

Briefing Memorandum

TO: The Honorable Tom Price, M.D. Secretary, Health and Human Services The Honorable Seema Verma Administrator, Centers for Medicare and Medicaid Services

FROM: The Honorable Nancy L. Johnson
Gary Puckrein, PhD
Brett Katzman, PhD
Thomas J. Milam

RE: Crisis in the Medicare diabetic population

DATE: 13 April 2017

Issue

Immediate removal of the mail order diabetes test supply (DTS) product category from the DME Competitive Bidding Program (CBP) and a restructuring of the CBP for DTS are ***urgently needed:***

- Significant and harmful disruption for access to DTS has occurred.
- Research documents a coterminous increase in Emergency Department visits and inpatient utilization and costs for Medicare’s insulin-dependent diabetics and an increase in mortality.
- The proof of harm and billions in increased costs is clear and cannot be contested.
- Beneficiary safety has been compromised. It is a time of crisis for Medicare’s diabetics.

Background (Appendices 1-A, B, C and D)

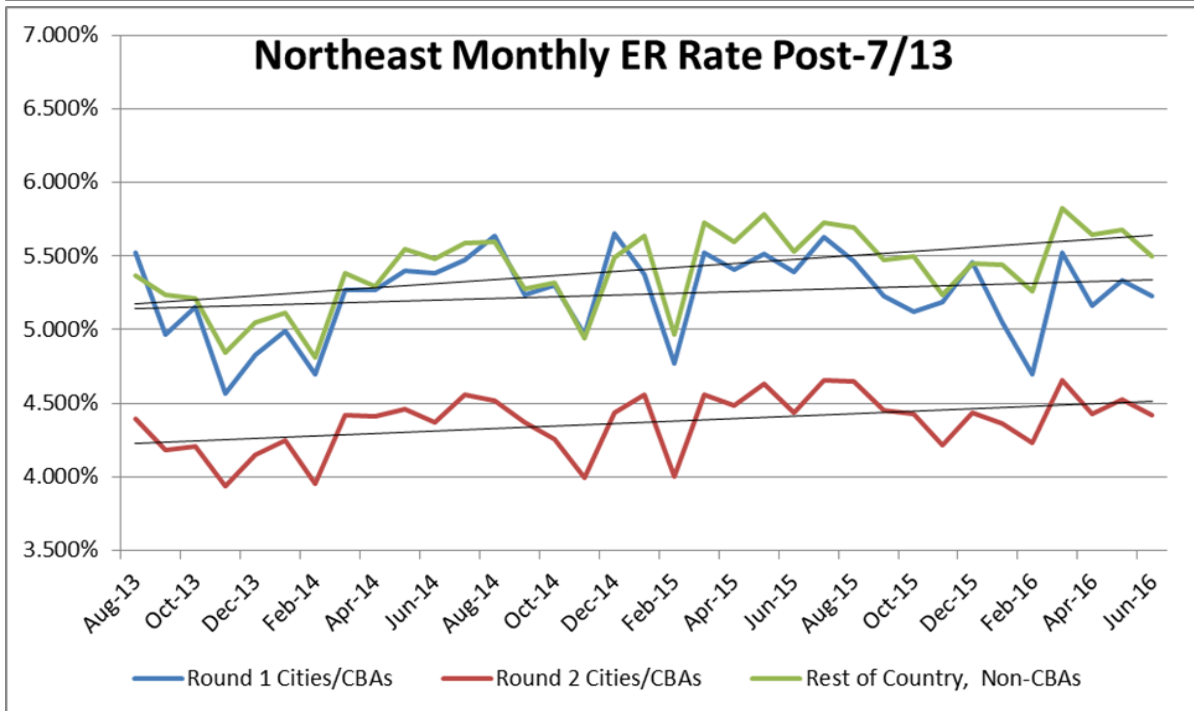
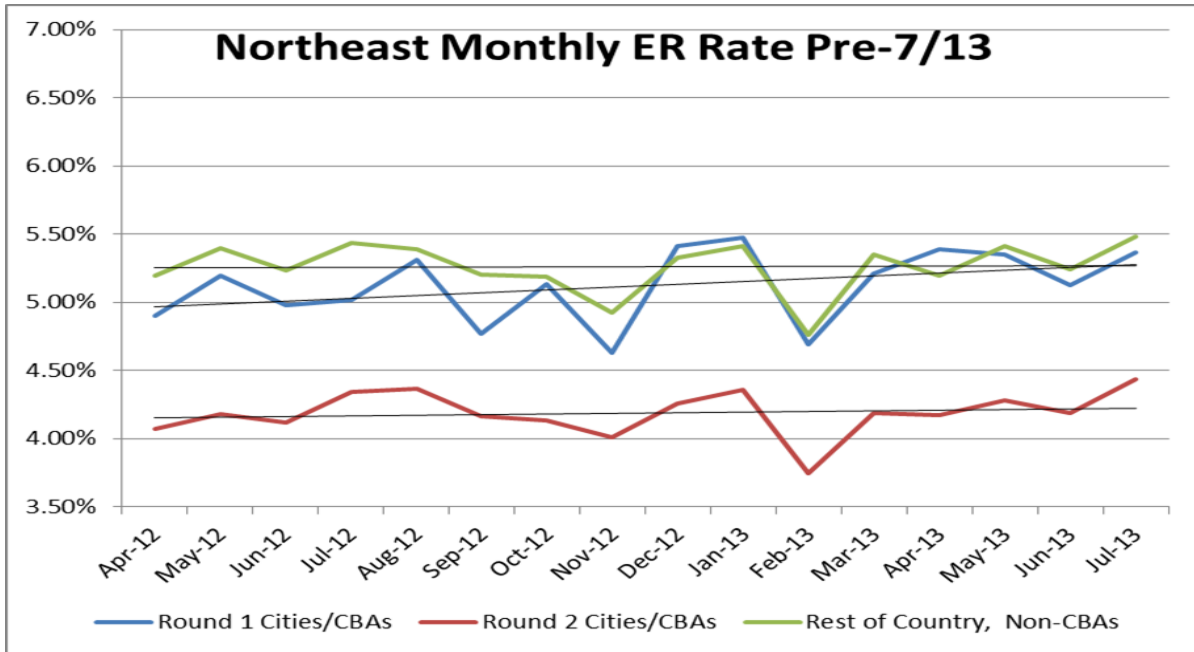
Summary: More than NINE MILLION fee-for-service beneficiaries live with diagnosed diabetes. This is a fragile and high utilization population. “Small changes” can mean hundreds of thousands of beneficiaries impacted with adverse health events.

The Medicare CBP reduced the diabetes mail order supplier community a **breathtaking 99%**. Medicare reimbursement for DTS has been **slashed 72%**. CMS has a system for monitoring beneficiary health status. The agency’s most recent statement: “The data have not indicated any negative changes in beneficiary health outcomes in any group” (Appendix 2). This is a misleading and inaccurate statement, as CMS’ own data now documents.

Current Status

The CMS Health Status Monitoring data documents a notable increase in Emergency visits

- Prior to implementation of the National Mail Order program for DTS, the rates of Emergency visits for beneficiaries with diabetes was generally flat, with the EXCEPTION of some areas subject to Round 1 of the CBP (see Appendix 3), where the rates were INCREASING to a “new normal” higher rate of Emergency visits. An example from Appendix 3 for Region A/Northeast:



- Coterminous with the July 2013 implementation of the National Round 2 for DTS, the annual rate of Emergency visits for Medicare diabetic population has steadily increased, as above, in all four Regions (Appendix 4).

- What can be viewed as “small changes” monthly equal three to five percentage points annually. More than 9 MILLION beneficiaries have diabetes, which means BIG NUMBERS of increased emergency visits and hospitalizations.
- An annualized four percentage point increase results in 350,000+ more emergency visits each year.
- These emergency visits translate to 160,000+ more annual inpatient stays – BILLIONS in costs.

AHRQ HCUPnet documents this big increase in emergency visits and inpatient stays

- The number of emergency visits by beneficiaries with diabetes INCREASED by nearly ONE MILLION combined for 2013 and 2014 following the nationwide implementation (Appendix 5).
- 47% of beneficiaries with diabetes with Emergency visits are admitted for inpatient stay.
- 75% of ALL inpatient discharges for beneficiaries with diabetes came from an emergency room visit with a hospital admit – a sharp increase from the pre-Round 2 national rate of 67%.
- With its high Medicare population, Florida EXPLODED in 2014 with a 13% INCREASE in Emergency visits by diabetic beneficiaries.
- The one million new Emergency visits results in 400,000-plus hospital admissions for 2013 and 2014 – BILLIONS in costs at \$15 - 20,000 per hospital stay.

Newly updated research by the NMQF again documents severe disruption (Appendix 6)

- NMQF followed 529,627 insulin-treated FFS beneficiaries from 2009 through 2013.
- NMQF found a 60% *increase* in non-compliant testing following the first 6 months of the national rollout for DTS (July through December 2013)

All data available signals serious issues may be or are associated with the continued use and expansion of the DME Competitive Bidding Program for Diabetes Testing Supplies.

Recommendations

1. Immediately Suspend the Competitive Bidding Program for DTS.

- A. Replace, using an Interim Final Rule, the current “competitively set” Single Payment Amounts for DTS with a temporary administratively determined reimbursement based on a budget neutral calculation that accounts for the savings derived from the CBP, but also the additional hospitalization and associated costs arising from implementing the nationwide CBP for DTS.
- B. Allow any willing qualified supplier to furnish DTS to immediately improve beneficiary access.
- C. Multiple professional organizations and patient advocates support this suspension (Appendix 7).
- D. Authority for the Secretary to act is clearly supported by legal analysis (Appendix 8).

2. Restructure the Competitive Bidding Program for DTS consistent with recommendations from the auction and market design experts.

- A. Contract with independent experts who have successful experience in government procurement programs (to be consistent with the recommendations in Appendices 1-B and 1-C).
- B. Incorporate and enforce all existing statutory requirements, including the “50% rule.”
- C. This concept enjoys broad stakeholder support.