

MAX BAUCUS, MONTANA, CHAIRMAN

JOHN D. ROCKEFELLER IV, WEST VIRGINIA
KENT CONRAD, NORTH DAKOTA
JEFF BINGAMAN, NEW MEXICO
JOHN F. KERRY, MASSACHUSETTS
RON WYDEN, OREGON
CHARLES E. SCHUMER, NEW YORK
DEBBIE STABENOW, MICHIGAN
MARIA CANTWELL, WASHINGTON
BILL NELSON, FLORIDA
ROBERT MENENDEZ, NEW JERSEY
THOMAS R. CARPER, DELAWARE
BENJAMIN L. CARDIN, MARYLAND

ORRIN G. HATCH, UTAH
CHUCK GRASSLEY, IOWA
OLYMPIA J. SNOWE, MAINE
JON KYL, ARIZONA
MIKE CRAPO, IDAHO
PAT ROBERTS, KANSAS
MICHAEL B. ENZI, WYOMING
JOHN CORNYN, TEXAS
TOM COBURN, OKLAHOMA
JOHN THUNE, SOUTH DAKOTA
RICHARD BURR, NORTH CAROLINA

United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

RUSSELL SULLIVAN, STAFF DIRECTOR
CHRIS CAMPBELL, REPUBLICAN STAFF DIRECTOR

November 8, 2011

Donald M. Berwick, MD, MPP
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building – Room 445G
200 Independence Avenue SW
Washington, DC 20201

Re: Definition of “durable” in the End-Stage Renal Disease Prospective Payment System for CY 2012 Final Rule

Dear Dr. Berwick:

As you know, the Centers for Medicare and Medicaid Services (CMS) has been given discretion to determine what constitutes “durable” under the benefit category of Durable Medical Equipment in Part B. Under current Medicare guidance, DME products must be able to withstand “repeated use.” No specific “length of life” standard has previously been utilized by CMS, partially in recognition of the fact that the existing 17 types of DME are different and possess varying “lengths of life.”

We are writing to express our strong opposition to the new definition of “durable” recently included in the End-Stage Renal Disease Prospective Payment System for CY 2012 Final Rule. Under the rule, CMS has determined that newly approved durable medical equipment (“DME”) will have to demonstrate its use during a lifetime of at least three years in order to be eligible for reimbursement under Part B of the Medicare program.

While we understand that CMS receives many requests for coverage of new products and has a legitimate role to ensure that the program pays for quality products, this arbitrary threshold is not the appropriate metric for many products. Furthermore, the use of the End-Stage Renal Disease Prospective Payment System for CY 2012 Proposed Rule to establish a public record for this policy change is inconsistent with the Administration’s stated goal of transparency in decision-making. If CMS is considering redefining “durable” we strongly suggest the agency engage stakeholders and suppliers in a fully transparent and open process.

The revised definition of DME will discourage the development of new DME items and enhancements to existing DME items that may fail to meet the proposed three-year minimum lifetime criterion. We are concerned this additional regulatory threshold will hurt medical innovation, increase development costs for the companies investing in innovative products,

discourage hiring in industry, and have the effect of denying Medicare beneficiaries access to important treatments. A number of medical device manufacturers and other interested parties have approached our offices expressing concern and have submitted comments opposing the proposal because of its negative implications on innovation and patient access.

We urge CMS to reconsider the new three-year threshold. We should not be arbitrarily increasing regulatory burdens on our nation's medical technology companies. This policy will stifle innovation where a promise of lower costs can come from technological advances and new market entrants.

Sincerely,

Quinn Hatch

Tom Kelly

John Cornyn

Mike Crapo

Tom Coburn

[Signature]

Pat Roberts

Chuck Grassley

Mike B. Egan

Olympia Snowe

John Thune