

CMS Releases Proposed Rule on DMEPOS Competitive Bidding

On July 11, 2018, the Centers for Medicare and Medicaid Services (CMS) released a proposed rule that proposes several changes to the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) competitive bidding program. In addition to the proposed changes to the competitive bidding program, the proposed rule also solicits comments regarding ways to improve the gap filling methodology that is used to establish Medicare fee schedule amounts for new items and technologies.

Two items of note in the proposed rule include the fact that off the shelf (OTS) orthoses are not mentioned as a potential product category for any envisioned revisions to the competitive bidding program, and that the current DMEPOS competitive bidding program will be effectively suspended when existing contracts expire at the end of 2018 and will remain suspended until such time as any new contracts are awarded under the rules that are being proposed by CMS. While OTS orthoses are eligible for inclusion in competitive bidding under the law that created the program, CMS has, to date, not made, or announced any decision to include them as a product category in the competitive bidding program. The announcement that the competitive bidding program will effectively be suspended when current contracts expire in 2018 is a significant development in that it acknowledges the negative impact that competitive bidding has had on patient access to medically necessary DMEPOS services, especially in rural areas. While the competitive bidding program has not directly impacted the delivery of O&P care to date, we are hopeful that CMS' commitment to improving the program will help ensure that access to O&P care for Medicare beneficiaries remains available if the time comes when OTS orthoses might be included in competitive bidding in the future.

AOPA is currently reviewing the 368 page document and will prepare a full analysis for its members in the near future.

The CMS Fact Sheet regarding the proposed rule may be viewed by [clicking here](#).

The complete proposed rule may be viewed by [clicking here](#).

Questions regarding the proposed rule may be directed to Joe McTernan at jmcternan@AOPAnet.org or Devon Bernard at dbernard@AOPAnet.org.

DME MACs Retire Draft LCD and Policy Article for Lower Limb Prostheses

Earlier this month, AOPA reported that the report of the Inter Agency Workgroup that was formed to provide a consensus statement to inform Medicare coverage of lower limb prostheses had been published. As part of the consensus statement, the Inter Agency Workgroup recommended, and CMS concurred, that the draft LCD and Policy Article for Lower Limb Prostheses, that was initially released on July 16, 2015, should be removed from the DME MAC websites and that the current LCD and Policy Article should remain in force for the immediate future.

On June 21, 2018, the DME MACs released a joint publication announcing the retirement of both the draft LCD and Policy Article. AOPA is continuing to evaluate the full consensus statement of the Inter Agency Workgroup and will provide comments in the near future.

The announcement of the draft LCD and Policy Article may be viewed by [clicking here](#).

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

CMS' Lower Limb Prostheses Interagency Workgroup Releases a Consensus Statement

In 2016 the Center for Medicare & Medicaid Services (CMS) convened the Lower Limb Prostheses Interagency Workgroup in response to the comments received in regard to the 2015 Draft Local Coverage Determination (LCD) for Lower Limb Prostheses. The Workgroup's purpose was to "develop a consensus statement that informs Medicare policy by reviewing the available clinical evidence that defines best practices in the care of beneficiaries who require lower limb prostheses." The Workgroup has completed their review and released a consensus statement outlining their findings and suggestions.

Based on the findings and recommendations of the Workgroup CMS is taking the following immediate actions:

- Instructing the Durable Medical Equipment Medicare Administrative Contractors (DME MACs) to remove the Draft LCD
- Instructing the DME MACs that coverage for lower limb prostheses will remain under the current LCD, with no changes
- Future LCD changes must follow procedures set forth in the 21st Century Cures Act
- Considering creating a National Coverage Determination (NCD) to evaluate the use of microprocessor knees (MPK) in those individuals utilizing their prostheses as a limited community ambulator (K2 functional level)

The removal of the Draft LCD has been an aim of AOPA and its lobbying efforts, since it was introduced in 2015, and the official directions from CMS to remove it is a major victory.

AOPA is currently reviewing the full findings of the Workgroup and the consensus document, and there are some areas/conclusions where AOPA will likely disagree and wish to provide additional comments. For example, it appears that the consensus document may have been written before the enactment in February, 2018 of Section 50402 of the Bipartisan Budget Act of 2018 which recognizes the legitimacy of orthotist's and prosthetist's notes in the medical record for the justification of medical necessity. Even in light of the [recent letter from the CMS Deputy Administrator & Director of Program Integrity](#) instructing the implementation of Section 50402, CMS has yet to revise the Program Integrity Manual to reflect the directions from the Deputy Director, the head of CMS' own Program Integrity Center, and the current status of the prosthetist's notes continues to be misstated.

In addition the recommendation that the potential for MPK devices for K2- limited community ambulators- be done by a NCD is an important step forward as it represent CMS taking back this authority from the DME MACs. LCDs are the province of the DME MACs, while a NCD is a strict ***Federal Register*** CMS-driven rulemaking process. CMS has consistently said that the only way they could take this matter out of the authority of the DME MACs would be to invoke a NCD. AOPA will also be submitting comments on the proposed NCD and potential for microprocessor knees to be used by K2 -limited community- ambulators in accordance with established guidelines.

[Click here to access the document.](#) Then click to go to the Lower Limb Prosthetic Workgroup Consensus Document link.

AOPA will keep you posted about any additional actions taken as a result of the Workgroup's final findings. Questions? Contact Joe McTernan at jmcternan@AOPAnet.org or Devon Bernard at dbernard@AOPAnet.org.

CMS Issues Instructions for DME MACs to Immediately Implement Provisions that Require the Recognition of Orthotist and Prosthetist Clinical Documentation as Part of the Medical Record

AOPA and its lobbying team have been pressing CMS from all levels, most recently, including consultation with Trump Administration officials at the Office of Management and Budget, to formally implement the provisions of Section 50402 of the Bipartisan Budget Act of 2018 (Public Law 115-123) as it related to the prosthetist's and orthotist's clinical notes. AOPA was encouraged by the DME MAC notification 2-3 weeks ago where the DME MAC Medical Directors announced that they were 'retiring' the August 2011 "Dear Physician" letter on Lower Limb Prosthetics.

AOPA would like to share a recent letter from Alec Alexander, CMS' Director of Program Integrity which indicates that CMS "has issued instruction to the Durable Medical Equipment (DME) Medicare Administrative Contractors (MAC) to implement Section 50402 immediately." Section 50402 states:

“(5) DOCUMENTATION CREATED BY

17 ORTHOTISTS AND PROSTHETISTS.—For purposes of

18 determining the reasonableness and medical neces-

19 sity of orthotics and prosthetics, documentation cre-

20 ated by an orthotist or prosthetist shall be consid-

21 ered part of the individual's medical record to sup-

22 port documentation created by eligible professionals

23 described in section 1848(k)(3)(B).”.

Mr. Alexander's letter is a clear assertion of CMS' commitment to acknowledge immediate implementation of the new statutory provisions in Section 50402, accepting the orthotist and prosthetist clinical notes as part of the individual's medical record as to "determining the reasonableness and medical necessity of orthotics and prosthetics" e.g., functional levels, identification of broken, damaged parts and their repair, and identifying components in a category included in a physician approved detailed written order. We also suggest that AOPA members consider including a copy of the letter with all claims they file.

AOPA will continue to keep you informed of any developments in this important area. [Click here to view the letter from Mr. Alexander.](#)

To view the DME MAC announcement of the retirement of the Dear Physician letter for lower limb prostheses, [click here.](#)

DME MACs Announce the Retirement of the Dear Physician Letter for Artificial Limbs

Recently, each of the four DME MAC contractors has published a revised version of the Dear Physician letter regarding artificial limbs. The revised version of the letter states that the Dear Physician letter is being retired due to pending guidance from the Centers for Medicare and Medicaid Services (CMS) on potential program changes that may be necessary to implement the recently passed legislation that requires recognition of O&P practitioner notes as part of the patient's medical record.

The Dear Physician letter for artificial limbs, originally published in August, 2011, fundamentally changed how Medicare claims for artificial limbs were processed. Prior to the 2011 Prosthetic Dear Physician letter, practitioner notes were generally accepted as being valuable when making claim payment decisions. The Dear Physician letter made it clear that for Medicare purposes, "it is the treating physician's records, not those of the prosthetist's, which are used to justify payment." This statement, and the overall tone of the Dear Physician letter lead to years of frustration where the clinical notes of qualified, educated, certified, and often licensed prosthetists, were simply ignored during the claim review process. This exclusion of valuable clinical information led to higher claim denial rates and unacceptable delays in the appeal process.

With the February, 2018 passage of legislation that now requires documentation created by orthotists and prosthetists to be considered part of the patient's medical record for medical review purposes, the statement quoted above and other parts of the Dear Physician letter are no longer consistent with the law. The DME MACs have acknowledged this and have decided to retire the 2011 Dear Physician letter for artificial limbs until they receive further guidance from CMS.

While the retirement of the Dear Physician letter does not mean that the DME MACs will no longer require physician documentation to support claims for artificial limbs, it is a clear indication that they acknowledge and understand that the provisions of the original Dear Physician letter are no longer consistent with the law and therefore can no longer be used as the sole justification for denying a Medicare claim. It also indicates that the diligent AOPA efforts to convince CMS to provide guidance on this issue to their DME MAC contractors. While AOPA does not know what that eventual guidance will be, it is clear that CMS is aware of the legislation and intends to provide guidance to the DME MACs regarding the role of O&P practitioner notes in the medical review process.

[View a sample of one of the Dear Physician letters indicating its retirement.](#)

Exhibit at the AOPA National Assembly – Sept. 26-29 in Vancouver, Canada



AOPA is currently accepting exhibit applications for the 2018 AOPA National Assembly which is to be held September 26-29, 2018 in beautiful Vancouver, Canada. Now is your chance to sign up and showcase your products at the largest O&P tradeshow in the Western Hemisphere. This world-wide convention opportunity features 4 days of high-level networking, exhibits, the latest

techniques in O&P treatment, and the finest industry specific business and clinical training programs. We hope you make plans to join us.

Exhibiting at this important event will give you the opportunity to:

- Build your customer base and increase sales by meeting with Facility Owners and decision-making practitioners.
- Experience face-to-face time with existing customers to answer questions and build new relationships.
- Enjoy sponsored networking opportunities, including an opening welcome reception in the exhibit hall.
- Take advantage of fun traffic-building opportunities.
- Take advantage of education sessions to learn what's happening with U.S. health care reform, Medicare, and other regulatory agencies that affect the success of your products.
- Increase visibility for your company/organization in a targeted market.
- Host a Manufacturer's Workshop and/or Product Preview Theater presentation.
- Speak to AOPA coding experts to learn what's happening with U.S. government sponsored healthcare programs.
- Increase your exposure through a wide variety of advertising and sponsorship opportunities.
- Hear from top-researchers and clinicians to learn what products and support is needed from manufacturers.
- Participate in key education programs and plenary sessions.
- Benefit from global exposure.
- Much more!

[Click here to sign up](#) today to exhibit at the 2018 AOPA National Assembly. Questions? Contact Kelly O'Neill at kelly.oneill@AOPAnet.org or call (571) 431-0852.



Join your colleagues at the Vancouver West Convention Center, Vancouver, BC, Canada for AOPA's 101st Assembly! Enjoy the best in business education and advanced clinical programming, the largest O&P exhibit hall, networking with the most influential people in the profession, must attend events, and 30+ CE credits. [Register and learn more here.](#)

| Upcoming AOPA Events | |
|----------------------|--|
|----------------------|--|

| | |
|-----------------------|---|
| August 8, 2018 | <i>Outcomes & Patient Satisfaction Surveys</i> AOPA Webinar Learn more and register here |
| September 12, 2018 | <i>Medicare as Secondary Payer: Knowing the Rules</i> AOPA Webinar Learn more and register here |
| September 26-29, 2018 | AOPA National Assembly Vancouver, Canada Learn more and register here |