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

CMS Retreat from Its Proposed Rule on Off-the-Shelf Orthotics: One Trench in the Battle Against Commoditization of Orthotics

ON JULY 2, CMS unleashed a brush back pitch, tackling in one rulemaking a plethora of issues bedeviling the widely misunderstood world of orthotics. It was a 'high hard one' that sought to broaden the definition of minimal self-adjustment, to go beyond the stated topic of off-the-shelf orthotics to also define custom-fitted orthotics and limit the persons who could provide them thereby "outing" anyone other than physicians, nurse practitioners, therapists and certified orthotists (sweeping out uncredentialed manufacturers' reps and certified orthotic fitters in one double-wide whisking of home plate. For good measure, the proposed rule would have substituted CMS federal horse sense for the annoying and divergent inconsistencies of state scope of practice laws and the actions of national credentialing bodies under the 'deemed authority' bestowed on them by that one and the same CMS. Barely four months later, on October 31, CMS seemingly reversed fields, sighed an exasperated "never mind" and shelved the entire undertaking, declining to announce anything relating to orthotics in its final rule.

It is hard to declare victory, or even assess exactly what has happened, when CMS declines to give even a hint of why they exited from the field. But, like any 'pitch with a purpose,' those on the receiving end will remember it and be challenged to factor it into their preparations for the next time they face that pitcher.

Baseball analogies aside, the CMS turn-about on off-the-shelf and other orthotics is an important benchmark in a longer-term struggle where CMS and other payers scratch their heads and try to both understand orthotics and contrive a way to stop or greatly reduce paying for them. We do not know, and can only speculate as to why CMS reversed directions, but we do know that, at minimum, if there IS going to be a day when orthotics is thrown under the bus by CMS through either competitive bidding, or some other indiscriminate, professional service negating cost reduction process, this false start has delayed that date.

The Core of the Issue

From the AOPA side, we saw this battle taking shape, as CMS ignored the statute, medical literature and public comments in fashioning an expansive interpretation of the term "minimal self-adjustment" which defines the only sub-segment of orthotics they have authority to regulate via competitive bidding. The AOPA Board crafted a strategy that emphasized education and data. Specifically, we set out to: (a) educate AOPA members about the very intricate regulatory landscape of OTS orthotics; (b) articulate a very strong position and rationale in engaging with CMS around the proposed rule; (c) work in conjunction with others, both within the O&P field and beyond, including physicians, therapists and others, to advance the science and medical literature about orthotics—how and why orthotics is important to quality patient care and outcomes; and (d) to engage and educate patients, encouraging them to make their voices heard.

In its haste to commoditize all orthotics, or at least as much as it possibly could under the masthead of "off-the-shelf orthotics" we believed CMS had overlooked two critical pieces of data from Medicare's own experience. First, the Dobson-DaVanzo study demonstrated that prosthetics and orthotics treatment is cost-effective—patients who receive timely and proper orthotic care cost payers less money than those patients who do not receive that treatment. The unavoidable backdrop for any discussion on orthotics is that for lower limb orthotics, for example, the total health care expenditures of patients who receive orthotic treatment are 10 percent less than expenditures for untreated patients with the same diagnosis.

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Orthotics saves Medicare money—over $200 million in savings in the first ten months of 2014! Secondly, some surprising data shows that 19 percent of the Medicare patients who receive a Medicare reimbursed OTS orthotic device subsequently also receive a Medicare reimbursed custom-fitted or custom-fabricated device. We know that a portion of these cases are part of an appropriate pattern of care, and patients with chronic conditions do see deterioration, but this is a very large number. We are examining it more thoroughly, but this high percentage of multiple orthotic devices does call into question any simplistic maxim that handing every mobility-impaired patient an OTS device without any clinical professional service is somehow going to save payers money. Clearly, the patient's predisposing conditions and the treatment paradigm is more complicated than that!

Why Is It Important to You?

A large portion of the current and future expenditures in the O&P field revolve around orthotics. When we look at the trend lines for diabetes, stroke, obesity and other conditions, we see that orthotics both outpaces prosthetics in both the numbers of patients and the total expenditures, even if the average expenditure per patient /per device is, of course, much higher in prosthetics. The OTS rule was one important skirmish, but this battle is far from over. We must recognize that we will have to fight hard, and do plenty of homework, and invest significantly into scientific research if we are to continue to demonstrate that orthotic intervention—including BOTH the professional clinical service as well as the device DOES improve patient quality of care and outcomes. This is a fight worth fighting, and it is one that is dramatically important to the future of the O&P profession.

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The Bottom Line

Timing can be critically important in these endeavors. On October 15, after months of consultation, and meetings on Capitol Hill initiated by AOPA's legislative representatives, two senior U.S. Senators—Senators Charles Grassley (R-IA) and Tom Harkin (D-IA)—both with distinguished reputations and long experience with health policy, sent a joint letter to CMS Administrator Marilyn Tavenner, in essence saying that CMS had gotten it wrong in its manipulations of the clear statutory words "minimal self-adjustment." On October 31, CMS announced that it was stepping back from its position on OTS orthotics. How related were the two events? We can only surmise, but it is clear that Senators Grassley and Harkin did a great service to our profession, and perhaps more importantly to our patients by underscoring these CMS missteps.

But the CMS action was not entirely black and white. There were some aspects of the proposed rule where the agency got it right. For example, the agency was right to recognize that delivery of custom-fitted orthotic devices by uncredentialed personnel to patients in certain physician practices was not a good thing. CMS narrowed the eligibility a bit too stringently in limiting eligibility to deliver custom- fitted devices to physicians, nurse practitioners, therapists and certified orthotists, and the O&P Alliance threaded the needle in asking CMS to accept the following modest refinement in its proposal:

"As noted above, CMS's proposed rule precludes most unlicensed/non-certified personnel on the office staff in physician practices, therapy offices or orthotic facilities from fitting and adjusting prefabricated/custom-fitted orthoses for Medicare beneficiaries. The O&P Alliance agrees that the unlicensed/non-certified, non-clinical staff and persons who are in the health professional's practice should not be permitted to provide such services.

Unless the state's licensure statute provides otherwise, those licensed or certified healthcare professionals who regularly engage and/or assist in the care and treatment of patients with conditions requiring orthotic treatment (including certified orthotic fitters) that truly act under the supervision of a physician (or other individual who has specialized training*) should be permitted to continue providing such services with respect to custom-fitted orthoses."

* *Defined as a physician, treating practitioner, occupational therapist, physical therapist, or certified orthotist operating in compliance with all applicable federal and state licensure and regulatory requirements.*

The AOPA and O&P Alliance positions on both "minimal self-adjustment" and limiting custom-fitted services to include work by certified and/or licensed individuals working under the supervision of the physicians, nurse practitioners, therapists and certified orthotists struck a resonant chord, and many others outside O&P endorsed similar positions in their comments. CMS's good work in this area unfortunately also was retracted with its October 31 action.

If anyone needed a wake-up call about the future of orthotics and the need to arm ourselves for a battle against the commoditization of orthotics, the CMS rulemaking and events over the past 4-6 months should stir everyone's consciousness. More study, more vigilance, more data and more investment of time, energy and resources are going to be demanded as we move from this rulemaking to the next trench in this battle to preserve the valuable role of orthotics (yes, professional, clinical care plus the device) in providing patient improvement, and cost-effective outcomes.

Very truly yours,

Thomas F. Fise, JD
AOPA Executive Director