



MAY 06 2008

Michael D. Maves, M.D., M.B.A.
Executive Vice President, CEO
American Medical Association
515 North State Street
Chicago, IL 60610

Dear Dr. Maves:

Thank you for your letter on behalf of the American Medical Association (AMA) requesting clarification of the language in the Stark II Phase II rule that you believe may potentially restrict the ability of hospitals to provide free continuing medical education (CME) programs to physicians.

We understand the importance of ongoing CME in ensuring high quality patient care, and we recognize that some hospitals are willing to provide free or reduced cost CME in a manner that is convenient for physicians to remain currently apprised of developments in their areas of practice. Although you expressed concern in your letter regarding a statement in the Phase II rule that free CME may constitute remuneration, we continue to abide by the statements of former Administrator Mark McClellan in his March 13, 2006 letter that was intended to clarify such language. As stated in that letter, "traditional, on-site hospital grand rounds and other similar in-house education programs provided by hospitals are important and convenient ways for physicians to earn CME credit and for hospitals to ensure high quality patient care. We do not believe that such programs, which historically have been provided on-site at no charge, necessarily constitute remuneration to the physicians who attend them." To clarify further, for purposes of our physician self-referral rules, we do not consider on-site CME to be remuneration if it is primarily for the benefit of the hospital's patients, for example, training on the prevention of nosocomial infection. However, CME that is not primarily for the benefit of the hospital's patients is considered remuneration. Where a hospital or physician is uncertain as to whether CME would be primarily for the benefit of the hospital's patients, the hospital or physician may request an advisory opinion in accordance with the procedures set forth at 42 CFR section 411.370.

Moreover, to the extent that CME would constitute remuneration, there are several existing exceptions that may apply. The exceptions at 42 CFR sections 411.357(k) and (m) allow hospitals and other entities to provide non-monetary compensation up to \$300 (updated for inflation), and medical staff incidental benefits of less than \$25 (updated for inflation), and both such exceptions can cover grand rounds and other on-site CME. The exception at 42 CFR section 411.357(n) allows hospitals and other entities to provide physicians with compliance

training, including programs that offer CME credit, provided that compliance training is the primary purpose of the program. The bona fide employment relationships and personal service arrangements exceptions at 42 CFR sections 411.357(c) and (d), respectively, also may be applicable, depending on the circumstances.

Finally, to the extent that, in a given situation, CME constitutes remuneration and such remuneration is not protected by one of the exceptions described above, we believe that, ultimately, physicians should bear the cost of such CME. As stated in your letter, "Hospitals expect their medical staff to maintain a current knowledge base of state-of-the-art medical practice . . ." In other professions, it is not uncommon for the cost of continuing education to be paid for by the professional, rather than by another entity. Because of the variation in State CME licensing requirements, the variety of courses and seminars, and the wide ranges in the cost of CME programs, and other reasons, we remain concerned about the potential for Federal program abuse in the provision of certain CME training programs by hospitals. Section 1877(b)(4) of the Social Security Act gives the Secretary the authority to create an exception only in such cases that the Secretary determines, and specifies in regulations, that the financial relationship at issue does not pose a risk of program or patient abuse. As former Administrator McClellan stated in his letter to the AMA dated March 13, 2006, we do not believe "that a broad exception for CME is consistent with our statutory mandate to create by regulation only those exceptions that pose no risk of program or patient abuse."

I hope this information is helpful.

Sincerely,



Jeffrey B. Rich, M.D.
Director
Center for Medicare Management