



Michael D. Maves, MD, MBA, Executive Vice President, CEO

January 1, 2009

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

Re: CAG-00402N, Surgery on Wrong Body Part; CAG-00403N, Surgery on the Wrong Patient; and CAG-00401N, Wrong Surgery Performed on a Patient (December 2, 2008).

Dear Acting Administrator Weems:

On behalf of the physician and medical student members of the American Medical Association (AMA), we appreciate the opportunity to provide comments concerning the Centers for Medicare and Medicaid Services' (CMS) proposed National Coverage Determinations (NCDs) for *Surgery on the Wrong Body Part*, *Surgery on the Wrong Patient*, and *Wrong Surgery Performed on a Patient*.

We reiterate below our comments that we previously submitted to CMS in response to CMS' announcement of its plan to develop these proposed NCDs. The AMA is extremely disappointed that CMS is moving forward with the NCDs in this procedural manner. NCDs typically do not generate widespread public comment as does public notice and comment requested through a *Federal Register* proposed rulemaking. In addition, there is only a 30-day public comment period for these NCDs. This substantially truncated process affords little opportunity for adequate notice and public comment. The failure to elicit thorough public discussion on these important matters results in policies that leave many critical questions unanswered, such as defining the surgical event errors covered by the proposed NCDs, as well as accountability and the scope of non-payment for these events. Physicians and providers must have clear guidance on Medicare coverage and payment policy, but the NCD process in these instances is a complete obstacle to this goal. Without the benefit of public input from those with hands-on expertise in these matters, this NCD process only creates confusion and ill-conceived Medicare policy.

Medicare NCDs set national policy on whether Medicare will cover an item or service and under what conditions. The AMA does not believe that it is appropriate for CMS to use the NCD process to address its concerns regarding the aforementioned surgical procedures.

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Rather, CMS should develop a clear payment policy outlining the circumstances under which surgery claims would not be payable by Medicare. For example, if a physician failed to use commonly accepted patient safety practices which resulted in surgery on a wrong body part, a Medicare carrier might deny partial or complete payment for the service claim. The issue at question is not whether surgical procedures will be covered by the Medicare program, but rather under what circumstances the payment for covered surgical procedures will be denied or reduced. Further, because of the many nuances surrounding these surgical conditions, it is important that any payment policy determinations include an appeals process for physicians and hospitals to petition any decisions that they believe were made inappropriately.

CMS typically initiates a coverage review process due to questions about the evidence behind the clinical effectiveness of a service, conflicting local coverage policies, or medical advances in the care or diagnosis of a disease or condition. None of the three surgical conditions presents an issue that generally would qualify them for development of a NCD. Medicare claims processing personnel do not have the expertise necessary to make determinations about whether particular surgical procedures were performed correctly. We are very concerned that patients will wrongly be denied coverage of Medicare services due more to errors in judgment by contractors than errors by a surgical team. Further, coverage decisions are far-reaching. Would coverage denials extend to every facility and health professional involved in the person's care, or would contractors attempt to assess "blame" on a particular individual? **Therefore, we urge CMS to withdraw these NCDs, and explore options for revising Medicare payment policies associated with these three surgical conditions.** For example, CMS has established payment policies to address coding edits, as well as global and multiple surgery policy.

The AMA appreciates the opportunity to comment, and we look forward to working with CMS to achieve consensus on the foregoing matters. If you should have questions regarding this correspondence, please contact Jennifer Shevchek, Assistant Director, Federal Affairs, at 202-789-4688, or jennifer.shevchek@ama-assn.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Mike Maves". The signature is written in a cursive, flowing style.

Michael D. Maves, MD, MBA