ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

January 27, 2013

Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244–1850

Submitted Electronically

Re: **Draft Guidance for the Public, Industry, and CMS Staff Coverage with Evidence Development in the Context of Coverage Decisions**

Dear Acting Administrator Tavenner:

The Alliance of Wound Care Stakeholders ("Alliance") is submitting the following comments in response to the "**Draft Guidance for Coverage with Evidence Development in the Context of Coverage Decisions**". The Alliance is a 501 (c)(6) multidisciplinary trade association representing 19 physician and clinical organizations whose mission is to promote quality care and patient access to wound care products and services. These comments were written with the advice of Alliance organizations that not only possess expert knowledge in complex acute and chronic wounds, but also in wound care research. A list of our members can be found on www.woundcarestakeholders.org.

The Alliance appreciates the work that CMS has done with respect to this topic and agrees with the concept of coverage with evidence development. The recent coverage with evidence development for autologous platelet-rich plasma wound therapy was very well received in our industry. Many of the concepts that were outlined in the CED for this subject were in line with the wound research principles that the Alliance had created. This paper, "Consensus Principles for Wound Care Research Obtained Using a Delphi Process" was published in the May/June 2012 edition of *Wound Repair and Regeneration* which has been discussed with the Agency. We recommend that CMS continue to utilize the information contained in this paper in the context of first line coverage and when applying CED for wound care items and services.

That being said, we have concerns that the Agency might use CED as a first-line coverage mechanism for emerging or existing technologies; we urge CMS to continue its long-standing practice of allowing coverage at the local contractor level, and then considering alternative policies (including CED) when there is a reason to question the reasonableness and necessity of coverage under Social Security Act § 1862(a)(1)(A).

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In addition, we have the following concerns with the draft guidance:

1. CMS has noted that "there is a potential period of non-coverage between the end of the study and the agency's review of the scientific results". The Alliance requests that CMS continue to cover the item or service while the evidence is being reviewed and only if CMS determines the evidence to be insufficient or not satisfactory, to issue a non-coverage for the item or service. This will allow for more continuity of care – which benefits the patient. Therefore, the Alliance recommends that CMS continue to cover the item or service until CMS has reviewed the evidence and a decision has been issued.
2. We request further clarification about CED at the local contractor level. The Alliance recommends that CED be limited to national coverage decisions rather than at the local level due to the potential for duplicative and inconsistent evidence requirements across the various jurisdictions.
3. The Alliance also noted in its paper, "Consensus Principles for Wound Care Research Obtained Using a Delphi Process," issues in regards to study design. We stated that some patient populations – such as those patients that have diabetic foot ulcers, venous stasis ulcers among others – present unique challenges to the conduct of randomized trials, and other study designs may be more appropriate to achieve the desired result. We note that the revised CED guidance document does not address the study designs that can be used for CED studies (e.g., randomized controlled trials, observational studies) except in the context of closing the coverage gap between when a CED study ends and the evaluation of that study. In addition, the draft guidance document does not discuss expectations with respect to clinical outcomes. As CMS works to finalize the guidance document, the Agency should consider including a discussion of evidentiary expectations, noting that while randomized controlled trials represent one type of evidence that would be acceptable, other study designs may be also be acceptable and appropriate to generate evidence that addresses the clinical questions bearing on a coverage determination. In our view, there is a role for observational studies, the use of powerful, "real-life" data sets, and registries in the CED process.

With respect to clinical outcomes, CMS should consider discussing in its guidance document both intermediate outcomes associated with a procedure (e.g., 30-90 days) and longer-term outcomes (beyond 90 days), as well as quality of life and functional status, which are important considerations beyond mortality.

We appreciate the opportunity to comment on this guidance document. If you need more information or have any questions, please do not hesitate to contact me. The Alliance would be happy to serve as a resource to CMS.

Sincerely,

Marcia Nusgart R.Ph.
Executive Director