

**Congress of the United States**  
**Washington, DC 20515**

May 4, 2012

The Honorable Kathleen Sebelius  
Secretary  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Re: Definition of “Durable” in the Final Rule for Medicare Program: Changes to the  
End-Stage Renal Disease Prospective Payment System for CY 2012

Dear Secretary Sebelius:

We are writing to follow up on our previous correspondence and express our views regarding the guidance that will be issued by the Centers for Medicare & Medicaid Services (“CMS”) regarding the three-year minimum lifetime requirement (“MLR”) included in the recently revised definition of durable medical equipment (“DME”).<sup>1</sup> In order to preserve a climate of innovation, we want to ensure that CMS’s guidance clarifies that DME products introduced on or after January 1, 2012 are grandfathered, provided they maintain and/or build upon existing DME core clinical technology.

The final rule that set forth the revised definition of DME included a “grandfathering provision” that provided that the MLR would only be applied prospectively to products classified as DME after January 1, 2012. The final rule also stated that, “[t]o the extent that a modified product is not a new product (including an item that has been upgraded), the 3-year MLR will not be applicable.”<sup>2</sup> The final rule did not, however, provide any detail regarding the extent of changes that could be made to an existing DME product before such a “modified” or “upgraded” product would no longer be considered “new.” CMS indicated that it would be issuing guidance to provide additional clarification regarding the scope of the grandfathering provision.

We are encouraged by CMS’s decision to issue guidance clarifying the final rule’s grandfathering provision and are hopeful that this guidance will ensure that critical modified or upgraded medical devices from the DME category are subject to the grandfathering provision, including products that maintain and/or build upon the core clinical technology of existing DME

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<sup>1</sup> 76 Fed. Reg. 70228 (Nov. 10, 2011).

<sup>2</sup> 76 Fed. Reg. at 70290

products. We believe that this approach will preserve the incentive to innovate and develop new cost-effective technologies that will more rapidly improve the health of Medicare beneficiaries.

Thank you for your consideration.

Sincerely,



Marsha Blackburn  
Member of Congress



Brian Bilbray  
Member of Congress



Diane Black  
Member of Congress



Vern Buchanan  
Member of Congress



Michael Burgess, MD  
Member of Congress



Renee Ellmers  
Member of Congress



Gregg Harper  
Member of Congress



Robert Latta  
Member of Congress



Sue Myrick  
Member of Congress



John Sullivan  
Member of Congress