



August 30, 2011

Donald M. Berwick, MD, MPP  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1577-P  
P.O. Box 8010  
Baltimore, MD 21244-8010

**Re: ITEM Coalition Comments Regarding the Proposed Rule to Add a 3-year Minimum Lifetime Requirement to the Durable Medical Equipment Definition [CMS-1577-P]**

Dear Dr. Berwick:

The Independence Through Enhancement of Medicare and Medicaid (ITEM) Coalition appreciates the opportunity to comment on the proposed rule regarding the addition of a 3-year minimum lifetime requirement to the Durable Medical Equipment (DME) definition proposed in the July 8, 2011 Federal Register (76 Fed. Reg. 40,498). We are submitting comments to provide you with the ITEM Coalition's perspective on this proposed rule, which we fear has the potential to limit access in the future to the DME benefit for individuals with disabilities and chronic conditions.

The ITEM Coalition is a consumer-led coalition of disability-related organizations with the goal of improving access to assistive devices, technologies and related services for individuals with disabilities of all ages. We believe individuals with disabilities and chronic conditions should have access to specialized assistive devices to ensure quality care and the greatest function and independence possible for the individual. Although it is unclear if CMS intends to impact mobility devices and other assistive technology that allow individuals with disabilities to remain independent and restore or maintain function, we fear that the proposed requirement will unnecessarily complicate the DME benefit category determination process and restrict access to future devices that would be considered durable under current standards.

DME already has a 5-year reasonable useful lifetime (RUL) requirement that protects the agency from overpayments for replacement devices. In addition, equipment under the DME benefit is already well-defined by the following qualities:

- Can withstand repeated use; [i.e., the definition of "durable"]
- Is primarily and customarily used to serve a medical purpose;

- Generally is not useful to an individual in the absence of an illness or injury; and
- Is appropriate for use in the home.

Chapter 15 of the Medicare Benefits Policy Manual states that items satisfy the durability criteria if those items “can withstand repeated use, that is, the type of item which could normally be rented” and excludes items that are “of an expendable nature.” We believe these parameters adequately define the term “durable” in a way that is easily understood by manufactures and regulators.

The process of determining whether a device meets the 3-year requirement will likely delay or discourage new devices entering into the market at a time when we need to encourage advanced technology to improve the health of many individuals with chronic conditions and disabilities. In addition, a 3-year requirement to define the benefit category may be easily confused in the future with a requirement that the beneficiary must need the device for at least three years. There are many instances where the changing needs of the beneficiary would result in the use of DME for a time period that may not reach three years, but that does not mean the device should not be considered “durable,” or capable of withstanding repeated use and, therefore, covered DME.

Since the proposed rule does not apply to existing devices, these devices will have a significant advantage over new devices that enter the market. Manufacturers may develop “new” devices that are improved versions of existing devices, yet they would be subject to stricter standards than the older devices and potentially excluded from coverage under the DME benefit altogether. In addition, the new criteria would cause administrative complication and confusion among suppliers and beneficiaries when a new device expected to have a lifetime of three years proves to have, on average, a shorter lifetime. These devices would meet the current definition of durable, however, making this proposal a new, more restricted standard for DME coverage under Medicaid.

The ITEM Coalition finds it difficult to pinpoint the potential benefits gained through the proposed 3-year criteria, though clearly we are aware of the potential unintended consequences for individuals with disabilities and chronic conditions. Therefore, we urge you to reconsider adding the 3-year minimum limit to the DME definition and rely on the current DME definition in future DME benefit category determinations.

If you have any questions, please feel free to contact Peter Thomas, ITEM Coalition Counsel, at 202-466-6550.

Sincerely,

ADAP Advocacy Association  
Alpha One  
American Academy of Physical Medicine and Rehabilitation  
American Association for Homecare  
American Association for People with Disabilities  
American Foundation for the Blind  
American Medical Rehabilitation Providers Association

American Music Therapy Association  
American Occupational Therapy Association  
American Speech-Language-Hearing Association  
Amputee Coalition of America  
Association of Assistive Technology Act Programs  
Brain Injury Association of America  
Blinded Veterans Association  
Christopher & Dana Reeve Foundation  
Easter Seals  
Helen Keller National Center  
National Association for the Advancement of Orthotics and Prosthetics  
National Council on Independent Living  
National Disability Rights Network  
National Family Caregivers Association  
Paralyzed Veterans of America  
Rehabilitation Engineering and Assistive Technology Society of North America  
Spina Bifida Association  
The Arc of the United States  
United Cerebral Palsy