United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

June 8, 2012

Marilyn Tavenner
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert Humphrey Building – Room 445G
200 Independence Ave SW
Washington, DC 20201

Dear Acting Administrator Tavenner:

We write to request that the Centers for Medicare & Medicaid Services (CMS) provide additional guidance on the Final Rule for Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies, published in the Federal Register on November 10, 2011. Specifically, we request clarification that the revised, restrictive definition of DME (i.e. 3-year minimum lifetime requirement for all DME products versus the former flexible standard) will only apply to new products introduced on the market on or after January 1, 2012.

The Final Rule revised the definition of DME to require that all products classified as DME have a minimum lifetime of at least 3 years. It included a grandfathering provision that stipulated the revised definition would only be applied prospectively to products classified as DME after January 1, 2012. The rule further stated that modifications or upgrades to existing products that were not deemed to result in new products would also be exempt from the revised definition. However, the final rule in November did not 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 be considered "new." In response to comments submitted on the rule, CMS indicated that it would consider issuing guidance to provide additional clarification regarding the scope of the grandfathering provision.

We encourage CMS to release this additional guidance. We also encourage CMS to ensure that any additional guidance does not narrowly define the grandfathering provision. CMS should make sure that any modification, upgrade, redesign, improvement or new indication of an existing DME product that maintains the product's core clinical technology should be eligible for reimbursement under the DME benefit category and under the former, flexible definition of "durable." Thus, the link to existing DME products for the purposes of the grandfathering provision in the final rule should be the underlying technology used.

We believe that providing this clarifying guidance will preserve the incentive to innovate and develop cost-effective technologies that will continue to improve the health of Medicare beneficiaries.

Thank you for assistance and we look forward to working with you on this issue.

Sincerely,