THE ORTHOTIC AND
PROSTHETIC ALLIANCE

1501 M Street, NW, 7th Floor
Washington, DC 20005
Phone: 202-466-6550
Fax: 202-785-1756
Email: opalliance@gmail.com

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SUBMITTED VIA ELECTRONIC MAIL

Andrew Slavitt, Acting Administrator
Centers for Medicare and Medicaid Services
United States Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Request to Immediately Rescind Proposed/Draft LCD on Lower Limb Prostheses (DL33787)

Dear Acting Administrator Slavitt:

As our country celebrates the 25th Anniversary of the Americans with Disabilities Act, prosthetic limb care is a true health care success story. Decades of government research funding through the Veterans Administration, the Department of Defense, the NIH and other agencies, as well as robust innovation in the prosthetic field has enabled individuals who have lost limbs to regain remarkable levels of function and independence. The current standard of care in prosthetics is routinely depicted in the media as individuals with once disabling conditions return to active, healthy lives, re-engage in employment, pursue recreational and athletic interests, and even return to active duty military assignments. Due to the current standard of care, limb loss is simply not the disability it once was, for Medicare beneficiaries and all Americans.

This is why we, the Orthotic and Prosthetic (O&P) Alliance, representing the orthotic and prosthetic community, are stunned to learn that CMS, through its DME MAC contractors, has issued a proposed Local Coverage Determination (LCD) for Lower Limb Prosthetics that, if implemented, would send Medicare beneficiaries—and eventually all amputees in this country—back to 1970's technology and result in poorer functional outcomes.

The proposed LCD (DL33787) is a comprehensive re-write of Medicare's entire lower limb prosthetic benefit based on virtually no evidence to support the LCD. It would dramatically reduce beneficiary access to the current standard of prosthetic care. Because many of the proposed policies involve major changes to the Uniform Code Set administered by CMS (which all insurers use to cover and pay prosthetic limb claims), these changes have the potential to impact *all* amputees who use prostheses throughout the nation.

For these reasons, the O&P Alliance requests that you rescind immediately the Proposed/Draft LCD on Lower Limb Prostheses (DL33787) and establish a more rational and transparent process whereby experts in the O&P profession—as well as other physician, clinician and consumer stakeholders—can work with CMS to develop more reasonable policies to address any concerns CMS may have with the Medicare prosthetic benefit.

If this LCD is not immediately rescinded, we request that CMS suspend the LCD and host a national, in-person, meeting that is open to the public, on this LCD alone. The complexity of the prosthetic benefit and the comprehensive nature of this Proposed LCD necessitates such an approach. The existing opportunity for comment to the DME MAC Medical Directors scheduled for August 26th is simply insufficient for the Medicare Administrative Contractors to consider such a comprehensive proposal in a manner that provides a meaningful opportunity to address the widespread and unanimous disagreement with major aspects of this proposed LCD.

Finally, the Proposed LCD should be suspended until such time as CMS publishes the final rules for Prior Authorization of Certain DMEPOS, which we understand will impact lower limb prosthetic care and is in the final phases of regulatory clearance within the Department of Health and Human Services. It makes no sense for Medicare contractors to finalize medical policy through an LCD that is materially affected by, and not integrated into, a pending federal regulation on the same policy. Commenters should have the opportunity to examine all relevant rules being promulgated by CMS before being forced to comment in a piecemeal manner. The Prior Authorization final rule may or may not address the O&P community's concerns with the proposed rule on this topic, but the community should have an opportunity to examine it in the context of the overall scheme on prosthetic limb policy before commenting on an LCD that addresses many of the same issues.

Taking these measures are warranted in light of the enormity of the changes being proposed, the complexity of the Proposed LCD, and the impact these changes will have on patient access to appropriate prosthetic care, physician prescription options, and clinical prosthetic practice. For instance, the proposed LCD:

- Eliminates coverage of multiple prosthetic knees, feet and ankles that have undergone years of development, coding assignment, and widespread use by Medicare beneficiaries, causing them to live with prosthetic technology that is outdated and not consistent with the current standard of care;

- Eliminates twenty years of precedent by barring consideration of a beneficiary's *potential* to function and instead relying on "their documented performance using their immediately previous prosthesis (either preparatory or definitive)" when making a determination of the amputee's functional level. This new standard will drive beneficiaries into less functional prostheses and older prosthetic limb technology, some of which is no longer even available on the market;

- Creates multiple, new barriers to prosthetic care that will delay and, in some cases, deny prosthetic care to beneficiaries with limb loss. These barriers include the requirement for the beneficiary to undergo full rehabilitation programs before being eligible for prosthetic

coverage, secure detailed documentation from a newly designated set of providers known as "licensed certified medical professionals" or "LCMPs," and satisfy other prerequisites before a prosthetist can even interact with the patient;

- Fundamentally reworks the HCPCS coding system that has been developed and annually refined over the past forty years whereby "base" prosthetic codes are augmented with "add-on" codes to ensure that beneficiaries receive the most appropriate combination of prosthetic techniques, materials, and technologies to meet their specific functional needs and functional potential. (The DMAC Medical Directors have essentially usurped the authority of the HCPCS Coding Committee which has responsibility for maintaining and refining the Uniform Code Set used by all payers.);

- Eliminates coverage of some of the most effective suspension techniques to secure a snug fit between the residual limb and the prosthesis, techniques and technologies that are in widespread use today. Poor or inconsistent suspension during the course of a day's use of prosthetic limbs is a major contributor to skin breakdown and reduced function;

- Eliminates access to certain prosthetic components if the amputee uses a cane or crutches to ambulate, or cannot achieve "the appearance of a natural gait" while using a prosthesis, perhaps one of the most offensive proposals to Medicare beneficiaries;

- Contains a long set of requirements a patient must satisfy before being eligible to receive prosthetic care, including upper body strength, adequate posture, cognitive capability, sufficient neuromuscular control, sufficient cardio-vascular capacity, and numerous other prerequisites. This appears to be a thinly veiled attempt to use the existence of these conditions to disqualify amputees for coverage of more advanced levels of prosthetic care, or any prosthetic care at all. These requirements are overly broad, not medically supported, and will lead to denials of claims based solely on historical, clinical records, not the physician's judgment that a beneficiary is a candidate for prosthetic care;

- Eliminates the licensed/certified prosthetist—who has the most intricate knowledge of prosthetic care—in determining an amputee's functional capabilities/deficiencies which help determine the treatment plan designed to meet the specific functional needs of the amputee. The proposed LCD creates a new system where physicians, therapists, and others (not prosthetists) will be required to conduct subjective and objective functional assessments and develop significant documentation with little or no additional reimbursement;

- Reiterates misguided Medicare policies that prohibit the prosthetist's clinical notes from being considered as part of the medical record and requires new and unnecessarily-detailed proof of delivery documentation; and,

- Ignores recent Medicare-based data that establishes a clear link between patients who receive prosthetic components that are "above" their established functional level (i.e., K2 level patients who receive a K3 component) and less overall total health care cost.

Evidence is Severely Lacking
There are numerous additional proposed policies in the LCD that are just as alarming as the policies highlighted above. Yet, the LCD offers virtually no evidence for these dramatic changes in coverage, coding and payment for prosthetic care. This is contrary to the requirements of the Program Integrity Manual, Section 13.7.1, which states that LCDs shall be based on the strongest evidence available.

Such evidence is listed in priority order and includes published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, general acceptance by the medical community (standard of practice), as supported by sound medical evidence based on: scientific data or research studies published in peer-reviewed medical journals; consensus of expert medical opinion (i.e., recognized authorities in the field); or medical opinion derived from consultations with medical associations or other health care experts. PIM, Section 13.7.1 - Evidence Supporting LCDs (Rev. 473, Issued: 06-21-13, Effective: 01-15-13, Implementation: 01-15-13).

The fundamental changes in the Proposed/Draft LCD offer none of this evidence. However, the LCD shifts the burden onto stakeholders to demonstrate through such evidence why this comprehensive array of proposals should *not* be adopted. The O&P community is being placed in the position of undertaking a massive research effort to prove a long list of negatives by August 31st. The process is unfair, highly burdensome, and will result in poor Medicare policy that is to the detriment of patients, practitioners, and the rehabilitation teams that treat Medicare and other patients.

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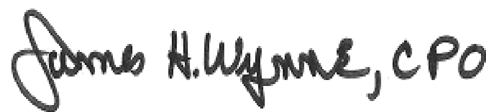
For the foregoing reasons, the O&P Alliance urges you to immediately rescind the Proposed/Draft LCD for Lower Limb Prostheses (DL33787) and set in place a more rational and transparent process where O&P stakeholders can meaningfully interact with CMS officials to develop more reasonable medical policy addressing lower limb prostheses and the beneficiaries who rely on them to be healthy, functional and independent.

For more information from the O&P Alliance, please contact Peter Thomas, O&P Alliance Counsel, at 202-872-6730 or at **Peter.Thomas@ppsv.com**.

Sincerely,

David McGill
President
National Association for the
Advancement of Orthotics and Prosthetics



James H. Wynne, CPO, FAAOP
President
American Board for Certification in
Orthotics, Prosthetics and Pedorthics, Inc.

James L. Hewlett, BOCO
Chair, Board of Directors
Board of Certification/Accreditation (BOC)

Charles H. Dankmeyer, CPO
President
American Orthotic & Prosthetic Association

M. Jason Highsmith, PT, DPT, PhD, CP, FAAOP
President
American Academy of Orthotists and Prosthetists

cc:

Sylvia Mathews Burwell, Secretary of Health and Human Services
United States Department of Health and Human Services

Sean Cavanaugh, Deputy Administrator and Director
Center for Medicare, Centers for Medicare and Medicaid Services
United States Department of Health and Human Services

Laurence D. Wilson, Chronic Care Policy Group Director
Centers for Medicare and Medicaid Services
United States Department of Health and Human Services

Dr. Shantanu Agrawal, Deputy Administrator and Director
Center for Program Integrity, Centers for Medicare and Medicaid Services
United States Department of Health and Human Services

Dr. Patrick H. Conway, Deputy Administrator & CMS Chief Medical Officer
Office of the Administrator, Centers for Medicare and Medicaid Services
United States Department of Health and Human Services

Sharon B. Lewis, Principal Deputy Administrator & Senior Advisor for Disability Policy
Office of the Administrator, Administration for Community Living
United States Department of Health and Human Services