APPENDIX 1-A

Background

Diabetes is a lifelong and progressive disease. Absent good self-care, its progression damages the vascular system, nerves and various organs, too often leading to costly Emergency and inpatient events. Self-monitoring of blood glucose helps people with diabetes better manage this chronic disease. Though less than half of diabetic Medicare beneficiaries acquire and use self-monitoring equipment, those who do so are making an effort to better manage their health or to calculate insulin dosing. It is a fragile population, averaging some 3,500 annual inpatient days per thousand beneficiaries, more than four times the average inpatient days of non-diabetics.

As mandated in the 2003 Medicare Modernization Act, and later amended in the Medicare Improvements for Patients and Providers Act of 2008, CMS implemented a "Competitive Bidding Program" for Durable Medical Equipment (DME). The agency eventually elected to include mail order DTS in this program, initially in the nine cities chosen for the Round 1 Re-Bid (1/1/11 through 12/31/12), and then nationwide in Round 2 (7/1/13 through 6/30/16) and the Round 2 Recompete (7/1/16 through 12/31/18).

2010: The nation's community of scientists and economists with expertise in the practice of auctions becomes aware of the design structure for this program. 167 from the leading institutions of our country write Congress urging an immediate fix to avoid certain harm (Appendix 1-B).

2011: CMS implements the 9-city Round 1, eliminating 480 (96%) of the 500 DTS suppliers in these markets, retaining a mere 20 (4%). More than 80% of beneficiaries using DTS must seek a new supplier or find a retail location if they are ambulatory. Reimbursement is reduced from 55% and 60%, depending on the city. This lower reimbursement is also applied to retail distribution. The expert community writes "with dismay" to the White House and HHS, now 244 strong and including four Nobel Laureates, to "direct CMS to proceed otherwise" using the best practice and the best science (Appendix 1-C)

2013: For the nationwide Round 2 expansion, the 900-plus active suppliers were reduced to 19, a 98% reduction. The reimbursement was further slashed with a 72% reduction to mail order and retail. At the end of the 36-month contract period, only 12 of the original 19 suppliers were still active and supplying beneficiaries.

2015: The National Minority Quality Forum (NMQF) undertakes a research effort to insure there have been no unintended disparities in access or health outcomes in the affected population.

2016: The American Diabetes Association publishes the NMQF research in the April issue of its scientific journal *Diabetes Care* (Appendix 1-D). The findings are startling: A ***doubling*** in the number of compliant insulin-dependent beneficiaries becoming ***non-compliant*** in the 9 cities. The rest of the country was unchanged from the historical pattern. This non-compliant population has a ***46% higher*** rate of inpatient admissions. There is an increase in mortality in the Round 1 cities.

2016: In July, the Round 2 Recompete expansion further contracts to a mere 9 suppliers (just 1% of the original base), with the reimbursement now representing a 78% reduction from the fee schedule. Of these 9, at least one has ceased operations and the largest, with over 50% of the remaining market, is subject to CMS attempts to exclude it from Medicare.

2016: In October, GAO Report 16-570 reports a "12% decrease between 2012 and 2014 in the number of beneficiaries receiving at least one diabetes testing supply it through ***any*** acquisition method." This translates to some 400,000 diabetic beneficiaries no longer monitoring blood glucose, another signal of severe disruption in access and utilization of this necessary health monitoring tool.