without fear that inadvertent errors may result in a large settlement with the government.

CMS should begin the process anew by gathering stakeholders together for the purpose of understanding the challenges that the current policy presents to providers, and collecting ideas about what is needed to resolve the myriad of problems. This information could be used to develop a notice of proposed rulemaking and ultimately the issuance of a final rule that revises, clarifies, and consolidates Medicare policies related to beneficiaries enrolled in clinical trials.

Examples of Issues to Be Resolved

Below is a list of some of the problems associated with the current clinical trial policy. It should not be considered comprehensive, but is meant to indicate the breadth of the problems and to underscore the need for CMS to act quickly to resolve issues that have arisen since the inception of the current policy.

1. Coverage for Phase I Clinical Trials

An informal survey of our members has revealed that some Medicare contractors cover the routine costs of beneficiaries enrolled in Phase I Clinical trials, and others do not. Those who do not often cite the requirement in the NCD that coverage requires that the trial have “therapeutic intent.” However, they misinterpret and narrow this requirement to mean that the **sole** intent of the clinical trial must be therapeutic. The result is inconsistent coverage for Medicare beneficiaries and potential problems for researchers conducting multi-site trials. CMS policy should provide for coverage of qualified phase 1 trials for any life-threatening condition, including cancer, because for these conditions, they are the only or among the only possibilities of amelioration of or intervention for the condition. Therapeutic intent necessarily is included under these conditions.

Although the scientific goals of a phase 1 trial are to determine the toxic effects, pharmacologic behavior, and recommended doses for future study of a new agent, there is a strong preclinical rationale for bringing the drug into the clinic with the expectation of positive clinical outcomes for some patients. Additionally, many NCI phase 1 trials involve agents that are already approved for the treatment of one type of cancer and are being studied in a different type of cancer, or in combination with other treatment. As a result, there is already evidence of therapeutic effectiveness that provides solid grounding on which to base therapeutic intent.

2. Beneficiaries Enrolled in Medicare Health Plans (Part C)

The NCD extends coverage to beneficiaries enrolled in Medicare health plans and requires the coverage to be on a fee-for-service basis. This means that beneficiaries who may have no or small co-pays for other medical care will be charged the same co-pay and deductible as those with fee-for service coverage. This is a disincentive for beneficiaries covered under Part C to enroll in clinical trials and may limit the number of Medicare patients who can be recruited to participate.

3. Medicare Secondary Payer Rules

CMS has never clarified the relationship between Medicare secondary payer rules and the common practice of a clinical trial sponsor to pay for medically necessary services related to injuries received as a result of participation in the trial, provided that these services are not otherwise covered by another payer.

4. Deemed Trials

Although the NCD describes a process whereby clinical trials other than those funded by certain federal agencies will be eligible for Medicare coverage, this provision has never been implemented.

5. Local Coverage Determinations

Coverage for clinical trials must be implemented on a national basis and should not be subject to local contractor determinations. Many trials are multi-site trials, and are conducted in various states. If the states in which the trial is conducted have different contractors, there may be different coverage decisions. This represents another disincentive to enrolling Medicare beneficiaries in a multi-site trial, as consistency in enrollment criteria and coverage are essential. It disadvantages Medicare beneficiaries nationwide and excludes an important population from study participation, analysis, results, and, in fact, therapy. It has the potential to skew results. This situation must be remedied.

6. Need to Coordinate Device Policy and Other Clinical Trial Policies

Medicare coverage for Category A and B clinical devices is covered outside the NCD, in regulations found at 42 CFR §405.201 *et seq.* Many questions have arisen as to the application of the NCD requirements to these devices. CMS should develop a clinical trials policy that is all-encompassing, and is consistent for trials involving device, drugs, and procedures.

7. This Policy Should Be Issued Through a Rulemaking, Not An NCD

On several occasions, CMS tried to revise the NCD. However, the NCD process itself is designed to make determinations about whether particular items and services are reasonable and necessary. Most frequently, these decisions relate to devices, drugs, and new procedures. Clinical trials are not the equivalent of discrete items and services. They comprise an entire protocol, typically encompassing numerous items and services that, when taken together, constitute the clinical trial. The NCD process was never intended to tackle the complexities raised by clinical trial coverage and should no longer be used for that purpose.

Thank you for your consideration of these comments. We look forward to working with you to achieve the goal of a clear, consistent, comprehensive, and understandable clinical

trials policy that will encourage the enrollment of Medicare beneficiaries and will be not put providers at risk for inadvertent errors.

If you wish to discuss these suggestions further, contact either Ivy Baer, ibaer@aamc.org or 202-828-0499, or Susan Ehringhaus, sehringhaus@aamc.org or 202-828-0543.

Sincerely,

Joanne Conroy, M.D.
Chief Health Care Officer

Cc: Stephen Phurough, M.D.
Leslye Fitterman, Ph.D.