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February 3, 2003

Janet Rehnquist
Inspector General
Department of Health and Human Services
Attention: OIG-72-N
Room 5246, Cohen Building
330 Independence Avenue, SW
Washington, DC 20201

Dear Ms. Rehnquist:

The Association of American Medical Colleges welcomes this opportunity to provide comments as requested in the *Solicitation of Public Comments on Exceptions Under Section 1128A(a)(5) of the Social Security Act (* 67 *Federal Register* 72892). The AAMC represents the nation's 125 allopathic medical schools, over 400 major teaching hospitals and health systems, and more than 92 academic societies. The AAMC comments focus on the development of an exception for "inducements to participate in bona fide clinical trials."

The notice states that "we are concerned that section 1128A(a)(5) not unduly impede valuable clinical trials." The AAMC shares that concern and believes it is essential that the research conducted by academic institutions and those who work within them be allowed to continue, with scientific investigators unimpeded by fear that they may be prosecuted for violating the fraud and abuse laws for activities that are within the scope of their research design.

The *Federal Register* notice suggests four possible criteria around which an exception could be created: threshold level of Medicare reimbursement; sponsorship of studies; type of inducements; and source of benefits. The AAMC believes that clinical trials are sufficiently different from traditional care and operate under a system that provides adequate protections to research subjects, that it is not possible to develop criteria for clinical trials with the specificity envisioned by the OIG. For example, in the Special Advisory Bulletin, "Offering Gifts and Other Inducements to Beneficiaries," the OIG has defined a minimal, allowable inducement from a provider to a beneficiary as no more than $10 per item or $50 annually per patient. As will be discussed below, payments to a participant in a clinical trial must relate to that specific trial and are intended to ensure sufficient participation in a trial, regardless of an individual's financial abilities. Thus, it is virtually impossible to draw the "bright lines" that appear elsewhere in exceptions to the fraud and abuse laws.

If an exception is created, it should include deemed trials (as defined by the National Coverage Decision) that have obtained approval from an IRB, and for which the Principal Investigator is an employee of the university, medical school, and/or teaching hospital/health system.

The Role of the IRB

Neither the OIG nor CMS has the expertise to judge the soundness of any particular trial, nor the relationship between what is provided to a participant and the ability to recruit participants for the research study. However, the system of IRB review is designed to protect subjects by examining these issues, while evaluating the specific requirements of a clinical trial and the personal circumstances of the participants.

Understanding the system that is in place to protect human subjects underscores the difficulty of adopting the type of standard that seems to be contemplated by the OIG's notice. IRBs regularly evaluate the size and nature of incentives offered to participants, and determine whether the incentives constitute undue inducement or coercion, taking into consideration such details as the subjects' medical, employment, and educational status, and their financial and other resources. Federal regulations (45CFR46 and 21CFR50, 56) require that IRBs consider whether participants in research are recruited fairly, informed adequately, and paid appropriately, as part of their mandate to evaluate whether consent is voluntary.

Admittedly, none of the regulations issued by FDA or NIH that relate to human subjects research are designed to ensure compliance with the fraud and abuse laws. However, items such as free medical care or free transportation are designed to eliminate barriers to participation, exactly what was envisioned by the National Coverage Decision. They are not intended to induce beneficiaries to obtain either too many services or services that are unnecessary. For example, some Medicare beneficiaries would be unable to participate in a research study if transportation were not provided to them. Any inducements that survive IRB scrutiny represent an informed judgment that they are necessary for obtaining an adequate subject pool, rather than that they are inducements for unnecessary service utilization.

The IRB's determination of whether a payment is appropriate for a given clinical trial is dependent on the particular facts of that clinical trial, making it impossible to craft a "one size fits all" de minimis exception for clinical trials in any of the categories suggested by the notice. Moreover, the system of IRB oversight of research has been strengthened over the last several years, as many institutions have allocated significantly increased resources to their human research protection programs, implemented new NIH requirements for investigator training, developed stronger policies for the responsible conduct of research, and taken other steps recommended in the OIG's 2000 report, *Recruiting Subjects: Pressures in Industry-Sponsored Clinical Research.*

The Move Towards IRB Accreditation

Another trend towards strengthening the IRB system is the movement towards accreditation. Both the Association for the Accreditation of Human Research Protection Programs (AAHRPP) and the National Committee for Quality Assurance (NCQA) released standards for the accreditation of human research protection programs during the last year. NCQA recently announced that it has formed a partnership with the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to create a program for protecting human subjects in clinical research.

The AAHRPP strives to improve human research protections by assisting institutions to attain performance standards that surpass state and federal requirements, and was created jointly by several organizations, including the AAMC. The NCQA is an independent, non-profit organization that focuses on assessing and reporting on the quality of the nation's health care organizations. Its standards are the product of the organization's contract with the Department of Veterans Affairs (VA) to develop an accreditation system for VA human research programs. Currently, the VA accepts consolidated accreditations for VA facilities when the institutional review board (IRB) has been reviewed by the AAHRPP. The FDA is also encouraging accreditation of IRBs that oversee clinical trials regulated by the agency.

At some point in the future, when accreditation has been established and is widely used, the OIG may want to consider including that as a further criterion for an exception. Imposing such a criterion today would be premature since IRB accreditation is in its infancy and few IRBs are accredited.

Conflicts of Interest Guidelines

The AAMC also has adopted as official association policy two sets of financial conflict of interest guidelines, one that addresses individual conflicts of interest and a second that addresses institutional conflicts of interest. Both are available on the AAMC website at www.aamc.org/members/coitf/. Many AAMC members are working to implement the guidelines contained in these documents, which are stringent and set a high bar against the conduct of human subjects research by financially self-interested individuals and institutions.

If you would like to discuss any of these comments, please contact either Ivy Baer at 202-828-0490 (ibaer@aamc.org) or Rina Hakimian at 202-828-0484 (rhakimian@aamc.org).

Sincerely,

Jordan J. Cohen, M.D.