COMMENTARY

Reevaluation of CMS' Competitive Bidding Program

Desmond Schatz[1] and William T. Cefalu[2]

Diabetes Care 2016;39:1078–1079 | DOI: 10.2337/dc16-0903

Given the ongoing epidemic and rising costs of diabetes in the U.S., it is critical that health care resources be allocated in both efficacious and cost-effective ways. Among Medicare beneficiaries, patients with diabetes consume >32% of total Medicare expenditures (1). In 2011, the Centers for Medicare & Medicaid Services (CMS) implemented competitive bidding for selected product categories in nine "test" markets. Among these products was diabetes testing supplies (2). The intent of the program was to lower costs without jeopardizing patient health. In 2012, CMS issued its report, stating that it had found "no disruption in access to needed supplies for Medicare beneficiaries" and that "there have been no negative health consequences to beneficiaries as a result of competitive bidding" (2). CMS has continued to make this claim. However, at least in our review of the issue, a recent study may suggest otherwise.

As reported by Puckrein et al. (3) in *Diabetes Care*, implementation of the Competitive Bidding Program in nine Medicare "test" markets appeared to cause significant disruption among Medicare beneficiaries in acquiring the necessary supplies for self-monitoring of blood glucose (SMBG) (3). The analysis included CMS records from 529,627 beneficiaries with insulin-treated diabetes, 65.9% of whom were treated with short- or rapid-acting insulin. This disruption was associated with increased migration from full acquisition of SMBG to partial or no SMBG acquisition, and from this report, there appeared to be increases in inpatient admissions, costs, and mortality. Unfortunately socioeconomic data were not available in CMS beneficiary files.

If the findings are indeed substantiated, the inability of CMS to detect problems with SMBG supply acquisition is concerning given the numerous signals of disruption that occurred during the early stages of program implementation. During the first 6 months, CMS received >27,000 calls from beneficiaries regarding diabetes testing supplies. Prior to 2011 implementation, one company had the dominant market share of mail order but did not win the bid when the program was implemented. The only notification that beneficiaries received was a letter, instructing them to call CMS or access the agency's website to select a new company. One would have expected that CMS would have more closely monitored the implementation and outcome of competitive bidding. The sheer volume of beneficiary calls should have prompted CMS to conduct an immediate and thorough assessment of the program. This supplier disruption is scheduled to occur every 3 years with the Competitive Bidding Program.

It also appears that the information provided by CMS regarding the SMBG products available from the new suppliers was inconsistent with the products that the suppliers were actually offering (4). In late 2011, the American Association of Diabetes Educators reported their findings of a survey that found that the SMBG suppliers offered ~38% of the products listed on the Medicare.gov website, and some offered products that were not listed on the website. In a 2014 follow-up survey, the American Association of Diabetes Educators reported that the competitive bidding continues to limit access to popular brands of diabetes testing supplies and that the limited availability of products from suppliers is compounded by inaccurate information from Medicare and the suppliers themselves. It is clear that patient compliance with monitoring regimens may decrease and adverse complications may increase if beneficiary access to the most appropriate monitoring system is disrupted or any change is made without proper education. Congress had previously ruled that competitive bidding should have provided at least 50% of the systems on the market, and in this case, one can argue that the program failed to meet that objective (5).

[1]Department of Pediatrics, University of Florida, Gainesville, FL
[2]Pennington Biomedical Research Center, Louisiana State University, Baton Rouge, LA

Corresponding author: Desmond Schatz, schatda@peds.ufl.edu.

In December 2015, the National Minority Quality Forum (NMQF), assisted by the Diabetes Translational Research Center, published a comprehensive analysis of the inherent limitations of CMS' methodology (6). According to the report, investigators determined that the study design used by CMS was flawed. Because CMS failed to establish baseline values for acquisition behaviors and health status, it was impossible to determine whether changes in either acquisition behaviors or health outcomes actually occurred during establishment of their metrics. Additionally, the agency failed to construct a matched control group, which would have enabled CMS to determine whether competitive bidding was an independent contributor to any changes detected, and the significance of those changes, compared with beneficiaries not included in the nine test markets. There was also a lack of transparency in describing their methodology and reporting their findings.

One major unanswered question is why these signals were not recognized by CMS. We know that Medicare beneficiaries treated with insulin or other insulinotropic medications are at significantly higher risk of hypoglycemia (7,8). SMBG is a critical component of preventing hypoglycemia. If competitive bidding is disrupting beneficiary access to needed SMBG supplies, then it may follow that one may see increased adverse events, such as hypoglycemia, perhaps leading to an increase in morbidity and mortality. Thus, the resulting implications may well continue to increase the cost of diabetes care. Thus, it is imperative that the findings from the study by Puckrein et al. (3) be considered, evaluated, and addressed by CMS.

Duality of Interest. No potential conflicts of interest relevant to this article were reported.

References

1. Centers for Medicare & Medicaid Services. Medicare Health Support (formerly CCIP) [Internet]. Available from https://www.cms.gov/Medicare/Medicare-General-Information/CCIP/index.html?redirect=/CCIP/. Accessed 7 March 2016

2. Centers for Medicare & Medicaid Services. Competitive bidding update—one year implementation update [Internet], 2012. Available from http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Downloads/Competitive-Bidding-Update-One-Year-Implementation.pdf. Accessed 1 August 2014

3. Puckrein GA, Nunlee-Bland G, Zangeneh F, et al. Impact of CMS Competitive Bidding Program on Medicare beneficiary safety and access to diabetes testing supplies: a retrospective, longitudinal analysis. Diabetes Care 2016;39:563–571

4. American Association of Diabetes Educators. Competitive Bidding Program for mail-order diabetes testing supplies: product availability survey [article online], 2014. Available from https://www.diabeteseducator.org/docs/default-source/legacy-docs/_resources/advocacy/aade_study_on_suppliers_2014.pdf?sfvrsn=2. Accessed 6 May 2016

5. Centers for Medicare & Medicaid Services. National mail-order competition for diabetic supplies [Internet], 2011. Available from http://www.dmecompetitivebid.com/Palmetto/Cbic.nsf/files/R2_Fact_Sheet_Mail-Order_Diabetic_Supplies.pdf/$FIle/R2_Fact_Sheet_Mail-Order_Diabetic_Supplies.pdf. Accessed 6 March 2016

6. National Minority Quality Forum. Centers for Medicare & Medicaid Services Competitive Bidding Program: assessment of impact on beneficiary acquisition of diabetes-testing supplies and durable medical equipment prosthetics orthotics and supplies—associated health outcomes [Internet], 2015. Available from http://www.nmqf.org/wp-content/uploads/2015/11/National-Minority-Quality-Forum-Report-on-CMS-Competitive-Bidding-Program.pdf. Accessed 18 February 2016

7. Meneilly GS, Cheung E, Tuokko H. Counterregulatory hormone responses to hypoglycemia in the elderly patient with diabetes. Diabetes 1994;43:403–410

8. Meneilly GS, Tessier D. Diabetes in the elderly. Diabet Med 1995;12:949–960