March 8, 2013

George G. Mills, Jr., Director, Provider Compliance Group
Centers for Medicare and Medicaid Services
Office of Financial Management
Mail Stop C3-09-27; Room C3-09-17
7500 Security Boulevard
Baltimore, MD 21244

Subject: Jurisdiction B K-Level Policies and Their Resulting Discrimination Against Medicare Amputees and Other Disabled Persons; Claims Reviewers Overruling K-Level Determinations

Dear Mr. Mills:

I am writing to inform you, and to request your action to ameliorate a recent, inappropriate and illegal action undertaken by one of the Medicare contractors. Specifically, I am referring to the attached announcement issued by Jurisdiction B, which was presented as a 'clarification' of its policy relating to K-level determination and concomitant determination of eligibility for advanced prosthetic technologies. Unfortunately, what we have seen transpire in Jurisdiction B makes clear that this is not being applied as a clarification of existing policy, but instead is staking out dangerous new policies. As you know from our previous communications dating back to the "Dear Physician" letter issued August 11, 2011, AOPA has expressed grave concerns about the practice of CMS contractors establishing new policies for the Medicare program, in CMS's name, without observing the formal rulemaking responsibilities for government actions set forth in the Administrative Procedures Act.

It is clear that a new, and we believe profoundly inappropriate, policy is now being implemented, at least by Jurisdiction B, and quite likely in the other Jurisdictions. As with the misguided "physician documentation requirements" this new policy represents an acute disruption of patient care. According to prevailing Medicare policy, the K-level assessment is made by the amputee Medicare beneficiary's physician, with potential input from the prosthetist. This assessment amounts to that physician's prognosis of the likelihood of the patient's ability to become a community ambulator, able to discharge the activities of daily living most fully, with the mobility assistance provided by a specific advanced technology incorporated into a prosthetic limb.

Like any prognosis, this assessment is based on science and principles of medicine, practice and experience, and an underlying assumption as to the patient's medical progress. However, Jurisdiction B now states that assumptions as to medical progress cannot have a part in that patient assessment/determination. Even more disturbing than what Jurisdiction B has said, is what they have started to do. Specifically, we are aware of claims in which Jurisdiction B claims reviewers have been using details of the patient's health that are unrelated to their amputation or limb loss. These factors include the use of hypertensive medications to treat blood pressure, history of cancer treatment, history of peripheral vascular disease, body weight conclusions derived from scrutiny of every factor in the patient's medical record. Claims reviewers are relying on these factors as the basis for overturning the comprehensive K-level determination. Taking isolated facts about a particular patient's medical history out context and without the ability to directly engage the patient and then rendering a decision is venturing into dangerous territory. Claims reviewers are rejecting the determination made by trained professionals who have actually examined the patient, and substituting a lower K-level determination, even though the claims reviewer has never even seen the patient and often has little if any experience in prosthetics or the care of amputee patients.

AOPA believes that this type of contractor activity is totally inappropriate and represents a modification of the standard of care for Medicare beneficiaries. It further is an inappropriate misuse of contractor access to physician documentation as well as possible interference with the practice of medicine. Moreover, it creates new, inappropriate and unfair impediments that discourage claims, regardless of merit, involving the more advanced (and therefore more expensive) technologies for prosthetic feet. This activity seeking to 'downshift' the standard of care of these Medicare amputee beneficiaries to a new, lower level emphasizing a shift to less advanced (less expensive) technologies—occurs in a manner which discriminates, and operates to the detriment of amputees, i.e., disabled persons as defined by the American for Disabilities Act.

This new policy by Jurisdiction B may not have the intent of discrimination, but the fact is that it interferes to reverse the physician's judgment and to provide less sophisticated technologies to Medicare beneficiaries. This may be deemed, by some, to be appropriate behavior as a matter of private sector insurance plans, but it is clearly inappropriate and illegal behavior for the Medicare program.

We recognize the value that claims reviewers can provide in preventing waste, fraud and abuse in the Medicare program. However, such value arises from claims reviewers finding inconsistencies between diagnoses and prescriptions, noting critical missing documentation or coding mistakes, or analyzing suspicious patterns in treatments. By contrast, there is no value to claims reviewers attempting to substitute their medical judgment for that of trained professionals, particularly when the claims reviewers have never even examined the patient. Congress recognized the need for actual examinations of patients in the Affordable Care Act, when it directed that physician orders for certain medical equipment not be issued unless the physician certifies that he or a member of his staff has physically seen the patient. We do not see why claims reviewers should not be held to the same standard.

We therefore request that you immediately reverse this new Jurisdiction B policy, instruct the Jurisdiction B contractor, as well as contractors in other Jurisdictions, to limit the ability of claims reviewers to override the K-level determination of physicians unless the claims reviewers have actually examined the patient. Amounts already withheld as a result of any cases in which a claims review has resulted in a reduced Medicare amputee beneficiary K-level below that determined appropriate by the patient's own physician should be returned in full with interest to the prosthetic providers, and these beneficiaries be cleared for treatment and reimbursement consistent with the K-level the physician established.

Fairness in the Medicare system demands strong and effective oversight and management of Medicare contractors. This represents an instance in which we believe that oversight management has been lacking, and needs to be remedied immediately to avoid further severe and potentially irreparable damage to Medicare disabled beneficiaries. If Medicare is unhappy with the existing K-levels and how these decisions are being made by the physicians who are involved in actually treating Medicare amputee beneficiaries, CMS has the ability to change those policies—but NOT in the manner in which Jurisdiction B has attempted. Rather, the policies could be reviewed in an open, full, notice and comment rulemaking process that would afford beneficiaries an opportunity to be informed and to participate in crafting any new or revised policies.

We would be pleased to discuss directly, on an expedited basis, any questions relating to this requested action. We believe immediate Medicare intervention is required.

Very truly yours,

Thomas F. Fise, J.D.
Executive Director

cc: Marilyn Tavenner, CMS Administrator
The Honorable L.F. Payne, McGuireWoods
Thomas A. Scully, Esquire, Alston & Bird
Thomas Mills, Esquire, Winston & Strawn

National Government Services

Jurisdiction B Daily News

Documentation for K Levels for Prosthetics

National Government Services, the Jurisdiction B Durable Medical Equipment Medicare Administrative Contractor (DME MAC) has received several inquiries in regards to what documentation must appear in the medical record to support the K level for prosthetics.

Potential functional ability is based on the reasonable expectations of the prosthetist, and treating physician, considering factors including, but not limited to:

1. The beneficiary's past history (including prior prosthetic use if applicable); and
2. The beneficiary's current condition including the status of the residual limb and the nature of other medical problems; and
3. The beneficiary's desire to ambulate.

This information must be documented by the **treating physician and the prosthetist**.

The medical record should reflect that a comprehensive medical assessment has occurred. The medical record should include, but is not limited to, past history, current functional capabilities and the beneficiary's expected functional potential, including an explanation for the difference, if that is the case. The medical record should establish the severity of the beneficiary's condition and the immediate and long term need for the prosthetic and the therapeutic benefits the beneficiary is expected to realize from its use. An entry in the medical record of therapeutic effectiveness or benefit based on speculation or theory alone cannot be accepted. When restoration of function is cited as a reason for use of the prosthetic, the exact nature of the deformity or medical problem should be clear from the medical evidence submitted. Also, the manner in

which the prosthetic will restore or improve the bodily function should be explained by the treating physician. The K-level selected must be consistent with the overall health status of the beneficiary.

Coverage is extended only if there is sufficient clinical documentation of functional need for the technologic or design feature of a given type of prosthetic.

Note: Suppliers are reminded per the Centers for Medicare & Medicaid Services (CMS) Internet-Only Manual (IOM) Publication 100-08, *Program Integrity Manual*, Chapter 5, Section 5.7-5.9, supplier-produced records, even if signed by the ordering physician, and attestation letters (e.g. letters of medical necessity) are deemed not to be part of a medical record for Medicare payment purposes.