

United States Senate
WASHINGTON, DC

January 25, 2013

Via Electronic Submission

Ms. Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201

Dear Acting Administrator Tavenner:

We write to follow up on our previous correspondence regarding implementation of the three-year minimum lifetime requirement for items covered under the Medicare Part B category durable medical equipment (DME). Specifically, we want to ensure that the upcoming CMS guidance clarifies that modified or upgraded DME products that maintain their existing core clinical technology are subject to the grandfathering provision in the Final Rule.

We appreciate your response to our earlier letters, confirming that the three-year minimum lifetime requirement "will not apply . . . to items covered as DME before 2012" and that CMS will be providing more detailed instructions on the implementation of this requirement "in the near future." Your letter also stated that the grandfathering provision would apply to "*technically refined*" items, but not "*significantly redesigned*" products. However, we are concerned that a narrowly defined grandfathering provision could create a disincentive for manufacturers to make minor product improvements or develop new and innovative indications for their existing technologies because of the potential to lose Medicare reimbursement.

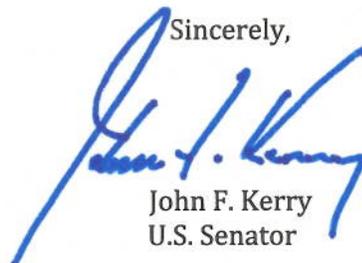
To promote innovation of medically necessary medical technologies, we believe upcoming guidance should ensure that any modification, upgrade, redesign, improvement or new indication of an existing DME item that maintains its core clinical technology should be eligible for reimbursement under the DME benefit category. This approach to the grandfathering provision would preserve the incentive to innovate and develop cost-effective technologies that will continue to improve the health of Medicare beneficiaries.

We appreciate your continued assistance on this matter and look forward to your prompt response.

Sincerely,



Tom Coburn, M.D.
U.S. Senator



John F. Kerry
U.S. Senator



Richard Burr
U.S. Senator