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

What Will the New Year (and new HCPCS Codes) Bring in Terms of Prospects That We Will Face Competitive Bidding for Off-the-Shelf Orthotics?

The Core of the Issue

Any CMS regulatory authority must start with some authorization in the statute. When Congress authorized competitive bidding, it constructed an important fence around O&P:

- Competitive Bidding Authority limited to off-the-shelf orthotics only
- Defined OTS as a device that could be used with "minimal self-adjustment"

From day one, CMS has tried to expand that definition—they would love to remove the word "self" from the statute and they adopted regulations inexplicably defining "minimal self-adjustment" as "an adjustment that the beneficiary, caretaker of the beneficiary, or supplier of the device can perform and does not require the service of a certified orthotist." AOPA believes this definition is contrary to the statute's "minimal self adjustment" definition.

CMS conducted two demonstration projects on OTS competitive bidding which seemed to show that any potential savings would not offset the administrative costs. However, contrary to these findings, in the summer of 2011 CMS said in a memo to Senator Rockefeller and staff that it had a list of over 100 OTS items which could save roughly $200 million. The O&P Alliance requested a copy of its OTS list from CMS. CMS published a list of 62 codes in February 2012 that it considered OTS. Both AOPA and the O&P Alliance filed comments objecting to the list. AOPA's nearly 500 pages of comments included literature supporting clinical care and identified potential patient harm if qualified clinical care was not provided. AOPA believes CMS' actions are arbitrary, and that eventually, unless CMS appropriately submits to the clear limitation in the statute, it may be necessary to mount a legal challenge. In advancing those concerns, here is an excerpt from the letter prepared by AOPA's attorneys which accompanied AOPA's substantive comments on the OTS list:

> **"Perhaps a better question is whether CMS anticipates savings by expanding the definition of "minimal self-adjustment" to mean "self-adjustment-with-a-little-help-from-our-friends" which will justify the anticipated degradation in care for those Medicare beneficiaries not so fortunate."**

Why Is It Important To You?

CMS has a modicum of legitimate authority to exercise competitive bidding in orthotics. All indications are that if CMS implemented that authority as Congress intended, it would save very little if any money, but CMS is seeking to inappropriately expand its authority to generate big savings: (1) in violation of the statute; (2) to the detriment of orthotics patients; and (3) in a way that could wreak financial havoc upon the entire field of orthotics. For the protection of our patients' quality of care, and to preserve our profession, this threat demands consistent and intensive attention, and could require a legal challenge against Medicare's grossly overstepping the bounds of its limited authority.

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What Is AOPA Doing About This?

(A) What the Law Says, Forces Demanding Change, and What CMS Has Done:

In July 2012, the O&P Alliance had a "show and tell" meeting with CMS focusing on 9 specific devices, showing: (a) how they are used; (b) why clinical services are needed; (c) support from the scientific literature; (d) manufacturers' labeling; and (e) explaining patient harm if not properly fitted.

Strong, albeit uninformed, voices have argued for very broad applicability of competitive bidding, purporting it would save many billions of dollars. In August, 2012, an article authored by several prominent physicians, under the aegis of the Center for American Progress, appeared in the *New England Journal of Medicine*, arguing for universal competitive bidding of all medical devices, specifically

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including orthotic and prosthetic devices. Subsequently, a *Washington Post* editorial by Dr. Ezekiel Emanuel, President Obama's lead health adviser, made a similar argument. In December 2012, a new report from the HHS OIG challenged pricing on code L0631, asserting its "estimate" that 1/3 of suppliers **admitted** that no clinical services were provided. AOPA had two letter exchanges challenging OIG and these revealed that they do not appear to have any solid data to back up the "one-third" claim. AOPA and the Amputee Coalition petitioned every member of Congress in December 2012 to avert patient harm that could result from excessive competitive bidding in O&P.

In August 2013, CMS cited the OIG report in publishing its "final" list of OTS devices, announcing that CMS would be *"exploding codes such as L0631 into two codes so that items furnished OTS and for which custom fitting is not necessary can be billed under one code while items for which custom fitting by individuals with appropriate expertise is medically necessary and is furnished can be billed under a second, separate code."* The scorecard on CMS OTS list:

- 55 codes CMS considers OTS
- 23 codes to be "exploded" in two separate codes; re-clinical care
- 32 codes always OTS

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CMS removed 6 codes (one other dropped from HCPCS) but rejected comments and literature AOPA presented on 85-90% of the codes. In an August 26 meeting with CMS, O&P Alliance partners argued that CMS' list was misdirected because: (a) accurately identifying clinical codes is impossible because of CMS' failure for the past 13 years to publish a rule to define accreditation/qualified providers under Section 427 of BIPA 2000; (b) exploding codes does not circumvent CMS' clear violation of statutory definition of "minimal self-adjustment"; (c) CMS has ignored comments, including rejecting virtually all of our Alliance July meeting "show and tell"; and (d) CMS' plans for OTS competitive bidding are nowhere near being ready for 'prime time' as CMS has showed they did not know: (i) who could determine when

clinical care required for the 23 proposed 'exploded codes'; (ii) how that health professional would be paid (ABN?); and (ii) how absence of clinical care would impact patient health.

(B) Speculation—What Could Happen in the Short Term, What Changes May Be in the Wind?

Nothing significant has changed in terms of actual implementation of competitive bidding for off-the-shelf (OTS) orthotics. But, whether as a result of the government shutdown, the craziness of the Healthcare.gov website, or whatever, CMS has delayed the release date for new HCPCS codes to take effect on January 1. Normally, they would have already made those announcements—we are now hearing it will be another couple of weeks. We are hopeful that perhaps all the wild HHS/CMS happenings may have diverted them from implementing this coming year the projected new "exploded" OTS codes for devices without clinical care being included. Obviously, that is purely speculative, but it clearly will have an impact, regardless of the fact that actual competitive bidding for OTS devices does not appear imminent. Suppose they do publish these exploded codes—how and when might it impact actual payment amounts independent of implementation of competitive bidding?

1 Joe McTernan from our AOPA staff tells me that when a new HCPCS code is established, it typically takes up to 6 months for CMS to establish a fee schedule payment amount for the code. CMS must gather current pricing data and then apply the "gap filling" method to deflate the fee schedule amount to the base year (1987) level and then re-inflate the fee using the annual percentage increase from 1987 until the current year. While this is being done, the carriers are given discretion to process and pay claims on an individual consideration basis meaning that they gather service specific pricing information from providers and make a case by case decision regarding appropriate reimbursement for the service or item.

Being that the proposed "exploded" codes are based on existing codes minus a service component, CMS may or may not have to gap fill the pricing for the new codes. This may result in the creation of fee schedule amounts prior to the July quarterly update but as a general rule, allowables for new codes are not published until July of the year they are introduced.

2 I have not seen anything to date that would lead us to expect any reduction in payment amount for the HCPCS code that includes fitting. Anything is possible, and I would not be stunned if there were a reduction, but following the lead of the December 2012 OIG report, CMS seems to be focusing its attention on orthotic devices where the payment includes clinical care, but where they believe clinical care perhaps is not being provided together with the delivery of the device. The amount of reduction in the non-fit brace is at best a guesstimate. The OIG went on the internet and found an average acquisition cost of $191 for each L0631 back orthosis included in the study, with an average allowable of $919. AOPA wrote to the OIG objecting to this assertion and underscoring the significant adverse impact such a policy direction would have on the quality of patient care for back patients. Of course, in the absence of competitive bidding, where there is a licensed/accredited orthotist I would expect they will usually continue to provide clinical care with the device, and likely to continue to bill the device/services under the long-existing, non-exploded code—but that situation might be very different where devices find their way to patients through other channels where there may not be a licensed/accredited orthotist delivering both the device and the concurrent clinical care.

The following are two troubling paragraphs in the CMS August 12 announcement of these new codes:

From narrative responses to Comments:

> **N. CONCLUSION**
> **After reviewing all of the comments and thoroughly examining each HCPCS code that is included on the final OTS list we are revising the original list. We believe the final OTS list contains orthoses that meet the OTS definition as outlined in 1861(s)(9) of the Act requiring minimal self-adjustment for the appropriate use and does not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual. The HCPCS codes finalized on this list will be considered OTS effective January 1, 2014.**

From the actual listing of new OTS Split Codes

> ***The "split" column identifies current HCPCS codes that include items that are sometimes furnished off-the-shelf and sometimes custom fitted. Effective for items furnished on or after January 1, 2014, the existing code listed in the "split" column may only be used for those orthotics that require custom fitting by a certified orthotist or an individual who has specialized training necessary to custom fit the device. Effective for items furnished on or after January 1, 2014, new codes are being established for the items that are furnished off-the-shelf and are currently described by a code in the "split" column. The new codes are listed as placeholders (e.g., Lxxx1).**

The terms of art seem to be: "a certified orthotist or an individual who has specialized training necessary to custom fit the device." A certified orthotist is pretty easy to define, based on section 427 of BIPA 2000. However, the exact meaning of "an individual who has specialized training necessary to custom fit the device" is anyone's guess, I believe. I am sure that lots of folks will seek to show that a fitting course or other educational activity provides that specialized training. My guess is that this may be a little loose in the beginning. It is noteworthy though, that CMS Administrator Tavenner has committed to publishing a proposed rule implementing Section 427 of BIPA 2000 by the end of the calendar year—again, the craziness in health care/Medicare right now might push that date back, but I would guess the publication of that rule might tighten up on who qualifies as the 'individual who has the specialized training' parameters.

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3 I think CMS is definitely setting the table for moving these new OTS items into bidding. As we have discussed before, on August 26, AOPA and others met with CMS Chronic Care Chief Laurence Wilson to attack any idea that CMS was in any sense ready to move to OTS in the near term. I believe we demonstrated pretty clearly several things that CMS either did not know, or did not understand. CMS showed they did not know:

- Who could determine when clinical care required for the 23 exploded codes
- How that health professional would be paid (ABN?)
- How absence of clinical care would impact patient health.

We re-stated at that meeting what we have said many times previously—CMS has a huge problem because the statute includes a definition of off-the-shelf orthotics as devices which can be used by the patient with "minimal self-adjustment." CMS wishes the word "self" were not in that definition, but we have pressed our position that they are at grave risk of a legal challenge if they soft-pedal the clear words of the statute. We came away from this meeting thinking that it will be some time before CMS actually moves to implement competitive bidding for OTS orthotics. Obviously, we could be wrong, but my sense is to believe similar "going slower" signals we have heard indirectly from CMS.

The Bottom Line

CMS has broad authority / latitude to implement Medicare, but they must follow rules for the process. They have not followed that process with the OTS list – subject to challenge. Within the past 10 weeks, AOPA has Initiated specific recommendations to omit certain codes from OTS list, and has received strong reliable indications that decision to implement an OTS competitive bidding is not imminent… a long way off, possibly years. This is like an active volcano that could erupt in an instant, or could lie dormant for a long time, but it does pose a threat that demands vigilance.

Very truly yours,

Thomas F. Fise, JD
AOPA Executive Director