



Mr. Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
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March 21, 2016

Dear Mr. Slavitt,

The National Volunteer Diabetes Leadership Council is writing to you today to urge that the Competitive Bidding Program for diabetes testing supplies be immediately suspended. On Friday March 18, *Diabetes Care*, the journal of the American Diabetes Association, published a scientific analysis that clearly demonstrates that patient harm has occurred as a result of the Competitive Bidding Program. This peer reviewed analysis was thoroughly vetted and scientifically reviewed prior to acceptance for publication. According to the article, patient access to supplies has been impacted, inpatient hospitalizations have increased, inpatient hospitalization costs have doubled and, most disturbingly, the analysis confirms an increase in mortality in the nine test markets studied. The program should be immediately suspended until CMS can affirmatively refute the data or make such changes to the program to avoid these intolerable consequences. A copy of the *Diabetes Care* article is attached.

The goal of competitive bidding was to reduce costs for both patients and the American tax payer and to ensure access to quality products and services; for diabetes testing supplies, the program has failed on both of its objectives.

This should not be a surprise. The Centers for Medicare and Medicaid Services has had a history of strong signals that there were issues in the marketplace concerning patients with diabetes and access to their testing supplies. For example, when the CBP was first rolled-out in test markets, the number of calls into CMS concerning diabetes supplies was greater than in all other categories in the competitive bidding program combined.

Surveys conducted by the American Association of Diabetes Educators (AADE), in test markets and subsequently when the program was expanded nationally, clearly demonstrated that access to the products specifically prescribed to patients was significantly disrupted. Further, patient choice was restricted and many suppliers failed to meet the "50% Rule" as passed by Congress to ensure patient access to high quality testing supplies. AADE, based on its direct contact with patients they serve, has expressed its concern about the implications of the disruption of access to supplies and the consequences of such disruption.

In 2015, at both the American Association of Clinical Endocrinologist (AACE) and the American Diabetes Association (ADA) Scientific Sessions, the National Minority Quality Forum (NMQF) presented data that demonstrated the negative association between restricted access to SMBG supplies and the correlation to increased mortality in CBP test markets. Still, despite the mounting evidence that the program is causing harm and costing money, CMS has yet to act. The "silver lining" in the NMQF data is that when patients have access to diabetes testing



supplies and adhere to their prescribed self-management protocols, mortality is diminished and costs reduced.

The data analyzed in the *Diabetes Care* article is based only on the first nine test markets. We do not know, nor can CMS quantify, the unintended consequences that have resulted from the national roll-out of this well-intentioned but poorly managed program. The implications of the test-market data are staggering, yet the program continues.

There are ethical rules that guide patient interventions. In a clinical trial, for example, when patient harm is detected, the trial must be suspended to allow investigators to evaluate what happened. Until the cause is determined and understood, the trial is stopped. Based on this data and analysis, continuing this program would be unethical. We strongly urge you to suspend the Competitive Bidding Program for diabetes testing supplies to prevent any further patient harm.

Sincerely,

The leadership of the National Diabetes Volunteer Leadership Council

Larry Ellingson, R. Ph., NDVLC Chair, ADA Chair of the Board, 2004-2005

Larry Smith, NDVLC President, ADA Chair of the Board, 2005-2006

George Huntley, NDVLC Treasurer, ADA Chair of the Board, 2009

Stewart Perry, NDVLC Secretary, ADA Chair of the Board, 2008

John Griffin, Esq., ADA Chair of the Board, 2011

Hunter Limbaugh, ADA Chair of the Board, 2012

Stan Panasewicz, ADA Treasurer, 2003-2006

ABOUT THE NATIONAL DIABETES VOLUNTEER LEADERSHIP COUNCIL

The National Diabetes Volunteer Leadership Council (NDVLC) is an organization comprised of former chairs of the board and past officers of the American Diabetes Association who are committed to ensuring the well-being of diabetes patients across the country. NDVLC is committed to improving the quality of life for all.