A TOPIC AOPA IS WORKING ON THAT IS IMPORTANT TO THE FUTURE OF YOUR BUSINESS

Policy Changes on AFO/KAFO Documentation Requirements Without Due Process Once Again Rears Its Ugly Head to the Detriment of O&P Patient Care

The Core of the Issue

Just as the August 2011 "Dear Physician Letter" dramatically changed the landscape for O&P patient care and the ability of providers to receive payment, another CMS action involving required documentation for AFO/KAFO claims threatens to cause similar havoc and confusion. It came in the following language addition to the Local Coverage Determination for AFOs/KAFOs effective for claims with a date of service on or after July 1, 2012:

> **"For custom fabricated orthoses, there must be a detailed documentation in the treating physician's records to support the medical necessity of a custom fabricated rather than a prefabricated orthosis. This information will be corroborated by the functional evaluation in the orthotists or prosthetist's records. This information must be available upon request."**

Why Is It Important To You?

The true import of this change didn't really come to light until a recent Jursdiction D DME MAC report on pre-payment reviews of claims for L1960 during the second quarter of 2013 revealed a 99% error rate on those claims that were reviewed. 27 percent were denied solely because the prescribing physician's records did not contain detailed documentation to support the medical necessity of a custom fabricated rather than a pre-fabricated orthosis. Just as the RAC Audits gave urgency to the significance and importance of the "Dear Physician Letter" on lower limb prostheses, the Jurisdiction D pre-payment claims review demonstrates how significant the Local Coverage Determination language addition is and again really represents another CMS policy change without the required due process. And it most certainly means a harmful change to patient care in delays for devices based on securing needed documentation, not to mention the financial hardships visited on providers seeking to provide these devices. Another and possibly more troubling issue related to the LCD language addition is the impact of distinguishing off-the-shelf devices from prefabricated devices that require clinical service in bending, trimming and adjusting to the patient's anatomy, as well as in demonstrating medical necessity appropriateness for patients.

What Is AOPA Doing About This?

On August 7, 2013 AOPA sent a letter to the DME MAC medical directors challenging the language addition as representing a substantive change to existing medical policy and therefore making it subject to appropriate notice and rulemaking provisions of the Administrative Procedure Act. Failing to provide an opportunity for all stakeholders, including AOPA members, physicians and patients, to provide comments on the potential impact of this policy change circumvents the law and shortchanges providers and patients. The failure to provide public notice and a comment opportunity contributed to the lack of awareness on the part of physicians and O&P providers that resulted in the 99 percent error rate. Couple that with the inability of the O&P provider to control the availability of the prescribing physician's documents and yet saddle the provider with the total financial liability should the claim be deemed not medically necessary is an untenable position created by the policy change.

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The letter to the medical directors reiterated, "Further, the statute says the orthoses for a Medicare patient must be 'reasonable and necessary.' CMS might maintain that concrete standards for determining whether a prosthesis is 'reasonable and necessary' are set forth in the MPIM and LCDs—none of which was promulgated by regulation. The government can pick its poison—either it set or it changed the standard without going through the required rulemaking. In either case, the absence of appropriate procedure under

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the Administrative Procedure and Medicare Acts renders the LCD language addition (if not the entire LCD) void and in violation of the Congressional statute."

Absence of any reference to off-the-shelf orthoses which are defined as "those which require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual" is troubling. The omission of this statutorily defined subset of prefabricated orthoses within the context of the policy article creates the potential for a lack of differentiation between off-the-shelf orthoses and prefabricated items that must be custom fitted by a properly trained, educated, and qualified individual, such as an orthotist, in order to provide proper therapeutic benefit to the patient.

The Bottom Line

AOPA firmly believes that continued vigilance in making sure CMS adheres to the rules is a major focus of our advocacy effort and truly, the devil is often in the details. A slight wording change that may initially seem innocuous can have unintended consequences as the glide to new policy is somehow undertaken without a compensating opportunity to create awareness of a policy change through proper notice and public comment. Not only is this part of the education process when new policy is adopted but it often can bring to light significant issues that ultimately need to be thoughtfully considered and carefully resolved. The aim of proper care and quality level for all Medicare patients is a joint goal of the government and the O&P practitioner and AOPA has to be in the forefront of making sure the needs of patients and their O&P providers are articulated and protected every step of the way. That's our job and that's a reasonable expectation for you to have as part of your support for AOPA's advocacy on your behalf.

Sincerely,

Thomas F. Fise, JD
AOPA Executive Director