Congress of the United States
Washington, DC 20515

June 10, 2014

Daniel R. Levinson
Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue, SW
Washington, DC 20201

Dear Inspector General Levinson:

We are writing to request that the Office of the Inspector General (OIG) conduct a study of the impact on senior health of the Medicare Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) competitive bidding program and the National Mail Order Program for diabetic testing supplies, as implemented in the Round 1 Recompete, Round 2, and the Round 1 Rebid.

We make this request because the lack of transparency in the competitive bidding program from its inception and the limits of the studies and evaluations done to this point make it impossible to judge the impact of the program on the health and well-being of the particularly vulnerable group of Medicare beneficiaries for whom this Medicare benefit was specifically developed. They are beneficiaries with severe disabilities and/or multiple chronic illnesses who need DMEPOS products that enable them to care for themselves at home and avoid costly use of hospitals, emergency rooms, and nursing homes. Many are fragile and unable to have an effective voice in describing how the changed payment policy for DMEPOS has adversely impacted their health.

At this point there is abundant and concerning evidence of arbitrary manipulations of the price-setting system that directly limits seniors' access to care and technology, an inattention to growing contractor non-compliance that is significantly impacting the quality and choice of technologies and services, and inadequate efforts to measure health impacts on beneficiaries.

Members of Congress need a much better understanding of the impact this program has on our seniors. It would be a grave error if the bidding structure developed by the Centers for Medicare &Medicaid Services (CMS) severely reduces access to home support services just as Congress seeks to enhance care quality through greater coordination of care, especially for patients with complex and multiple chronic conditions. We believe competitive bidding can help Medicare to improve the quality and efficiency of care, but it has to be done in a way that assures both improved care outcomes and system efficiency. We ask your assistance in investigating and reporting on the following concerns:

I. The process by which CMS develops the composite price from which the median price is derived, as it directly impacts seniors' access to products and services.

- How was the capacity of the individual supplier established? How was the future capacity of each supplier determined? If a bidder's future capacity exceeded current capacity, precisely what criteria were relied on to evaluate a bidder's ability to support any expansion of their business? Were the criteria consistent with small business administration's criteria for business expansion and that of other government competitive bidding systems?

- Because supplier performance is key to senior access, and because significant concerns have been raised about winning bidders ability to perform in accord with their contract, we request the OIG to examine the winning bids of the attached companies to:

  1) Verify if they were licensed and certified in every competitive bidding area (CBA) for every product by the deadline in the Request for Bids;
  2) Document the financial resources relied upon by CMS to substantiate their ability to fulfill their expansion plans, in some cases more than 10,000% in a few months;
  3) Verify that each supplied all products in all categories in all CBAs each won on the first day of their first contract year and have continued to do so, as specifically required by Medicare; and
  4) Report your findings and any abnormalities noted, such as no record available that a supplier made a specific bid for a specific code in a product category and CBA.

- To better understand the accuracy of the price setting process, for the Round 1 Rebid, Round 2, and the Round 1 Recompete, please report the de-identified array of winning bids for the two lead products in each category (defined as the two Healthcare Common Procedure Coding System (HCPCS) codes with the largest dollar claims in a year), the actual units allowed for each winning bidder for that HCPCS code for the preceding year, the future annual capacity attributed to each of these bidders for each of the two HCPCS codes and whether the median price was calculated correctly for those products. Please also calculate what the median price ***would have been*** if it was based on the bids of the actual contracted suppliers 6 months after the date of program implementation.

II. Enforcement of Contracted Supplier Obligations

- CMS directs bidders be very clear that all suppliers must supply all products in every category in every CBA that supplier won. Moreover, failure to supply is a breach of contract. As a result, please report for each CBA and each product

category for the Round 1 Rebid, Round 2, and Round 1 Recompete the following information:

a) How many suppliers accepted and signed contracts;
b) How many of the contracted suppliers supplied all products in each category and in each CBA they won during the program's first 6 months;
c) How many supplied only a nominal amount (defined as 10% or less in the first six months of the annual capacity for which they bid);
d) The number of these total suppliers that were out of area (defined as more than 100 miles from the city center);
e) The number of out-of-area suppliers that either did not supply during the first 6 months following implementation or supplied a nominal amount as defined above;
f) The number of suppliers accepting contracts for categories of products for which they had no previous supplier experience in the category as a whole;
g) The number of suppliers of the total number of suppliers in the General Home Equipment and related supplies category and the External Infusion Pump and Supplies category in the Round 1 Recompete who had never supplied all the products in the category and whether claims data now shows them supplying all such products. This will help us understand how the grouping of disparate products has affected beneficiary access to included products; and
h) The number of suppliers withdrawing or excluded from the program, by product category and CBA, the reasons for withdrawal or exclusion, any actions taken to replace these suppliers, and the median price as recalculated at the time new suppliers were brought into the program.

- Please lay out in detail CMS' enforcement policy for supplier performance, its structure, and evidence of its systematic implementation and effectiveness. In addition, please address the following specific enforcement challenges:

  a) How CMS enforces the mandated 50% rule and whether CMS has authority to apply the rule on a contractual term basis, the anti-switching rule, and other regulatory requirements governing the provision of diabetic supplies, as successful self-care both deeply effects patient well-being and Medicare costs;
  b) Contractor compliance with nondiscrimination requirements under which a supplier is required to furnish beneficiaries with the same items that it would furnish to other customers;
  c) Differences between the brands of items listed on bids submitted by suppliers selected as contract suppliers and those provided over time to beneficiaries by such suppliers;
  d) Differences in functionalities or therapeutic advantage of the items furnished to Medicare beneficiaries in CBAs and those used by Medicare beneficiaries in non-CBAs;
  e) Differences between the average rental periods for various items in CBAs vs. non-CBAs;

f) Changes in the level and kind of services being offered to patients in conjunction with advanced technologies such as negative pressure wound therapy (NPWT), and the extent to which accreditation agencies use interpretive guideline standards established for NPWT to determine supplier compliance with quality standards; and
g) Changes in products and treatment patterns of enteral nutrition patients residing in skilled nursing facilities, nursing facilities, and intermediate care facilities, and whether the use of new enteral nutrition suppliers has increased costs to facilities and the Medicare program.

This information is crucial because if suppliers don't provide products and services as required by their contracts, then seniors' access to the products prescribed by their physicians is compromised, especially for products that are among the more expensive in any given HCPCS code.

Not making available to beneficiaries all products in a category is a **breach of contract** according to CMS' own explanations of the program. In fact, CMS argues that binding bids are not needed in the program because of this requirement. We note, however, that CMS is not enforcing the requirement. For example, upon hearing that beneficiaries were having problems with access to TENS from winning suppliers for the new General Home Equipment category used in the Round 1 Recompete, a manufacturer of the devices contacted each of the winning suppliers in this category and found that only 44 percent of the suppliers were offering TENS to beneficiaries. This is a form of market failure as argued by Professor Charles Plott and associates at the California Institute of Technology in their independent evaluation of the structure and bidding methodology used by CMS for the program. (http://www.caltech.edu/content/caltech-research-shows-medicare-auction-w

IN SUM, STRONG OVERSIGHT OF SUPPLIER PERFORMANCE IS KEY TO PRESERVING ACCESS TO DMEPOS THAT SUPPORT SENIORS' MAINTAINING HEALTH IN THE HOME.

III. Evaluating the Health Impact on Beneficiaries

- Given GAO's comments that CMS' methodology for evaluating the program's impact on beneficiary health was inadequate (12-693, page 41 and thereafter), and given that in its new report, GAO made no independent evaluation of the program's impact on beneficiary health, please include the following:

  - Evaluate the methodological differences between CMS and GAO in their approach to measuring the impact of the program on senior health;

  - Examine the health impact on seniors who lost access to their DME through the program by examining a statistically valid number of beneficiaries who were receiving DME in 2010 but not in 2011 in each product category and each CBA in Round 1 Recompete and in Round 2 to find out if the beneficiary

no longer needed their products, became self-pay and did not submit claims to Medicare, went without suppliers regardless of the health impact, moved to a nursing home, are frequently hospitalized as a consequence, visit emergency rooms regularly for supplies, are managing in some other way, or have died. CMS has testified that they track only beneficiaries with current claims (within the last 120 days) -- that is, the people that are getting their prescriptions filled. The health impact on all seniors is the right measure of the program.

- Conduct a detailed medical review or audit of a sample of patients, comparing total Medicare spending for those beneficiaries who have received DMEPOS through winning contractors with beneficiaries not residing in those areas and receiving DMEPOS paid for under fee schedules, as well as quantifying differences in rates of utilization of other covered Medicare services.

- Explore the potential for the OIG to establish an appeals office to evaluate stakeholder concerns while the process is underway.

In sum, while we believe competitive bidding can reduce costs while maintaining beneficiary access to quality care, this hybrid program appears to be compromising seniors' health by reducing beneficiaries' access to the supportive technologies and care that enables them to maintain their independence. Without the information requested above, Members of Congress cannot responsibly assure the well-being of the seniors they represent or the sustainability of this extremely important program designed to support the quality care of Medicare beneficiaries in their homes cost effectively.

Sincerely,

Rep. Tom Price, MD

Rep. Bruce Braley

Rep. Tom Reed

Rep. Tammy Duckworth