AOPA In Advance SmartBrief
Breaking News
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AOPA Headlines:

Medicare Participation and Competitive Bidding: How Your Status Affects Your Reimbursement

In January of 2016, new authority granted to CMS to build on DME competitive bidding to set pricing more broadly and nationally took effect. This authority allows CMS to use pricing established as a result of competitive bidding programs for specific DME products in certain parts of the country to be applied more broadly to those same DME products in non-competitive bid areas. On May 19, 2016, the *AOPA SmartBrief* included an article highlighting reports from CMS underscoring the success of these efforts, essentially concluding that since DME providers accepted this reduced pricing, everything must be fine at these rates. This contention could prove very important in the future as CMS continues to look for ways to reduce spending by cutting reimbursement.

The May 24, 2016 *SmartBrief* contained a link to an article in *HME News* citing feedback from leaders in the DME world stating that the analysis by CMS was simplistic, inappropriately using one or two small bits of isolated information, as the basis for reaching a broad generalized conclusion about the effectiveness of applying competitive bid rates to non-bid areas relative to both market-based and patient care based impacts.

This matter is **NOT** directly germane to either orthotics or prosthetics because the authority Congress has granted to CMS with respect to competitive bidding for prosthetics and orthotics is limited to a very small subset, i.e., off-the-shelf (OTS) orthotics, and CMS has, to date, never competitively bid any such OTS orthotics devices. The changes in Medicare reimbursement referenced in this notice does not currently have a direct impact on prosthetics and/or orthotics. That said, AOPA tends to agree with DME industry sources quoted by *HME* News that the analysis seems to rest on a somewhat questionable assumption that if the nation's largest health care payer unilaterally, and seemingly without any rulemaking process, reduces its payment for devices, and if the impacted provider community largely continues to deliver those devices, that one can assume both that the reduced payment is fair, and that the impacted providers will be able to remain as viable, operating businesses in the long term, and that neither the quality of care, nor the access to care for the patient community will be adversely impacted.

The circumstance above has prompted some in the O&P industry to ask the question, what options does a provider have if they decide that Medicare payment is not enough? Or stated differently, if in the future, Medicare precipitously cuts O&P reimbursement, similar to what was outlined in its recent announcements about major cuts in DME fee schedule pricing, what could you do? While entirely theoretical, this article will take a few minutes to outline reversion to being a non-participating Medicare provider as a potential alternative to simply accepting unsustainable reimbursement rates.

Be a Participating or a Non-Participating Medicare Provider—It's Your Choice, and What That Means

The term "participation" is often misunderstood in the context of the Medicare program. Rather than the traditional meaning of the term, which implies that by participating you have the ability to provide services to Medicare patients, "participation" in the Medicare program only relates to how you submit claims and receive reimbursement under the Medicare program. The ability to provide services to Medicare beneficiaries is established when you enroll in the Medicare program as a DMEPOS supplier, regardless of whether you decide to be a participating provider or not. When you submit your initial application to the National Supplier Clearinghouse to become a DMEPOS supplier, you have the option to complete and submit a Medicare Participation Agreement (Form CMS-460). If you do not complete the participation agreement, you will automatically be enrolled as a non-participating supplier. If you choose to complete this form and become a Medicare participating supplier, you are bound by the terms of the participation agreement for at least the remainder of the current calendar year. It is very important that you make an informed decision as to whether becoming a participating provider is in the best interest of your organization.

If you enroll as a Medicare participating provider you agree, in advance, to accept assignment on all Medicare claims submitted during the term of the participation agreement. What this means is that for every Medicare claim you submit that is approved for payment, you will receive 80% of the Medicare published allowed amount directly from the Medicare program. It is your responsibility to collect the remaining 20% from the patient directly or by submitting a claim to their secondary or supplemental insurance carrier. Alternatively, providers who elect a non-participating status are free to make an individual decision, on a claim by claim basis, whether or not to accept assignment. Theoretically you can elect to be a non-participating provider and still accept assignment on all of your Medicare claims. Non-participating status allows you the freedom to accept assignment on some claims but not others. In the context of the potential impact of any future decision to apply competitive bidding rates to OTS orthoses in non-bid areas,

non-participating status allows suppliers to not be tied to the reduced rates by choosing to not accept assignment on the claim. When submitting a non-assigned claim, suppliers may collect their full usual and customary charge from the Medicare beneficiary at the time of delivery of the completed device. Non-assigned claims must still be submitted to Medicare by the supplier and, if approved, Medicare will send payment of 80% of the Medicare allowed amount directly to the patient. It is important to note that not accepting assignment on a claim does not change the supplier's financial liability for services that are deemed not medically necessary by Medicare. If a non-assigned claim is deemed not medically necessary, the supplier is required to immediately refund any money collected from the patient at the time of delivery unless a properly executed Advanced Beneficiary Notice (ABN) is in the supplier's files.

The obvious question that remains is, how can non-participation status help my business should Medicare decide to apply competitive bidding rates to OTS orthoses in non-competitive bidding areas? While this discussion remains hypothetical as OTS orthoses have yet to be included in any Medicare competitive bidding program, let's take a look at a potential scenario where non-participation status may be to your benefit. Again, this is a hypothetical scenario for illustration purpose only.

Let's assume that the Medicare allowed amount for an OTS walking boot is $150 and your company's usual and customary charge for this item is $200. Let's also assume that through application of competitive bidding rates, Medicare reduces the allowed amount for a walking boot to $100. If you have elected to be a participating Medicare supplier and you submit a claim for a walking boot in this scenario, Medicare would reimburse you $80 and you could collect an additional $20 from the patient or their secondary/supplemental insurance. Total reimbursement in this scenario would be limited to $100. If you have elected to be a non-participating provider, you could choose not to accept assignment on the claim and charge the patient up to $200 at the time of delivery. You would still be required to submit a non-assigned claim to Medicare and Medicare would send a payment of $80 directly to the patient, representing 80% of the reduced allowed amount as a result of the application of competitive bidding prices.

While this scenario may present some business challenges relative to your patient's willingness to pay more for the device than Medicare is willing to reimburse them, it remains a viable alternative to simply accepting reduced reimbursement should Medicare ultimately decide to bring OTS orthoses into the competitive bidding environment.

While the inclusion of competitive bidding pricing does not appear to be imminent for OTS orthoses, since the decision to be a Medicare participating provider is applicable for a full calendar year, it may be prudent to review your current Medicare participation status and decide whether Medicare participation is in your company's best interest. If you are currently a participating supplier your next opportunity to change your status is effective January 1, 2017. To change your status from participating to non-participating you must submit a written notification on your company letterhead to the National Supplier Clearinghouse during the annual open enrollment period which spans from mid-November until December 31st of each year. This letter must be signed by the authorized official for your company on file with the NSC. It is important to note that the participation decision applies to all locations under a single Tax ID.

Your Patients May Be Your Best Advocates—Keep Them Informed!

Beyond a provider's option to choose Medicare participating vs. non-participating status, another option that AOPA members should consider is assuring optimal communication with your

Medicare patients on any changes in Medicare's payment policies. For example, in the recent CMS announcement on the 'success' of its payment reduction policies in the DME arena, it was noted that the measuring stick they used did not include any confirmation 'that neither the quality of care, nor the access to care for the patient community will be adversely impacted.' Medicare may not take the initiative to speak to its beneficiaries about changes, and that may be all the more reason why you may want to strengthen your own outreach to your Medicare patients. If Medicare takes steps which make it harder for you to deliver what the patient expects, poses additional steps which delay your ability to make timely delivery, cuts payments which in turn force you to scale back services—those are all things you likely want to tell your patients about. If patients are unhappy or unsatisfied because Medicare belt-tightening results in less options or quality/timeliness limitations in the care they receive, by having alerted them in advance, they will know that it is Medicare to whom they should voice their disappointment, rather than thinking you have somehow shortchanged them. Your patients are your best advocates—Medicare listens to them much more closely than they listen to any providers. So, it is very much in your interest to take steps to assure your patients are 'in the loop' on how new Medicare changes may be impacting them.

AOPA hopes that the information in this article has been helpful, especially in the context of the recent announcement by CMS regarding the perceived effectiveness of applying competitive bidding rates for DME in non-competitive bidding areas. While the decision to become a Medicare participating provider must be made according to the individual needs of your company, it is important to consider the impact of this decision carefully.

The FDA and 3-D Printing: What Potential Regulatory Action Means for O&P

On May 10, 2016, the Food and Drug Administration (FDA) released a document entitled, *Technical Considerations for Additive Manufactured Devices: Draft Guidance for Industry and Food and Drug Administration Staff.* The publication of this document marks the first foray of the FDA into potential regulation of devices that use additive manufacturing as a means of fabrication of medical devices. Additive manufacturing is a broad term that encompasses 3-D printing as a means of creating functional medical devices. The guidance document has been published in order to solicit public comment regarding the FDA's current thinking on the topic of 3-D printing and "is not intended to be a binding document on either the FDA or the public."

The bulk of the document relates to specific considerations that Additive Manufacturing devices need to address in order to assure that they meet the Quality System requirements of 21 CFR section 820.198 (good manufacturing practices). The document, which specifically mentioned the conference on 3D devices FDA conducted on October, 2014, does make a few important things clear:

a. Standard FDA requirements, e.g. 510(k), premarket approval, and investigational device exemption requirements apply to additive manufactured devices. Likewise the classification regulations for products are referenced as specifically applicable.
b. If the device classification provides for exemption from either 510(k) or 21 CFR Section 820.198; quality standards, those exemptions would appear to apply when the device is fabricated using an AM process. However, it is noted that some aspects of 21 CFR Section 820.198 quality system requirements, e.g., maintenance of complaint records apply to virtually all devices, even those exempted (via published classification regs) from some other aspects of 21 CFR section 820.198.
c. The document mentions apparently more stringent requirements which may be applicable to AM devices that are, for instance, used as implants, or which are load-bearing.

The draft guidance may ultimately not have a very substantial impact on all O&P devices. FDA places medical devices into one of three regulatory categories: Classes I, II, and III. While medical devices (including most O&P devices) that are manufactured using 3-D printing processes will be subject to the same exemption from most FDA regulation as Class I devices manufactured in a more traditional manner, AOPA believes that the publication of this document remains a significant development. The publication of the document clearly indicates the intent of the FDA to ultimately regulate the 3-D printing process in regards to its use in the manufacture of medical devices.

Some Class I O&P devices have been designated by FDA as exempt from either premarket notification [section 510(k)], or many aspects of GMPs, i.e., Quality Systems rules, or both. It is clear from this FDA notice that whatever rules apply to traditional O&P devices will also apply to similar devices fabricated using 3-D techniques and introduced for sale/commerce. So, while one or both of these specific exemptions may have been identified for a specific 3-D fabricated O&P device, it is important to note that the FDA continues to require manufacturers of all Class I devices to register with the FDA through its device establishment registration process. In addition, Class I device manufacturers are almost never exempted from FDA general requirements on record keeping and maintenance of complaint files. While some Class I O&P devices have been designated as not being subject to more rigid regulation such as the 510(k) pre-market notification process and complete compliance with all aspects of Good Manufacturing Processes (GMPs), in addition virtually no one is exempted from complaint record rules under the GMPs, and failure to comply with the record keeping and complaint file requirements could lead to trouble for both traditional O&P manufacturers as well as those that incorporate 3-D printing into their manufacturing process.

The FDA guidance document is a total of 28 pages, most of which focus on suggested quality systems and basic manufacturing processes that should be followed when using 3-D printing as a means to manufacture completed medical devices. While this guidance is more relevant to ALL Class II and Class III devices, and to some Class I O&P devices, it is a valuable resource regarding the intent of the FDA to ensure that 3-D printed medical devices do not pose a danger to the public. Even though FDA has couched this as a guidance document and non-binding, no one could read this document and conclude that all aspects of FDA's medical device regulation and structure are not seen by the agency as applicable to Additive Manufacturing Devices that are offered for sale to patients/consumers/public.

Individual manufacturers of O&P devices that currently use, or intend to use additive manufacturing as part of their manufacturing process should familiarize themselves with the specifics of the guidance document. Areas of focus of the guidance document include sections on device design, software workflow, material controls, process validation and acceptance, quality data, device testing including both mechanical and material testing, cleaning and sterilization, biocompatibility, and labeling considerations.

The guidance document discusses, in detail, the differences between the manufacture of standard size devices and patient matched devices and the design alterations that must be made to accomplish both manufacturing styles. The document also highlights the need to ensure that the software that is used to convert a digital design into a physical device is efficient and not subject to error through file conversion. The guidance document then provides information on making sure that the materials used to create the medical device are appropriate both in material and structure, especially regarding implantable or load bearing devices. The guidance document

continues by discussing the importance of process validity to ensure that using different machines to fabricate the devices will not result in significant alteration of the device itself. The document closes by discussing the need to not only assure the quality of the finished device, but also to ensure that the device is properly tested to confirm its effectiveness.

The complete document may be viewed here.
The FDA will accept public comment on the draft guidance document until August 8, 2016 (90 days from the publication date of May 10, 2016. Electronic comments may be submitted through http://www.regulations.gov and written comments may be submitted to the following address:

Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

AOPA will be preparing comments and will share them with AOPA members prior to submission.

Jurisdiction D DME MAC Publishes Results of Pre-Payment Review of Ankle Foot Orthoses (AFO)

Noridian, who serves as the Jurisdiction D Durable Medical Equipment Medicare Administrative Contractor (DME MAC), has released the most recent quarterly results of its ongoing pre-payment review of claims for AFOs described by HCPCS codes L1960, L1970 and L4360.

From December 2015 through March 2016, a total of 1008 claims were reviewed; 855 of which were denied. This error rate varied for each code. The L1960 had an error rate of 69%, the L1970 had an error rate of 70%, and the L4360 had an error rate of 99% (484 out of 488 claims were denied). Based on these results Noridian will continue its pre-payment reviews for codes L1960, L1970 and L4360.

The DME MAC noted that common denial reasons included a lack of proof of delivery documentation, failure to include documentation to show "substantial" modifications were made to the custom fitted item (L4360), documentation was not received in response to the ADR, and insufficient documentation to establish a need for a custom fabricated item (L1960 and L1970) . You may view the full results of the quarterly review here. AOPA members are reminded to make sure all of the required documentation for Medicare reimbursement is obtained prior to submitting a claim for any O&P device.

Questions regarding this issue may be directed to Joe McTernan at jmcternan@aopanet.org or Devon Bernard at dbernard@aopanet.org.

Jurisdiction D DME MAC Publishes Results of Pre-Payment Review of Knee Orthosis (KO) L1833

Noridian, who serves as the Jurisdiction D Durable Medical Equipment Medicare Administrative Contractor (DME MAC), has released the most recent results of its ongoing pre-payment review of claims for L1833 (knee orthosis, adjustable knee joints (unicentric or polycentric), positional orthosis, rigid support, prefabricated, off-the-shelf).

From September 2015 through December 2015, a total of 627 claims were reviewed, 607 of which were denied for an overall claim error rate of 96%.

Noridian noted that claims were denied due to a failure to respond or a late response to additional documentation requests (which will result in an automatic denial), the submission of an invalid proof of delivery, a missing/incorrect ICD-10 code, and documentation that did indicate the patient is ambulatory (as sometimes required by policy).

You may view the full results of the review here. Based on the results, Noridian will continue its pre-payment review for code L1833.

Questions regarding this issue may be directed to Joe McTernan at jmcternan@aopanet.org or Devon Bernard at dbernard@aopanet.org.

Jurisdiction D DME MAC Publishes Results of Pre-Payment Review of Spinal Orthoses

Noridian, who serves as the Jurisdiction D DME MAC contractor, has released the results for its ongoing pre-payment review of claims for spinal orthoses described by HCPCS codes L0631 and L0637.

From December 2015 through March 2016, a total of 291 claims were reviewed and 492 were denied, a denial rate of 99% for L0631 and 94% for L0637.

The DME MAC provided the following five top reasons for why the claims were denied:

- Submitted documentation didn't identify the modifications made for the custom fitted brace
- Documentation was not submitted in response to the ADR request
- Missing or invalid proof of delivery
- Documentation didn't meet basic coverage criteria
- Brace provided didn't have a PDAC coding verification (required by policy)

Based on the results Noridian will continue its pre-payment review for codes L0631 and L0637. You may view the full results of the review here.

Questions regarding this issue may be directed to Joe McTernan at jmcternan@aopanet.org or Devon Bernard at dbernard@aopanet.org.

Federal Overtime Rule Update

On May 18, 2016, the US Department of Labor issued final regulations regarding the minimum salary level for an employee to be exempt from overtime pay, and this rule is estimated to affect up to 4 million workers. The changes are effective December 1, when employees making more than the $47,467 threshold must be classified as non-exempt and paid overtime. Note that this is the Federal Law and state laws may vary.

Read further about the rule and steps your business may need to take.

Don't Miss This Symposium at the September 8-11 National Assembly

About AOPA | Register | Attend | Exhibit

Outcomes of Partial Foot Amputation Can Inform Difficult Decisions About Amputation Surgery Using a Shared Decision-Making Approach

Saturday, September 10 at 8:45 AM

In this symposium, learn what shared decision-making is and why it is an effective way to make decisions about treatment. The team will share some of the key outcomes of dyvascular partial foot amputation and how this evidence has been used in the design of decision aids and conversation guides that help patients and doctors share in the process of informed decision making.

Meet the Panel:

Michael Dillon, PhD, BPO (Hons) is a Senior Lecturer in Prosthetics and Orthotics at La Trobe University, and an Honorary Research Fellow at the Royal Melbourne Hospital where he supports clinicians to undertake research and translate research evidence into practice. Dr. Dillon's research has focused on the outcomes for people with lower limb amputation; in particular, people with partial foot amputation. His research spans a variety of areas including biomechanics, quality of life, edidemiology, workforce analyses and studies of prosthesis efficacy.

Tammy Hoffman, BOccThy (Hons1), PhD is Professor of Clinical Epidemiology at the Centre for Research in Evidence-Based Practice, Bond University. She has over 170 journal publications and is the lead author of widely used inter-disciplinary evidence-based practice book (*Evidence-Based Practice Across the Health Professions,* 3rd Edition underway). She is currently leading a number of international initiatives to more closely align shared decision making and evidence-based practice, and to improve the reporting and uptake of effective non-pharmacological interventions into practice (including development of the TIDieR statement).

Stefania Fatone, PhD, BPO (Hons) is an Associate Professor in the Northwestern Universeity Feinberg School of Medicine Department of Physical Medicine and Rehabilitation where she leads O&P research and teaches in the Masters of Prosthetics and Orthotics program. Dr. Fatone's research examines the effects of prostheses and orthoses on human locomotion in order to increase understanding, establish efficacy, and improve effectiveness of O&P interventions. Dr. Fatone is internationally recognized as a leading prosthetics and orthotics researcher and has more than 50 peer-reviewed publications.

Learn More or Register Now

Attend the 9th Annual Wine Tasting & Auction

NINTH ANNUAL AOPA 2016
WINE TASTING & Auction

During the 2016 National Assembly AOPA will be hosting the 9th Annual Wine Tasting & Auction, on Friday, September 9th from 6:00-8:00 PM. This exciting event provides attendees with a unique opportunity to mingle, network, learn about and taste a variety of wines, but most importantly raise awareness of and funds for AOPA's Government Relations outreach. Let's keep the tradition of success alive and make the 9th Annual Wine Tasting & Auction the best ever.

Please join the fun, the "good cause" and add to the continued success of the Wine Tasting & Auction by donating today! ***Your special donations are what make this event unique.*** Your donation may be one of the gems of your cellar, jewelry, artwork, wine glasses, a bottle of your favorite spirit, cigars, etc. We also have a team of personal shoppers who can locate that perfect item for you if you would prefer to make a monetary donation.

Please consider donating today! The donation form is available here.

Thank you in advance and we look forward to seeing at the 2016 National Assembly and the 9 Annual Wine Tasting & Auction.

Questions? Contact Devon Bernard *via email or at (571) 431-0854.*

2016 O&P Benchmarking Survey is Now Available

Have you ever considered using a benchmarking survey to measure your company's financial performance to strengthen your business? If so, now is the time.

You won't want to miss this opportunity particularly if you have been asking yourself questions like these:

- *How does our spending on materials, advertising or other expenses compare with other companies similar to ours?*
- *Is our gross margin better or worse than other facilities of the same size?*
- *Are our employees generating enough sales?*

Opportunities to participate in the survey come around once a year. 2016 surveys were mailed to AOPA members May 1. **Participation for AOPA members is FREE**, and includes a complimentary final report (a $185 value) AND a free customized company report, comparing your company results to businesses of similar size and location. Participants this year will also receive a **FREE 2016 Coding Pro**, single user edition, with Medicare fee schedules for all 50 states and other customizable fee schedules.
BEGINS: Surveys mailed May 1, 2016 and open until June 21st
***YOUR INVESTMENT*:** 60 minutes to compile information for survey
COST: FREE published report and FREE customized company report for AOPA members
***HOW*:** Submit the survey online at: www.aopa-survey.com OR Complete the mailed hard copy, OR submit your financials and Industry Insights will confidentially enter the data for you.
IT's CONFIDENTIAL: Only Industry Insights, under a strict confidentiality agreement, knows your data.

Look for your survey in the mail or click here. Don't let this opportunity pass you by.

It's hard to chart a course for success if you don't know where you are starting from.

For questions or more information contact Bleppin@AOPAnet.org, 571-431-0810.

Upcoming AOPA Events

June 8, 2016	*Physician Documentation: How to Get It & How to Use It* AOPA Webinar Learn more or register here
June 13 & 14, 2016	*Coding & Billing Seminar* San Antonio, TX Learn more and register here
July 13, 2016	*Strategies and Levels: How to Play the Appeals Game* AOPA Webinar Learn more and register here