Stacey Brennan, M.D.
National Government Services
8115 Knue Road
Indianapolis, Indiana 46250

Dear Dr. Brennan:

The Veterans Health Administration (VHA) Orthotic and Prosthetic Services (OPS) appreciates the opportunity to provide the following comments regarding Centers for Medicaid and Medicare Services (CMS) Local Coverage Determination (LCD) draft proposal “Lower Limb Prostheses” (DL33787). Historically, VHA OPS has worked in collaboration with CMS and the Alpha-Numeric Workgroup Coding Committee. VHA Orthotists and Prosthetists use and rely upon existing CMS Healthcare Common Coding Procedural System definition and standards to properly identify and code prosthetic and orthotic devices for classification and reimbursement.

VHA carefully reviewed the draft LCD and supporting bibliography. Adoption of DL33787 by CMS will have the likely consequence of establishing two distinctly different standards of care for Veterans with amputation. Veterans receiving care through VHA will continue to receive a high standard of prosthetic care and access to technology. Veterans receiving care outside VHA and relying upon CMS as a payer source would realize a sub-standard and encumbered level of care with limited access to appropriate technology. VHA believes that all Veterans with amputation, regardless of payer source, should have access to appropriate prosthetic care and technology.

In general, the following restrictive and limiting protocols that are foundational to DL33787 will adversely impact Veterans with amputation receiving care through CMS:

A. Specific, rigid language is used to define classes of prostheses and place new limitations on services available within each class. This will restrict opportunity for Veterans with amputations to obtain appropriate prosthetic limbs and services.

B. Rigid linkage, without a base of supporting evidence, is established between functional (K) level and prosthetic technology. This will restrict the opportunity for Veterans with amputations to experience benefits of new prosthetic technology, and inhibit functional improvement and functional outcomes.

C. Subjective functional levels are developed by a newly classified workforce labeled “Licensed or Certified Medical Professional (LCMP)”. This workforce has no formal prosthetic education, excludes prosthetists, has no clearly defined qualification standards or expertise in orthotic and prosthetic services, and yet will determine the functional (K) level and therefore the level of technology available to the Veteran with amputation. According to this policy change, critical functional levels are based
common to all amputees of every K-level, may eliminate consideration to a higher functional (K) level.

D. The strict evaluation and re-evaluation process to receive a definitive prosthetic limb will likely result in delayed care to Veterans with amputations. For example, to obtain a definitive prosthesis, Veterans with amputation must participate in a rehabilitation program. Then, they will need an appointment with their provider, who will refer them to a LCMP for evaluation. After making an appointment with the LCMP, they are referred back to their care provider for a prosthetic prescription, if medically appropriate and clinically indicated. The provider then works with the prosthetist to supply all CMS required documentation, requiring an additional appointment with the prosthetist, all prior to getting official approval. Requiring multiple appointments for an eligible Veteran with amputation to receive approval for a prosthesis is both burdensome and inefficient. Further, DL33787 poses subjective criteria for prosthetic delivery such as, "achieving a natural and symmetrical gait", that cannot be standardized or objectively measured.

VHA OPS is the Federal Government's foremost expert workforce on subjects related to prosthetic and orthotic clinical services, with over 80 nationally accredited orthotic and prosthetic laboratories, and over 300 board certified clinicians providing direct patient care services to eligible Veterans across the United States. In fiscal year 2014, VHA OPS provided care to over 305,000 unique Veterans with disabilities. VHA cannot support changes that would prohibit Veterans with amputation from being able to receive medically appropriate and clinically necessary prosthetic care and technology.

VHA advocates the current draft LCD be rescinded in its entirety, and extends the offer to partner with CMS to assist with drafting realistic, appropriate LCDs that benefit both government agencies, and ultimately assures high quality care to Veterans and others. Thank you for the opportunity to comment on this draft LCD and for carefully considering VHA's input, as we look forward to our further collaboration with CMS.

Respectfully,

Joseph A Miller, PhD, CP
Veterans Health Administration
National Program Director, Orthotic and Prosthetic Services

Cc: DMAC_Draft_LCD_Comments@anthem.com