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Medicare's Competitive Bidding Program Puts Diabetes Patients' Lives at Risk

DPAC's Statement

The Diabetes Patient Advocacy Coalition (DPAC) is an alliance of people with diabetes, caregivers, patient advocates, health professionals, disease organizations and companies working collaboratively to promote and support public policy initiatives to improve the health of people with diabetes. DPAC's guiding principles focus on 3 key areas:

- *Safety (enforce established safety standards on devices, medications and practices for diabetes care)*
- *Quality (advance the standards of care for diabetes management)*
- *Access (access to health care and quality diabetes products for all 29MM Americans with diabetes)*

Given the rising costs of diabetes in America, it is critical that Americans have access to **ALL** components of diabetes training and treatment programs to prevent costly hospitalizations and complications. Yet Medicare continues to support a program that continues to disrupt access to diabetes testing supplies and has led to increased mortality, hospitalizations and overall costs. Among Medicare beneficiaries, patients with diabetes consume over 32% of total Medicare expenditure[1].

In January 2011, the Centers for Medicare and Medicaid Services (CMS) implemented the Competitive Bidding Program (CBP) in 9 pilot markets for certain durable medical equipment (DME), including self-monitoring blood glucose (SMBG) supplies via mail order for patients with diabetes[2]. The intent of the CBP was to reduce out-of-pocket expense for fee-for-service Medicare beneficiaries and provide cost savings to Medicare[2]. Reimbursement for a 50-count vial of test strips dropped 72% but over 95% of mail order diabetes suppliers were eliminated[2]. In April 2012, CMS reported that there was no disruption of access to diabetes testing supplies and that there were no negative health care consequences to beneficiaries[2]. In May 2012, the Government Accountability Office (GAO) challenged the CMS report, stating that the monitoring methods used by CMS in assessing the impact of the CBP did not show directly whether beneficiaries received necessary DME on time or whether health outcomes were impacted by problems accessing DME supplies[3].

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[11]Centers for Medicare and Medicaid Services (CMS). Medicare Health Support. Accessed Marcy 7 2016 from http://www.cms.gov/Medicare/Medicare-General-Information/CCIP/index.html?redirect=/CCIP/.

[2] Centers for Medicare and Medicaid Services (CMS), Competitive Bidding Update-One Year Implementation Update April 17, 2012. Accessed August 1, 2014 from http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Downloads/Competitive-Bidding-Update-One-Year Implmentation.pdf

[3] United States Government Accountability Office. Medicare: Review of the First Year of CMS's Durable Medical Equipment Competitive Bidding Program's Round 1 Rebid, May 2012 (GAO-12-693). Accessed April 25, 2015, from http://www.gao.gov/products/GAO-14-156.

In February 2014, the National Minority Quality Forum (NMQF) engaged some of the nation's leading endocrinologists to undertake a longitudinal study to confirm CMS's conclusions that Medicare patients with diabetes that are using insulin were not negatively impacted by implementation of the CBP. This approach allowed the team to measure the occurrence of change in SMBG acquisition behaviors and subsequent outcomes at the individual level[4]. NMQF obtained data from CMS to assess the impact of CBP on almost 530,000 Medicare patients with diabetes that are using insulin (44,000 in the test markets), as of 2009[4]. In the test markets, the number of beneficiaries that experienced disruption in the acquisition of SMBG in 2011 increased 58.1% (vs. a 14.4% decrease in non-test markets)[4]. The percentage of test beneficiaries with no record of SMBG acquisition increased 16.6% in 2011[4]. Various studies have shown the importance of SMBG in a patient's diabetes management program and is even more critical for those patients that use insulin, as it is used for dosage calculation and prevention/detection of hypoglycemia and hyperglycemia[56789].

Even worse, in the test markets the NMQF analysis showed that there were 42 additional deaths associated with those beneficiaries and twice as many hospitalizations and associated costs. These results were counter to CMS's report in 2012 that patient supply was not disrupted and that patients were not negatively impacted[4]. At the behest of the Senate Finance Committee staff, NMQF and the Diabetes Translational Research Center reviewed CMS's methodologies for monitoring the impact of the CBP on beneficiaries' access and health outcomes. The white paper detailed there were several deficiencies with CMS's methodologies including inappropriate study design, unstable/unrepresentative study cohorts, lack of transparency and incomplete disclosure of methodology, and failure to identify the appropriate research questions[10].

Despite GAO concerns, in July 2013, CMS implemented CBP nationally for not only mail order SMBG supplies but also supplies obtained from retail channels, affecting more than 30 million Medicare

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[4] Puckrein 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. (In Press)
[5] Diabetes Control and Complications Trial Study Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. N Eng J Med 1993;329:977-986.
[6] Polonsky WH et al. Structured self-monitoring of blood glucose significantly reduces A1C levels in poorly controlled, noninsulin-treated type 2 diabetes: results from the Structured Testing Program study, Diabetes Care 2011;34;262-267.
[7] Franciosi M et al. ROSES: role of self-monitoring of blood glucose and intensive education in patients with Type 2 diabetes not receiving insulin. A pilot randomized clinical trial. Diabet Med 2011;28:7889-796.
[8] KempfK et al. ROSSO-in-praxi: a self-monitoring of blood glucose-structured 12-week lifestyle intervention significantly improves glucometabolic control of patients with type 2 diabetes mellitus. Diabetes TchnolTher2010;12:547-553.
[9] Bailey TS, Grunberger G, Bode BW, et al. American Association of Clinical Endocrinologists and American College of Endocrinology 2016 Outpatient Glucose Monitoring Consensus Statement. EndocrPract 2016;22:231-61.
[10] National Minority Quality Forum (NMQF), Centers for Medicare and 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, November 13, 2015.

beneficiaries with diabetes and decreasing reimbursement by another 25% and eliminating over 98% of suppliers that provide mail order diabetes supplies[11]. A preliminary study has shown that this disruption continued in ALL markets, which is concerning in that the beneficiaries in the test markets had previous experience with the CBP and still experienced disruption in acquiring SMBG supplies[11]. What is also concerning is that over 1/3 of beneficiaries on insulin are not acquiring SMBG AT ALL, which means that they are calculating their insulin dosages with inadequate or no SMBG to guide their therapy decisions[11]. CMS implemented the second round of bidding in July 2016, with reimbursement dropping another 20%[12].

While both studies acknowledge that it is not possible to identify the specific reasons for the disruption to access, several factors do help explain it. First, the national roll-out included not only mail order but also retail outlets. The first round in the 9 test markets only included mail order suppliers. During the national roll out, beneficiaries could purchase SMBG at retail outlets but were forced to pay higher out of pocket costs if those outlets did not accept Medicare assignment (accept the reimbursement amount that CMS will allow). Second, the number of mail order suppliers continued to shrink from 891 in 2011 to 21 in 2013 and eventually 15 due to business failures and noncompliance[13]. This is a significant disruption to beneficiaries who receive SMBG via mail order outlets. Fewer choices and limited access would certainly help explain these disturbing results.

While DPAC applauds CMS for attempting to reduce out-of-pocket expenses for Medicare patients with diabetes, we are appalled at the lack of transparency and poor methodology that CMS has used in assessing the impact to patients. Any time access is disrupted this drastically, patients can be negatively impacted, as the NMQF studies showed. Not only did overall costs increase, but more patients died. It is particularly alarming that CMS continues to proceed with the CBP without making changes to safety monitoring and reporting. **CMS must exempt diabetes testing supplies from the CBP until they can employ transparent, scientific-based methodologies for monitoring the safety of patients and ensure that adequate access to SMBG is available to Medicare beneficiaries with diabetes.**

[11] Puckrein et al. Impact of the 2013 National Rollout of CMS Competitive Bidding Program: The Disruption Continues. Presented as a poster at the ADA Scientific Sessions, June 2017. Submitted for publication in Diabetes Care journal.

[12] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/DMEPOS-Fee-Schedule.html

[13] http://www.gao.gov/assets/680/679771.pdf