

May 5, 2016

Mr. Andy Slavitt  
Acting Administrator  
Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
200 Independence Avenue Southwest  
Washington, D.C. 20201

Dear Mr. Slavitt:

I write to call to your attention a letter I recently received from Tom Watson, President of Tom Watson's Prosthetics and Orthotics Lab. Mr. Watson, an amputee himself, has concerns about the Centers for Medicare and Medicaid Services' (CMS) proposed draft Local Coverage Determination (LCD) for lower limb prosthesis and raises a number of important questions that merit your attention.

As you are aware, on November 2, 2015, CMS announced that the Durable Medical Equipment (DME) Medicare Administrative Contractors (MACs) will not finalize a draft LCD for lower limb prosthesis, but instead CMS will convene a multidisciplinary Lower Limb Prostheses Interagency Workgroup to identify steps forward.

Mr. Watson is concerned that the current status of the rule, neither implemented nor withdrawn, has caused insurers to limit the availability of certain prosthetics to amputees. As you will see in the enclosed correspondence, Mr. Watson has concerns about the decision to not rescind the proposed rule and questions the transparency involved in the makeup of the working group. I am contacting you to determine the following:

1. What is the current status of the rule? Why hasn't CMS rescinded the draft rule? Is there a plan to retract the proposal in the future?
2. Who are the stakeholders involved in the working group? How many prosthetic users and makers are represented on the working group?
3. Is the working group considering stakeholder comments submitted to the draft LCD?
4. Will the working group provide the industry with updates on the topics being discussed?

Thank you for your attention to this matter. I would appreciate any information that you can appropriately share in accordance with all federal regulations and U.S. Senate ethics rules. I look forward to your reply that I may share with my constituent.

Sincerely,



MITCH McCONNELL  
UNITED STATES SENATOR

MM/an

# *Tom Watson's Prosthetics And Orthotics Lab, Inc.*

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April 29, 2016

Senator Mitch McConnell  
The Mitch McConnell Building  
105 W. Third Street  
P.O. Box 1068  
Frankfort, KY 40602

Dear Senator McConnell,

It has been a very active week with the Policy Forum, and some notable related developments. I am attaching the summary just shared with the AOPA Board. I hope this information is helpful.

Some pretty remarkable things happened in conjunction with the AOPA Policy Forum this week. On Thursday, April 21, an AOPA sponsored press event underscored the damage caused by the continuing controversy about the proposed LCD for Lower Limb Prosthetics as private sector insurers like United and CIGNA have used the now discredited LCD as the alleged basis for their newfound decision, unsupported by science/evidence, to deny payment for vacuum technology in prosthetic sockets. On Monday, April 25, Rep. Renee Ellmers (R-NC), together with Rep. Jan Schakowsky (D-IL) introduced H.R. 5045, a bill that would establish a moratorium on any action on the LCD, at least through Spring, 2017 as well as removing the LCD from CMS and DME MAC websites and establishing that, contrary to some legal interpretations at HHS, CMS indeed can, and is obliged to manage and instruct its contractors, including the DME MACs, what to do across topics including LCD issues.

On Tuesday morning, April 26, former Senator Bob Kerrey led a one of a kind O&P Legislation-Writing Congress, where AOPA Policy Forum attendees actually authored a simple bill (fitting in a single piece of paper) that would fix most of the problems that are undercutting the quality of Medicare beneficiaries who have O&P needs. Tuesday afternoon, while Policy Forum attendees were learning the ins and outs of a range of government policies and actions, Senator Kerrey had personal meetings with eight Senators to explain the new bill, and how some simple steps could rectify the problems and injustices burdening Medicare beneficiaries and the O&P professionals committed to providing care for those patients.

On Wednesday, April 27, about 150 O&P providers and patients from over 30 different states spent the day on Capitol Hill in over 400 meetings with their legislators, seeking their support

for the new bill and related proposed legislation--the central, indispensable exercise of citizens' rights that is the core of every AOPA Policy Forum Forum.

On Thursday, April 28, the first fruits of a months-long effort spearheaded by AOPA appeared as the House Oversight and Government Reform Committee released a letter it has initiated to HHS Secretary Burwell, criticizing the prosthetic LCD efforts of CMS and its contractors, and launching an oversight inquiry with a request for a substantial collection of documents.

It has been a truly remarkable week for O&P, though there is much work that remains to be done to deliver on these needed remedies:

#### Legislative Needs

We need a simple bill that would mirror the actions outlined in S. 829, introduced by Senators Grassley and Warner. Specifically, it is extremely important to address by legislation three acutely needed actions:

(1) assure that The Center for Medicare and Medicaid Services (CMS) shall treat Prosthetics and Orthotics ("P&O") separately from Durable Medical Equipment and shall amend its regulations to define orthotics and prosthetics as a covered service, separate and distinct from the provision of durable medical equipment.

(2) assure that CMS shall enforce BiPA 427 through issuance of federal regulations and only reimburse custom P&O care upon receipt of proof that an appropriately credentialed prosthetist/orthotist—licensed and/or certified, has clinical notes and documentation sufficient to determine that the P&O care being provided to a patient is a medically necessary plan of care that is corroborated solely by a signed physician prescription. All such documentation is considered part of the patient's medical record for purposes of determining the medical necessity of P&O care. A rule to implements Section 427 is sixteen years overdue. We know that CMS will say that the first proposal ever to implement this provision is poised for release, but even if true, what counts is a fair rule in the form of a final rule on the books, and even if this proposal were released today, it would be a tall order to get that done before this Administration concludes on January 20, 2017.\*

(3) CMS needs to recognize that plans of care that include custom fabricated prosthetics and custom fabricated and fitted orthotics continue to be completely inappropriate for inclusion in competitive bidding and that the standards established in MMA needed to be diligently and narrowly construed and followed.

#### Administrative and/or Legal Action Required

With respect to the proposed draft Local Coverage Determination for Lower Limb Prosthetics (LD-33787), CMS should rescind this LCD. Just yesterday, the House Oversight and

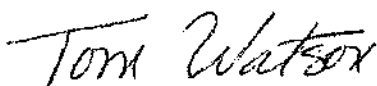
Government Reform Committee, in bipartisan action, has initiated oversight activities on this topic via a substantial request to the HHS Secretary for documents on this issue (letter attached). It seems broadly recognized that the proposal issued jointly by the four DME MACs in July, 2015 suffered from at least three serious shortcomings:

- (a) it was developed via a process that was not transparent;
- (b) that the process of preparing that draft LCD did not assure or include any stakeholder input; and
- (c) that there was little if any bonafide scientific evidence to support the proposed actions.

In the six month since the contemporaneous announcements on November 2, 2015 by the White House and CMS that they did not intend to pursue this proposal LCD, CMS has indicated that it has appointed an Interagency Committee comprised solely of federal employees to work on this issue, though CMS has refused to identify the names of any of those appointees. So, a process that was deemed deficient because it was *non-transparent and without stakeholder input has been replaced by another process that is not transparent and which offers not assurance or method for stakeholder input*. CMS needs to rescind that July, 2015 LCD, have it removed from ALL websites from entities supported by government funds; and assert that CMS DOES have the authority to manage all aspects of LCDs and other activities by all of its contractors, including the DME MACs. If CMS cannot accomplish those steps, H.R. 5045, a moratorium on this LCD, needs to be enacted into law to fix this horrendous problem hampering some of our most vulnerable citizens, patients who suffer from either limb loss or chronic limb impairment.

So, a very special week, though we obviously can't rest for a minute on these interim accomplishments—we need to drive hard to the finish line. Special thanks to those who attendees the AOPA Policy Forum, and supported the O&P PAC fundraisers over the past few days.

Sincerely,



Tom Watson

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard, Mail Stop S3-02-01  
Baltimore, Maryland 21244-1850



July 20, 2016

The Honorable Mitch McConnell  
United States Senate  
Washington, DC 20510-1702

Dear Senator McConnell:

Thank you for sharing your concerns about the local coverage determination (LCD) for lower limb prostheses proposed by the Durable Medical Equipment Medicare Administrative Contractors (DME MACs). The Centers for Medicare & Medicaid Services (CMS) is committed to providing high quality care to all Medicare beneficiaries, including any beneficiary in need of a prosthesis.

Regarding the status of the DME MAC's LCD, CMS announced on November 2, 2015, that the draft LCD would not be finalized at the time and established the Lower Limb Interagency Workgroup. The Workgroup is comprised of clinicians, researchers, policy specialists, and patient advocates from different federal agencies, including the Department of Veterans Affairs, National Institutes of Health, Department of Defense (including personnel from the Walter Reed National Military Medical Center), and the Administration of Community Living, as well as CMS. The purpose of the Workgroup is 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 may also identify areas where evidence gaps exist related to the prescription of lower extremity prostheses and make recommendations concerning the study designs and outcome measures that best inform patient-oriented function, quality of life, and service satisfaction in this realm. The goal of the Workgroup is to first develop a draft consensus statement. Once completed, CMS will publish the draft, requesting public comment, so that interested stakeholders will have the opportunity to critique the document. The Workgroup will finalize the consensus statement only after reviewing the comments of the stakeholders.

In the meantime, per Medicare policy, the draft LCD remains on the website, with the specific information attached that no further decisions will be made regarding the draft policy until after the workgroup has finalized the consensus statement. Furthermore, the website states that draft policies are works in progress and not necessarily a reflection of the current policies of the contractor.

Absent a new LCD, the previous LCD on lower limb prostheses remains in effect. Additionally, CMS has been in contact with the American Orthotic & Prosthetic Association (AOPA), who shared with us the correspondence causing a belief that two health insurance companies are denying state-of-the-art prosthetics based on the draft LCD. CMS has researched this allegation and discovered that both insurance companies performed their own literature searches on the matter to support their coverage policies.

CMS is committed to providing high quality care to all Medicare beneficiaries, including any beneficiary in need of a prosthesis. CMS looks forward to working with the public to ensure appropriate access to prostheses.

Sincerely,

A handwritten signature in black ink, appearing to read "Kate Goodrich".

Kate Goodrich, MD MHS  
Director, Center for Clinical Standards and Quality  
Centers for Medicare and Medicaid Services