July 24, 2008

Michael O. Leavitt
Secretary
Department of Health and Human Services (HHS)
Room 615F, Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

RE: DMEPOS Provisions in the Medicare Improvements for Patients and Providers Act of 2008 (P.L. 110-275)

Dear Secretary Leavitt:

As you are aware, Public Law No. 110-275, also known as the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), became law on July 15, 2008 with several provisions subject to a retroactive June 30, 2008 effective date. These provisions affect the administration of Medicare's durable medical equipment, orthotics, prosthetics, and supplies (DMEPOS) program. On behalf of the undersigned organizations representing physicians and licensed health care professionals integrally involved in the delivery of DMEPOS, we specifically inquire regarding HHS and the Centers for Medicare and Medicaid Services (CMS) plan for implementing MIPPA Section 154(b) which improves the overall DMEPOS quality standards and accreditation process under the program as previously articulated in 42 U.S.C. 1395(m)(a)(20).

I. The Secretary Received Expanded Authority with the Passage of MIPPA Section 154(b)

Under previous law, the Secretary was required by 42 U.S.C. 1395(m)(a)(20)(A) to "establish and implement quality standards . . . to be applied by recognized independent accreditation organizations." We have repeatedly submitted to CMS staff that the accreditation financial and administrative burden on physicians and licensed health care professionals will prevent many of them from dispensing necessary DMEPOS items at the point of treatment, thus reducing patient access to items essential to quality medical care.

It is in this context that the undersigned organizations believe the language in Section 154(b) expands the Secretary's authority to address these patient access concerns and has the potential to assure greater access to high quality and necessary DMEPOS at the point of care. MIPPA Section 154(b) amends 42 U.S.C. 1395(m)(a)(20)(E) by adding the following provisions:

> (ii) in applying such standards and the accreditation requirement . . . with respect to eligible professionals (as defined in section 1848(k)(3)(B)), and including such other persons, such as orthotists and prosthetists, as specific by the Secretary, furnishing such items and services-
>
> (I) such standards and accreditation requirement ***shall not apply*** to such professionals and persons ***unless*** the Secretary determines that the standards being applied are designed specifically to be applied to such professionals and persons; and
>
> (II) the Secretary ***may exempt*** such professionals and persons from such standards and requirement ***if*** the Secretary determines that licensing, accreditation, or other mandatory quality requirements apply to such professionals and persons with respect to the furnishing of such items and services.

[*Emphasis Added*].

Given this provision ***we request the Secretary of HHS to exercise the newly expanded authority to exempt physicians and licensed health care professionals from the quality standards and accreditation requirement considering the licensing, accreditation, and other quality requirements that physicians and licensed health professionals must meet.***

Physicians and licensed health professionals furnish the full range of Medicare-covered services and items pursuant to State law and licensure requirements. In addition, our members must meet additional regulatory requirements to enroll as a Medicare Part B provider, which ensure that physicians and licensed health professionals are legitimately educated and credentialed. In addition to state and Medicare regulation, we also believe that professional credentialing and training processes for physicians and licensed health professionals provide the necessary safeguards in this area.

II. Physicians and Licensed Health Care Professionals Need Guidance on Agency Transition Plan While Making Determination Regarding Application and Design of Quality Standards

As mentioned above, MIPPA Section 154(b) states that physicians and licensed health professionals *shall not* be subjected to the quality standards and accreditation process

unless the Secretary determines that the standards and process are applied to and specifically designed for physicians and licensed health care professionals.

Throughout the development process, we have become increasingly concerned that the quality standards and accreditation process are designed to address concerns regarding the provision of DMEPOS by commercial DMEPOS suppliers. Physicians and licensed health professionals are not similarly situated to commercial DMEPOS suppliers in that physicians and licensed health professionals provide DMEPOS in order to address a patient's condition *during* the patient visit. Therefore, the application of the quality standards and accreditation process to physicians and licensed health care professionals should not be the same as commercial DMEPOS suppliers; yet, despite numerous letters to and meetings with CMS staff, no changes have been made.

MIPPA established that "the Secretary shall require suppliers . . . ***on or after*** October 1, 2009 . . . to have submitted to the Secretary evidence of accreditation." [*Emphasis added*.]. CMS currently requires that DMEPOS suppliers submitting enrollment applications after March 1, 2008 must be accredited. This includes physicians and licensed health care professionals, many of whom are only seeking supplier numbers for new locations, not because they are "new suppliers." Therefore, ***the undersigned organizations request that the Secretary exempt physicians and licensed health care professionals from DMEPOS accreditation deadlines and acknowledge that the deadline for suppliers, including "new suppliers," who remain subject to accreditation is October 1, 2009 given*:**

- ***Clear Congressional concern about how these standards and requirements are being applied to physicians and licensed health care professionals;***
- ***The fact that the only accreditation deadline referenced in the law is October 1, 2009;***
- ***The time needed for the Secretary to make the determination required under MIPPA Section 154(b)(1)(A) regarding the application to and design of the standards and accreditation requirements for physicians and licensed health care professionals; and***
- ***That MIPPA delayed the implementation of the DMEPOS competitive bidding program, therefore giving HHS and CMS greater flexibility to implement the newly revised quality standard and accreditation requirements under 42 U.S.C. 1395(m)(a)(20).***

The undersigned organizations appreciate your attention to this issue. In addition, we pledge our assistance in providing necessary documentation regarding the licensing, accreditation, and other mandatory quality requirements that our members currently meet. Our organizations are committed to the safety of and access to medical services and items beneficiaries receive in the Medicare program. The ability of physicians and licensed health care professionals to address a patient's condition *during* the patient visit and to

ensure that the patient has received the appropriate DMEPOS with proper instruction on its use and application is integral to the quality and efficiency of patient care. We believe that the changes requested in this letter will give patients access to that level of care.

For questions or more information, please contact Bob Jasak at the American Association of Orthopaedic Surgeons at (202) 546-4430 or jasak@aaos.org or Harry Goldsmith, DPM at the American Podiatric Medical Association at (562) 809-9605 or hgoldsmith@apma.org.

Sincerely,

American Academy of Ophthalmology
American Association of Orthopaedic Surgeons
American Medical Association
American Optometric Association
American Occupational Therapy Association
American Podiatric Medical Association
American Physical Therapy Association
Medical Group Management Association

CC: Kerry Weems, Administrator (Acting), CMS
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