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SUBMITTED VIA ELECTRONIC MAIL

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Re: Proposed/Draft LCD on Lower Limb Prostheses (DL33787)

Dear Dr. Brennan:

We are writing today as concerned, independent researchers regarding the latest CMS draft LCD (DL #33787) for provision of Lower Limb Prostheses. It is important to note that we are not collectively affiliated with any organization, but are writing as individual researchers and authors.

It has recently come to light that the bibliography that was associated with the decision-making process for this draft LCD included papers that we had authored.

We would like to go on record as stating that the works referenced do not support any of the changes outlined in the CMS proposal. In addition, many of the citations in the CMS bibliography are not peer reviewed, are not current, or are not true citations in accordance with referencing standards by recognized entities.

We are extremely concerned that the CMS Draft LCD was not based at all on the current literature and science associated with the provision of prosthetic care.

According to the PIM the (Provider Integrity Manual), 13.7.1 – Evidence Supporting LCDs (Rev. 473, Issued: 06-21-13, Effective: 01-15-13, Implementation: 01-15-13):

LCDs shall be based on the strongest evidence available. The extent and quality of supporting evidence is key to defending challenges to LCDs. The initial action in gathering evidence to support LCDs shall always be a search of published scientific literature for any available evidence pertaining to the item or service in question.

In order of preference, LCDs should be based on:

- Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and
- General acceptance by the medical community (standard of practice), as supported by sound medical evidence based on:
 - o Scientific data or research studies published in peer-reviewed medical journals;
 - o Consensus of expert medical opinion (i.e., recognized authorities in the field); or
 - o Medical opinion derived from consultations with medical associations or other health care experts.

The articles referenced by CMS claimed to support the LCD, actually have no bearing on any of the policy changes described in the proposed LCD. In fact, many of the citations could be used to refute the proposed changes. Further, these selected references do not support the significantly diminished quality of care that beneficiaries would receive if the proposed changes were implemented. It is also clear that some of the articles referenced in the bibliography are not accessible for evaluation and comment, calling into greater question the quality of the science behind CMS's proposed decision making when drafting the LCD proposal.

The current standard of practice is fully supported by sound, (peer- reviewed) scientific evidence. The changes proposed are not consistent with the current standard of practice and not derived from consultation with any of the referenced authors. As CMS has used our works in the preparation of this ill-conceived proposal, we are led to question why we, as health care experts in this field, were not consulted.

The proposed changes described in DL#33787, in our expert opinion, would diminish both the quality and access to prosthetic care across our nation. We, as the experts cited in this document, wish to go on record as strongly opposing the draft LCD.

We look forward to working with CMS in the development of a more scientifically based approach to policymaking as outlined in the PIM.

Ultimately, we should remember where our collective focus should be: on the beneficiary. We are all working to ensure people with limb loss receive appropriate care that is supported by science.

Sincerely,



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