ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

October 6, 2014

Patrick Conway, M.D.
Deputy Administration for Innovation and Quality and CMS Chief Medical Officer
Sean Cavanaugh
Deputy Administrator and Director, Center for Medicare
Liz Richter
Deputy Center Director
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Dear Deputy Administrator Conway, Deputy Administrator Cavanaugh and Deputy Center Richter;

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), I want to bring to your attention four new and identical Local Coverage Determinations ("LCDs") on Pneumatic Compression Devices ("PCDs") issued in September 2014 as a mere public notification by the four DME MACs with an effective date of November 1, 2014. However, they are fatally flawed as described below. I am addressing this letter to all of you since there are clinical, procedural and DMEMAC contractor issues that fall under your purview. The Alliance is a nonprofit multidisciplinary trade association of physician and clinician professional organizations whose mission is to promote quality care and access to products and services for people with wounds through effective advocacy and educational outreach in the regulatory, legislative, and public arenas.

We request that the new LCDs be withdrawn while physician experts and other stakeholders work with the DME MAC Medical Directors to revise what has been a 2011 draft LCD. The Alliance is working rapidly and diligently to produce a redlined version of the new LCDs for the DME MAC Medical Directors to consider before November 1 that includes the Alliance's recommended revisions, addressing numerous significant clinical corrections and concerns as well as highlighting an overall failure of the new LCDs to address current medical literature published since the draft LCD was initially issued back in 2011. We plan to discuss these concerns with the DME MAC Medical Directors in our conference call with them on October 9, 2014. We are very grateful that they will give us their time to address these issues. We are hopeful that after they hear the concerns voiced by our clinical associations, they will decide to withdraw this future LCD before its implementation on November 1. Such a withdrawal or suspension would afford everyone more time to correct what needs to be corrected here. However, if we are not successful with them, we will follow-up and request a meeting with you.

**The Procedural and Substantive Flaws include the following:**

1. **The new LCDs are improperly more restrictive than the corresponding National Coverage Determination ("NCD") for Pneumatic Compression Devices (Section 280.6 of the Medicare National Coverage Determinations Manual), in violation of Chapter 13, Section 13.5 of the Medicare Program Integrity Manual** ("The LCD shall … not restrict or conflict with NCDs or

5225 Pooks Hill Rd | Suite 627S | Bethesda, MD 20814
T 301.530.7846 | C 301.802.1410 | F 301.530.7946
marcia@woundcarestakeholders.org

coverage provisions in interpretive manuals"). Despite this requirement in the Medicare Program Integrity Manual, the new LCDs include additional restrictive conditions for Medicare coverage for Pneumatic Compression Devices that either contradict the existing NCD or are otherwise not mentioned as limitations or exclusions in the existing NCD.

2. **The new LCDs create insurmountable barriers to beneficiary access to care, including the virtual elimination of coverage for Pneumatic Compression Devices used by post-mastectomy patients diagnosed with lymphedema.** Indeed, there are several significant clinical flaws in the new LCDs that will negatively impact beneficiary access to these important devices for the treatment of lymphedema and chronic venous insufficiency with venous stasis ulcers.
3. Although a draft LCD for Pneumatic Compression Devices was originally introduced in 2011, **no issuance has occurred between 2011 and now. However, the changes between the 2011 draft and the new LCDs are extensive and material. They include additional conditions for Medicare coverage never before mentioned. Examples of the material and substantive changes in the new LCDs that were not subject to a public comment period, as required under Chapter 13, Section 13.7.2 of the Medicare Program Integrity Manual**, include:
    a. A definition of the severity of lymphedema symptoms that qualify for Medicare coverage;
    b. When a trial period of conservative therapy is a prerequisite for coverage of Pneumatic Compression Devices, the new PCD LCDs impose a lengthier trial period even when the patient's treating physician determines that significant symptoms remain after the trial;
    c. Additional prerequisites for coverage of PCDs for lymphedema treatment;
    d. Additional prerequisites for coverage of PCDs for chronic venous insufficiency with venous stasis ulcers;
    e. New restrictive criteria for PCDs coded E0652 that will drastically reduce patient access to this treatment compared to the current LCD and NCD.
    f. Addition of coverage criteria for a whole new diagnosis (peripheral artery disease) that is not even mentioned in NCD 280.6.
    g. Alleged references to clinical literature that are, in fact, only references to other health plan policies so they are ***not*** references to clinical literature. **These references do not meet the requirement for evidence supporting LCDs as set forth in Chapter 13, Section 13.7.1. of the Medicare Program Integrity Manual** which states "…LCDs shall be based on the strongest evidence available…LCDs should be based on…scientific data or research studies…consensus of expert medical opinion…or medical opinion derived from consultations with medical associations…." The draft LCD fails to include significant published literature on lymphedema that is pertinent to the policy, and no mention is made of consultation with any applicable medical associations.
4. With so many new changes, at a minimum, **the DME MACs should have issued these new LCDs as proposed with an opportunity to comment; however, the DME MACs by-passed this mandatory step.** This resulted in an improper notice and a failure to provide an opportunity to comment on these new LCDs that are more restrictive than current LCDs for Pneumatic Compression Devices. Any time that a DME MAC intends to publish an LCD that restricts the terms of an existing LCD, the DME MAC must allow for a comment period and a notice period (*see* Chapter 13, Section 13.7.2 of the Medicare Program Integrity Manual, "Contractors shall provide for both a comment period and a notice period in the following situations: … Revised LCDs that Restrict Existing LCDs - Examples: adding non-covered indications to an existing LCD; deleting previously covered ICD-9 codes."). Unfortunately, the new LCDs were issued as a public notification or "future" only, which denied interested parties an opportunity to comment on the new language in the new LCDs. As a

result, **the new LCDs do not comply with the requirement in the Medicare Program Integrity Manual to provide a 45-day comment period** (*see* Chapter 13, Section 13.7.4 of the Medicare Program Integrity Manual, "When a new or revised LCD requires comment and notice (See §13.7.2) contractors shall provide a minimum comment period of 45 calendar days on the draft LCD."). The Alliance has engaged Epstein Becker & Green, P.C. ("EBG"), and EBG believes that there are critical legal and procedural violations that warrant having CMS suspend the implementation of the new LCDs at least until those violations can be corrected. The LCDs were in draft for over three years. There is no reason why the LCDs are so time sensitive that a comment period should not be allowed. The Alliance is prepared to help the DME MACs with revising the draft LCD appropriately.

5. By having all four DME MACs issue four new and identical "Local Coverage Determinations for Pneumatic Compression Devices" (*see* L11503, L27028, L5017, and L11492**), the DME MACs are essentially creating a national coverage determination without going through the required NCD process.** The new LCDs significantly alter the existing terms of coverage for these devices to the detriment of Medicare patients.
6. The draft LCD also precludes doctors of podiatric medicine (DPMs) from prescribing pneumatic compression devices (PCDs) in the treatment of conditions affecting the lower extremities, such as lymphedema and chronic venous insufficiency with venous stasis ulcers. This provision is incompatible with the national coverage determination (NCD) for PCDs as well as section 1861(r)(3) of the Social Security Act, which defines the term "physician" to include "a doctor of podiatric medicine…with respect to functions which he is legally authorized to perform as such by the State in which he performs them." DPMs have long prescribed PCDs for conditions affecting the lower extremities, as allowed by each respective state's scope of practice. There is no basis for the DME MACs' position precluding DPMs from appropriate prescription of a PCD for any foot-related manifestation of a systemic condition.

As previously stated, the Alliance appreciates that all four DMEMAC Medical Directors have graciously consented to convening a conference call this week with many of our physician and clinical organizations to discuss our serious concerns with the new LCDs. The Alliance believes that these significant legal, procedural and substantive violations, individually or in combination, are sufficiently substantial to warrant the withdrawal of the new LCDs until the public has had the chance to provide input on the substantive coverage policy changes included in these new LCDs. Failure to withdraw implementation of this new LCD will significantly and negatively impact beneficiary access to treatments that have been available for decades.

Through EBG, we already contacted HHS OGC to notify CMS of these violations. The HHS OGC attorney referred EBG counsel to the LCD Reconsideration Process defined in Chapter 13, Section 13.11 of the Medicare Program Integrity Manual. The Alliance is familiar with the LCD Reconsideration Process. However, this process is not the appropriate avenue to address the legal and procedural violations identified above. It would be futile to use this process here, which is intended to allow interested parties to submit new evidence to justify revisions to a final LCD based on clinical or scientific evidence or data, but not to address legal or procedural irregularities that have occurred before the new LCDs take effect.

Due to serious clinical flaws in the coverage policy and other concerns, it is critical for interested parties, including the Alliance, to have a meaningful opportunity to submit comments on the new LCDs to the DME MAC medical directors ***before*** they go into effect on November 1.

Hopefully, the DME MAC Medical Directors will do the right thing by withdrawing the new future LCDs. If

not, I will be back to request relief from you at CMS Baltimore.

Should you have any questions or need for additional information, please do not hesitate to contact me. Your consideration of this issue is greatly appreciated.

Sincerely,

Marcia Nusgart R.Ph.
Executive Director