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Dec. 23, 2008

Mr. Kerry N. Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 314-G Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: CAG-00401N, Wrong Surgery Performed on a Patient; CAG-00402N, Surgery on Wrong Body Part; CAG-00403, Surgery on the Wrong Patient

Dear Mr. Weems:

The American College of Cardiology (ACC) is pleased to offer our comments on the three National Coverage Determinations (NCDs) proposed by the Centers for Medicare and Medicaid Services (CMS) to protect patients from prevent surgical errors, released December 3, 2008. These NCDs would establish Medicare nonpayment for three so-called "never events" for wrong surgical or other invasive procedures performed on a patient, surgical or other invasive procedures performed on the wrong body part, and surgical or other invasive procedures performed on the wrong patient.

The ACC is a professional medical society and teaching institution made up of 37,000 cardiovascular professionals from around the world – including 90 percent of practicing cardiologists in the United States and a growing number of registered nurses, clinical nurse specialists, nurse practitioners, physician assistants, and clinical pharmacists. The ACC is committed to improving the health care of all Americans and advocates for quality cardiovascular care through education, research promotion, development and application of standards and guidelines, and aims to influence health care policy.

Our goal in reviewing proposed Medicare coverage changes is to assure access to quality cardiovascular care for Medicare beneficiaries. The ACC is strongly committed to quality improvement and we support collaborative efforts to reduce medical errors to ensure patients receive the appropriate treatment for their medical condition. While it is clear that the medical community must continually strive to establish systems to ensure these surgical "never events" are eliminated, the College would encourage CMS to establish an appeals process to allow physicians and other providers to gain recourse against any agency noncoverage decisions that may be made inappropriately.

Within the surgical system, infrequently, surgeries could have been performed correctly yet coding errors could have occurred. Additionally, attribution of the wrongful surgical event often is not clear.

The mission of the American College of Cardiology is to advocate for quality cardiovascular care — through education, research promotion, development and application of standards and guidelines — and to influence health care policy.

The ACC believes that setting ambitious goals can challenge health care providers to achieve quality improvement goals they may not have thought possible. However, these goals must be realistic and reasonably achievable. Moreover, providers need practical tools to help them take steps toward achievement of the goal. The College strongly urges CMS to focus its quality improvement efforts for physicians on working with hospitals and other providers to establish effective internal procedures that eliminate the potential for wrongful surgical procedures to occur. CMS may consider programs or policies that encourage adoption of Joint Commission policies of double identification checks, surgical team “time outs” and requiring the surgeon to physically meet with the patient to review the procedure and confirm the correct site prior to scheduled surgery.

The agency has identified a serious challenge to quality health care with its recognition that these events should never occur. Nonetheless, the proposed NCDs should develop processes that provide recourse in instances where coverage should be allowed. The ACC commends CMS efforts to work collaboratively with hospitals, physicians and other providers to ensure these “never events” related to wrongful surgeries and other invasive procedures are eliminated as quickly as possible.

The ACC appreciates the opportunity to comment on these proposed national coverage decisions and we remain eager to assist you and your staff as it considers whether to finalize the NCDs. If you have any questions, please contact Gretchen Wyatt, Sr. Specialist, Regulatory Affairs at 202.375.6392 or via e-mail at gwyatt@acc.org.

Sincerely,

W. Douglas Weaver, M.D., F.A.C.C.
President
American College of Cardiology

cc: Jack Lewin, M.D., CEO
American College of Cardiology