



VIA ELECTRONIC SUBMISSION: <http://www.regulations.gov>

September 10, 2018

Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1691-P  
7500 Security Boulevard  
Baltimore, MD 21244-1850

**Re: CMS-1691-P: Medicare Program: End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments to Correct Existing Regulations Related to the CBP for Certain DMEPOS**

Dear Administrator Verma:

The American Association of Diabetes Educators (AADE) is a multi-disciplinary association of healthcare professionals dedicated to integrated self-management as a key outcome in the care of people with diabetes and related chronic conditions. Representing over 14,000 professional members including nurses, dietitians, pharmacists, exercise specialists, and others, AADE has a vast network of practitioners working with people who have, are affected by, or are at risk for diabetes. AADE has a specific interest in the aspects of Medicare's Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) that relate to the quality, accessibility, and pricing of diabetes testing supplies (DTS). We appreciate the opportunity to offer comments relative to the CBP in response to the Proposed Rule referenced above as published in the *Federal Register* on July 19, 2018.

AADE has expressed serious concerns with the CBP since its implementation in 2011. We continue to urge CMS to address the many flaws inherent to this program. The CBP, as currently designed and functioning, limits choice of testing systems for Medicare beneficiaries and reduces access to safe, effective, and high-quality products. This has resulted in an increase in diabetes-related complications, negative health outcomes, and healthcare costs. CMS must immediately address issues of access, quality, and safety for Medicare beneficiaries accessing DTS.

### **DTS Pricing Concerns**

AADE believes that many of the issues referenced above stem from the unsustainably low reimbursement rate for DTS under the current system. We feel it's imperative for CMS to take

immediate steps to address this foundational issue. The current reimbursement rate for DTS was formulated based on a problematic, confusing, and non-transparent bidding process that drove down reimbursement for DTS provided through the National Mail Order Program (NMOP). For example, we have seen a 72 percent reduction in the current single payment amount (SPA) for HCPCS code A4253 (blood glucose reagent test strips) from the former fee schedule reimbursement rate. In 2011, the fee schedule price for the DTS was \$34. Later that year, after CMS implemented the CBP for DTS in 9 test markets, the price was reduced to just over \$14 –the result of HCPCS code A4253 being subject to this flawed bidding process where a remarkably low number of bids (only 7 percent of bidding suppliers) were used to administratively calculate the SPA for DTS.<sup>12</sup> We have continued to see a decrease in subsequent years, with the current rate being only \$8.32 (plus a minor CPI-U adjustment). This payment amount is too low and creates an unsustainable market for current mail order suppliers to continue their participation in the NMOP and restricts new mail order and retail suppliers from entering the market.

The continued reduction in reimbursement for DTS has had a considerable impact on the market and we have seen a dramatic decrease in the number of suppliers. Before CMS implemented the CBP NMOP, there were an estimated 500 mail-order DTS suppliers.<sup>3</sup> In April 2013, CMS released a press release on the Round 2 Rebid which stated that 245 bids were received for the NMOP. Stunningly, only 18 were announced as contracted DTS mail order suppliers.<sup>4</sup> Further compounding the issue, was the fact that just over 7 percent of bidders had to meet 100 percent of the demand of the national market, and many of these bid “winners” failed to supply DTS or ceased operations during the July 2013-June 2016 contract period. Evidence suggests that the reduction in DTS suppliers has created significant access issues for Medicare beneficiaries.

### **The CBP Restricts Access and Reduces Beneficiary Choice**

AADE has vocalized concerns about the flawed CBP program for many years and has been tracking the impact these policies have had on people with diabetes. When CMS first piloted the CBP in 2011, AADE received anecdotal reports suggesting that beneficiaries had a limited choice in products, that there was misleading advertising from contract suppliers, and that there were other predatory practices at play that could result in harm to beneficiaries. To investigate these claims, AADE conducted and published a series of beneficiary surveys or “secret shopper” studies (2011, 2013, 2017) designed to determine the range of DTS offered by contract suppliers to Medicare beneficiaries. These surveys showed that, in fact, the current program reduced beneficiary choice and decreased access to commonly used diabetes testing supplies DTS.

---

<sup>1</sup> Puckrein GA, Nunlee-Bland G, Zangeneh F, et al. (March 2016) “Impact of CMS competitive bidding program on Medicare beneficiary safety and access to diabetes testing supplies: a retrospective, longitudinal analysis.” *Diabetes Care*. 2016; doi: 10.2337/dc15-1264.

<sup>2</sup> <https://oig.hhs.gov/oei/reports/oei-04-16-00471.pdf>

<sup>3</sup> Cramton, Peter, (2012), *The Hidden Costs of a Flawed Medicare Auction*, Papers of Peter Cramton, University of Maryland, Department of Economics - Peter Cramton, <https://EconPapers.repec.org/RePEc:pcc:pccumd:12chcfma>.

<sup>4</sup> CMS Press Release (April 2013) “Contract Supplier Selected Under Medicare Competitive Bidding Program”. <https://www.cms.gov/newsroom/press-releases/contract-suppliers-selected-under-medicare-competitive-bidding-program>

AADE's most recent study, published in 2017, demonstrates that access to DTS continues to be limited, and that overall availability of different DTS has further deteriorated under the NMOP recompetete implemented by CMS in 2016. Our study found the following:

- During the initial phase of competitive bidding, suppliers offered DTS brands from 38 different manufacturers. This number fell to 34 with the implementation of the NMOP, and then dropped to just 20 different manufacturers with the implementation of the NMOP recompetete.
- The mix of models of DTS continues to decline. Under the NMOP recompetete, supplies offered only 36 different models of DTS. This was a dramatic (more than 50 percent) reduction from the Office of the Inspector General's (OIG's) finding that suppliers submitted claims for at least 75 types of DTS in 2009.
- The most commonly used tests strips used by beneficiaries before implementation of the NMOP are no longer offered to beneficiaries by NMOP suppliers.<sup>5</sup>

AADE recognizes that there are many factors that have led to the decline of product availability and a reduction in beneficiary access to supplies under the CBP, though the sharp and sustained reduction in payment for DTS continues to emerge as a major contributing factor. Payment is so low, that it drives suppliers from the market or incentivizes the remaining suppliers to make the cheapest supplies available regardless of the quality of the products. Low pricing also restricts suppliers from entering the market and further impeding access to diabetes care. These market effects limit the availability of DTS and put beneficiaries at risk for not being able to access necessary supplies or being switched to DTS outside of their preference and/or what was recommended by their healthcare team. The healthcare team includes physicians and diabetes educators who spend significant time and effort working with beneficiaries on the appropriate use of the preferred DTS. Not being able to access preferred DTS from mail order or retail suppliers and having this cycle repeated as suppliers decrease, means that beneficiaries must frequently consult with their healthcare team to be re-educated on new products. This takes time away from the critical need to treat the beneficiary's diabetes, disrupts beneficiaries from managing and monitoring the disease, and increases the risk of diabetes-related complications.

### **Negative Health Outcomes Associated with Reduced Beneficiary Access to DTS**

Recently, peer-reviewed studies have been published demonstrating that disruptions in access to supplies have contributed to an increased number of hospitalizations and deaths for Medicare beneficiaries with diabetes. The National Minority Quality Forum (NMQF), led by the research of Gary Puckrein, PhD, conducted a retrospective, longitudinal study of the CMS data set to examine the potential benefits of the CBP to Medicare beneficiaries. Instead of identifying benefits to the CBP, their findings showed that the system caused a significant disruption in beneficiary access to self-monitoring of blood glucose (SMBG) supplies, leading to an upturn in the number of beneficiaries that had either reduced or no access to supplies. This resulted in a decrease in beneficiaries engaging in appropriate testing protocols, leading to an increase in mortality, inpatient admissions, and cost. This study showed that total hospital inpatient admissions more than doubled (increasing from 460 to 980). Though the

---

<sup>5</sup> American Association of Diabetes Educators, "*Competitive Bidding Program for Mail Order Diabetes Testing Supplies: Product Availability Survey* (March 2017), [https://www.diabeteseducator.org/docs/default-source/advocacy/aade-study-on-suppliers-in-competitive-bidding-program\\_2016-\(002\).pdf?sfvrsn=2](https://www.diabeteseducator.org/docs/default-source/advocacy/aade-study-on-suppliers-in-competitive-bidding-program_2016-(002).pdf?sfvrsn=2).

system was designed to decrease healthcare costs, implementation of the CBP led to an increase in the costs associated with hospital admissions from \$4.69 million to \$10.72 million.<sup>6</sup>

Dr. Puckrein and the NMOP conducted a follow-up study on the 2013 national program rollout to determine if the problems identified in 2011 persisted. This study concluded that disruptions in access for SMBG not only persisted but worsened. They advised that DTS be excluded from the CBP until CMS could develop and adopt transparent, evidence-based methodologies for safe monitoring.<sup>7</sup> AADE strongly recommends that CMS consider this research and heed these recommendations by taking immediate steps to improve pricing for DTS and correct this flawed system. Further, in addition to concerns over access and availability of supplies, the quality and effectiveness of the DTS offered by the NMOP has also been called into question.

### **Ensuring Blood Glucose Monitoring Systems Meet Performance Accuracy Standards**

In June 2018, David Klonoff, MD published the results of his comprehensive evaluation of performance accuracy of some of the most commonly used blood glucose testing systems designated for personal-use. The systems evaluated included those most frequently provided to Medicare beneficiaries through the NMOP. The study tested home glucose monitors against the International Organization of Standardization (ISO) standards. Of the 18 different blood glucose monitors tested, only six met accuracy standards on three out of three trials.<sup>8</sup> Medicare beneficiaries rely on the NMOP for DTS to manage their diabetes. They determine the appropriate dosage of insulin and other diabetes medications based on the results provided by DTS, including blood glucose meters. It is incredibly concerning that the supplies furnished to Medicare beneficiaries may not be meeting quality and accuracy standards, creating yet another barrier to care. CMS must immediately work to verify and ensure the quality, safety, and accuracy of the products they are supplying through the NMOP.

### **Implementing the 50 Percent and Anti-Switching Provisions of the Bipartisan Budget Act (BBA) of 2018**

AADE was pleased when Congress included language from the Protecting Access to Diabetes Supplies Act in the Bipartisan Budget Act of 2018. These provisions include major fixes to the CBP including strengthening the 50 percent and anti-switching rules. The 50 percent rule is intended to ensure that beneficiaries still have access to commonly used testing systems. The provision in the BBA requires NMOP suppliers to make valid attempts to supply the types of products in their bid and that those bids accurately reflect the overall market for DTS. The anti-switching provisions of the BBA seek to empower beneficiaries by requiring suppliers to verbally provide beneficiaries with an explanation of the beneficiary's rights, including the beneficiary's right to receive DTS compatible with the beneficiary's blood glucose testing system, the right not to be influenced or incentivized to switch blood glucose testing systems, the right to obtain strips from another mail order supplier or retail pharmacy, and the

---

<sup>6</sup> Puckrein GA, Nunlee-Bland G, Zangeneh F, et al. (March 2016) "Impact of CMS competitive bidding program on Medicare beneficiary safety and access to diabetes testing supplies: a retrospective, longitudinal analysis." *Diabetes Care*. 2016; doi: 10.2337/dc15-1264.

<sup>7</sup> Puckrein, GA, et al. (May 2018) *Impact of the 2013 National Rollout of CMS Competitive Bidding Program: the Disruption Continues*, 41(5) DIABETES CARE 949-955 <https://doi.org/10.2337/dc17-0960>.

<sup>8</sup> Klonoff, David C. (August 2018). *Investigation of the Accuracy of 18 Marketed Blood Glucose Monitors*, 41(8) DIABETES CARE 1681-88. <https://doi.org/10.2337/dc17-1960>.

right to reject unwanted DTS. In the Proposed Rule, CMS did not include any policy changes implementing the provisions of the BBA, despite Congress' intention that these changes become effective in the next round of competitive bidding. AADE hopes that CMS has a clear plan for implementation of these provisions and will initiate a formal rulemaking process to finalize these changes.

## Conclusion

AADE asserts that it is critical for CMS to implement measures that would significantly raise the current rate of reimbursement for DTS for mail order and retail suppliers, and make improvements to the CBP so that beneficiaries can readily access quality DTS from a range of suppliers. CMS must create a more sustainable market where prices for DTS are stable and appropriate, there is a robust network of suppliers in the market, and the network of suppliers maintain and support access to and quality of supplies. In its current design, Medicare beneficiaries face significant barriers in accessing DTS that meet safety and quality standards. As a result, beneficiaries are at risk for serious complications and negative health outcomes, as they are unable to access the care and supplies they need to manage their diabetes. This impacts the overall health of the Medicare population and drives up healthcare costs for the entire system. CMS must act now to address the issues of access, quality, and safety for Medicare beneficiaries accessing DTS.

Diabetes testing systems and supplies are the cornerstone of patient self-management. Beneficiaries work with their healthcare team to determine what systems will work best to optimize the success of therapy and clinical outcomes. CMS should take every measure necessary to support these care decisions. As referenced above, a failure to do so can have disastrous consequences for both the individual and the health care system. AADE believes that an increase in pricing and subsequent market stabilization will help to improve the health status of and reduce negative health outcomes for Medicare beneficiaries with diabetes, while lower overall costs to the system. We look forward to working with CMS to provide the best care for Medicare beneficiaries with diabetes.

\* \* \* \* \*

AADE appreciates the opportunity to comment on this Proposed Rule. Please contact Kate Thomas, Director of Advocacy, by phone at 312-601-4821 or via email at [kthomas@aadenet.org](mailto:kthomas@aadenet.org) should you have any questions regarding AADE's comment letter.

Sincerely,



Charles Macfarlane, FACHE, CAE, Chief Executive Officer