



**Statement for the Record from the
Diabetes Patient Advocacy Coalition**

**House Energy and Commerce Committee
Subcommittee on Health**

**Examining Bipartisan Legislation to Improve the Medicare Program
July 20, 2017**

The Diabetes Patient Advocacy Coalition (DPAC) is pleased to submit this testimony in response to the above referenced hearing, and specifically on H.R.3271, the Protecting Access to Diabetes Supplies Act.

The 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 seeks to ensure the safety and quality of medications, devices, and services; and access to care for all 29 million Americans with diabetes. In light of this mission, the DPAC has a strong interest in the Medicare Competitive Bidding Program (CBP).

The DPAC believes that additional legislative action is necessary to improve the program's functioning and protect beneficiaries with diabetes. As such, the DPAC appreciates the Subcommittee's request for suggestions on how the Medicare program can be improved to protect beneficiaries and ensure that they are able to access the care that they need. We urge the Subcommittee to take swift action on the proposals discussed herein.

Diabetes

Diabetes is a complex disease that requires the active engagement of the patient and a number of health care providers. Among U.S. residents ages 65 and older, 11.2 million had diabetes in 2012.¹

Costly and debilitating complications – such as heart disease, blindness, nerve damage, kidney disease and amputations – are common among people with mismanaged diabetes. Blood glucose control can reduce the risk of developing the eye, nerve, and kidney complications of diabetes. For some people with Type 2 diabetes, blood glucose levels can be effectively managed by healthful eating and regular physical activity, but nearly 18 million of the 29 million Americans with diabetes take either or both insulin or oral medication to manage blood glucose levels.

¹ Centers for Disease Control and Prevention. *National Diabetes Statistics Report: Estimates of Diabetes and Its Burden in the United States, 2014*. Atlanta, GA: U.S. Department of Health and Human Services; 2014.

Treatment of diabetes among people aged 18 years or older with diagnosed diabetes, United States, 2010–2012

	Number of adults using diabetes medication* (millions)	Percentage using diabetes medication (unadjusted)
Insulin only	2.9	14.0
Both insulin and oral medication	3.1	14.7
Oral medication only	11.9	56.9
Neither insulin nor oral medication	3.0	14.4

*Does not add to the total number of adults with diagnosed diabetes because of the different data sources and methods used to obtain the estimates.
Source: 2010–2012 National Health Interview Survey.

Medicare’s Competitive Bidding Program

Congress established the Competitive Bidding Program (CBP) for Durable Medical Equipment and Supplies in 2003 to achieve savings and address fraud concerns. Diabetes testing supplies – blood glucose testing strips and lancets, *etc.* – were among the supplies included in the first rounds of the CBP.

Under the first round of the CBP, Medicare payment for a box of 50 diabetes test strips provided via a mail order supplier² fell from an average of \$32.47 per box to \$14.62 per box, a decrease of nearly 55 percent. Upon the implementation of the National Mail Order (NMO) Program for Diabetes Testing Supplies (DTS) in July 2013 the payment rate for diabetes strips further decreased to \$10.41 per box of 50 strips. Medicare payment under the NMO Recompete, effective July 1, 2016, fell an additional 20 percent to \$8.32 per box of 50 strips.

Beneficiary Concerns

While this consistently decreasing price-per-box of strips results in substantial savings on the amount of money spent on testing supplies by the Medicare program, it comes at a cost for beneficiaries and the Medicare program overall.

Since implementation of the NMO program for DTS in July 2013, Congress has seen reports and data indicating that beneficiary access to DTS is being significantly restricted. Recent studies by the Inspector General for the U.S. Department of Health and Human Services^{3,4,5} and the American Association of Diabetes Educators,^{6,7} for example, show a dramatic and continued shift in market availability of DTS. These studies show that the most common tests systems used by beneficiaries before implementation of the NMO program are now no longer available to beneficiaries.⁸

According to the Inspector General, in the CBP in 2009, claims were submitted for at least 75 types of diabetes test strips with two types of strips accounting for 26 percent of Medicare mail order market share. By comparison, the Inspector General study of the third quarter of 2013 (the first quarter after the

² Diabetes test strips purchased at retail locations were not subject to Round 1 of the CBP.

³ Office of Inspector General, Memorandum Report, “*Medicare Market Shares of Mail Order Diabetes Test Strips from July – September 2013*,” OEI-04-13-00680, June 13, 2014.

⁴ Office of Inspector General, Memorandum Report, “*Medicare Market Shares of Mail Order Diabetes Test Strips Immediately Prior to the National Mail Order Program*”; OEI-04-13-00681, June 20, 2014.

⁵ Office of Inspector General, Memorandum Report, “*Medicare Market Shares of Mail Order Diabetes Test Strips*”; OEI-04-10-00130; December 2, 2010.

⁶ “*Competitive Bidding Program for Mail-Order Diabetes Testing Supplies: Product Availability Survey*”; American Association of Diabetes Educators (November 17, 2011).

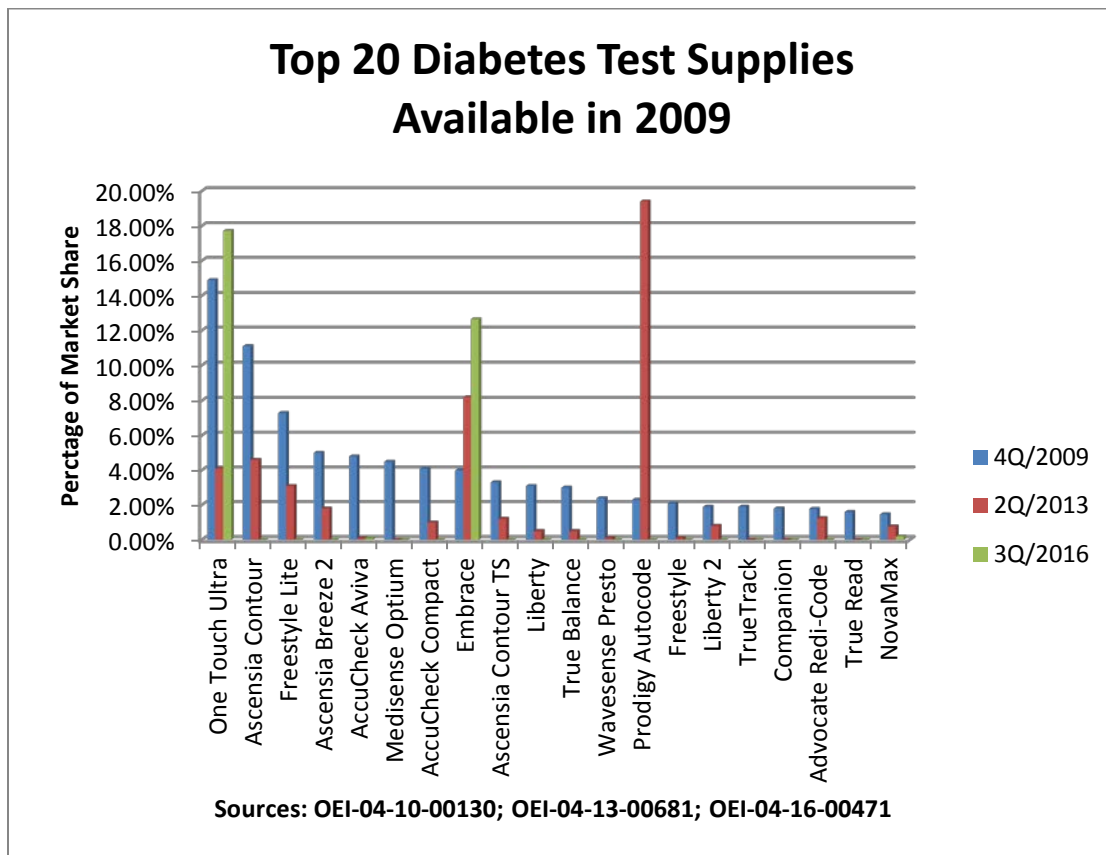
⁷ “*Competitive Bidding Program for Mail-Order Diabetes Testing Supplies: Product Availability Survey*”; American Association of Diabetes Educators (March 2017).

⁸ *Ibid.*

national CBP was implemented) shows claims were submitted for only 43 types of diabetes test strips, with two types of strips accounting for 45 percent of the Medicare mail order market share. These numbers represent a 43 percent decrease in types of strips available to Medicare beneficiaries. This trend continues into the Inspector General's study of the third quarter of 2016 (the first quarter after the NMO recompetete was implemented; showing claims submitted for only 18 types of strips with the top two types representing 60 percent of the market place.⁹

Even more significant, the most common tests strips used by beneficiaries before implementation of the National Mail Order Competitive Bidding Program are now no longer available to beneficiaries.

Rather than preserving access to a broad array of products, the CBP has forced the market to consolidate sharply, leaving beneficiaries with fewer options. This point is illustrated in the chart below, which shows that much of the product available in the marketplace in 2009 is no longer available to Medicare beneficiaries.



The DPAC has long been concerned about the negative effect this has on beneficiary health status, morbidity and mortality, and program costs. Unfortunately, some of our concerns are now substantiated by the results of a study recently published by a group of leading endocrinologists, diabetes researchers

⁹ Office of Inspector General, "Medicare Market Shares of Mail-Order Diabetes Test Strips from July through September 2016"; OEI-04-16-00471; February 2017.

and health services researchers in Diabetes Care, the clinical, scientific journal of the American Diabetes Association.¹⁰

The article, “Impact of CMS Competitive Bidding Program on Medicare Beneficiary Safety and Access to Diabetes Testing Supplies: A Retrospective, Longitudinal Analysis,” published in the April 2016 edition of Diabetes Care, studied the implementation of the CBP and its impact on access to blood glucose testing supplies and beneficiary health outcomes. Specifically, the authors conducted a longitudinal, retrospective study examining four years of Medicare claims data comparing a cohort of Medicare beneficiaries with diabetes who treat their diabetes with insulin and who reside in competitive bidding areas to those who reside outside competitive bidding areas. The study found, among other things, the following:

- A significant percentage of beneficiaries in areas subject to the CBP shifted from purchasing DTS from mail order suppliers to retail pharmacies after the CBP became effective.
- A significantly higher proportion of insulin-treated Medicare beneficiaries with diabetes who were adherent with insulin therapy and adherent to testing with DTS in areas subject to the CBP substantially reduced or even stopped purchasing diabetes testing supplies after the CBP became effective compared to matched populations in areas not subject to CBP. Not only did purchase patterns change, but these beneficiaries substantially reduced, and in some cases stopped, testing blood glucose levels, even though they continued to treat their diabetes with insulin.
- The drop-off in testing among these insulin-treatment adherent beneficiaries was associated with an increase in mortality, an increase in inpatient admissions, and higher inpatient costs.

These findings highlight a number of disturbing developments. First, the CBP was intended to control costs without impacting access to services. The study indicates that, in areas where competitive bidding for DTS was implemented, the program failed to achieve the desired effects. The study found that beneficiaries in CBP areas switched to traditional retailers as a source for their DTS, moving away from the mail order suppliers subject to the CBP. Beneficiaries who were able to navigate the new system were voting with their feet. Because of differences in the business model and how consumers interact with a retail pharmacy versus a mail order supplier, retail pharmacies tend to carry more of the brands and models that beneficiaries prefer, as opposed to only carrying the least expensive models.

Second, the study shows that a significant percentage of beneficiaries in CBP markets who were adherent to insulin treatment and previously adherent to testing with DTS reduced or eliminated their purchase of testing supplies after the implementation of CBP.

Last, and most critically, the study indicates that decreasing or eliminating testing among insulin-treated beneficiaries has a negative impact on beneficiary health outcomes. The study showed that in CBP markets, insulin-treated beneficiaries who were adherent to insulin therapy and migrated from being adherent to testing with DTS to only partial or no testing with DTS after the introduction of CBP had nearly twice as many inpatient hospital admissions as did matched beneficiaries in non-CBP markets, and those admissions were nearly twice as expensive. Most disturbing, the study showed that those insulin-adherent beneficiaries in CBP markets who migrated to not purchasing or purchasing fewer testing supplies were at greater risk of death than those who did not.

¹⁰ *Impact of CMS Competitive Bidding Program on Medicare Beneficiary Safety and Access to Diabetes Testing Supplies: A Retrospective, Longitudinal Analysis*, Diabetes Care, Puckrein, Gary A., et al., DOI: 10.2337/dc15-1264 (Apr. 2016).

Adding to these concerns are recent findings from the Diabetes Technology Society that indicate that, of the systems available to Medicare patients, a shocking number do not produce accurate test results.¹¹ The Diabetes Technology Society recently published the results of its testing of 18 different home blood glucose monitoring systems representing those commonly used by diabetes patients during the time period 2013 to 2015, when the study protocol was developed.

The Diabetes Technology Society tested these 18 different home blood glucose monitors against ISO standards in effect when the study's protocol was developed and the latest FDA guidance (FDA 2016, "Self-Monitoring of Blood Glucose Test Systems for Over-the-Counter Use"). The study's authors found that only six of these systems produced results that were consistently accurate.

Most notable among the study's findings is that all of the products used in the Medicare NMO CBP (that had more than 0.2 percent utilization in Q4 2016) that were tested – failed. The Medicare mail-order products tested represented 90 percent of Medicare mail order product volume as of Q4 2013 and 61 percent as of Q4 2016, based upon the respective OIG Medicare mail-order surveys. The products that passed the test and received the “Seal of Approval” were not available to Medicare beneficiaries through Medicare Mail order winning suppliers as of the Q4 2016 OIG survey.

The table on the following pages shows the main results of the Diabetes Technology Society's study.

¹¹ "Blood Glucose Monitor Surveillance Program"; <https://www.diabetestechology.org/surveillance.shtml>; Klonoff, D., *et.al.*; June 23, 2017; Last accessed July 17, 2017.

MAIN RESULTS																
			Study 1			Study 2			Study 3			Overall				
Brand	Blood Glucose Monitor	Test Strip	N	Percentage Compliant †	Pass/Fail	N	Percentage Compliant	Pass/Fail	N	Percentage Compliant	Pass/Fail	Passes out of 3 Studies	Seal of Approval ?	Valid Trials	Compliant N	Compliant %
Bayer	Contour Next	Contour Next	98	99%	PASS	101	100%	PASS	113	100%	PASS	3	YES	312	311	100%
Roche	ACCU-CHEK AVIVA Plus	ACCU-CHEK AVIVA Plus	97	97%	PASS	101	100%	PASS	113	98%	PASS	3	YES	311	306	98%
Arkray	Walmart ReliOn Confirm (Micro)	ReliOn Confirm/micro	100	96%	PASS	114	96%	PASS	103	99%	PASS	3	YES	317	307	97%
Agamatrix	CVS Advanced	CVS Advanced	101	96%	PASS	114	96%	PASS	103	98%	PASS	3	YES	318	307	97%
Abbott	Freestyle Lite	Freestyle Lite	98	92%	PASS	101	96%	PASS	113	98%	PASS	3	YES	312	298	96%
Roche	Accu-Chek Smart View	ACCU-CHEK SmartView	108	98%	PASS	106	96%	PASS	106	92%	PASS	3	YES	320	305	95%
Arkray	Walmart ReliOn Prime	ReliOn Prime	98	85%	FAIL	101	95%	PASS	113	96%	PASS	2	NO	312	288	92%
LifeScan	OneTouch Verio	OneTouch Verio	108	87%	FAIL	106	98%	PASS	105	91%	PASS	2	NO	319	294	92%
Prodigy	Prodigy Auto Code	Prodigy No Coding	98	86%	FAIL	101	92%	PASS	113	93%	PASS	2	NO	312	282	90%
LifeScan	OneTouch Ultra2	OneTouch Ultra	97	92%	PASS	101	84%	FAIL	113	94%	PASS	2	NO	311	280	90%
Abbott	Walmart ReliOn Ultima	ReliOn Ultima	107	96%	PASS	106	97%	PASS	106	75%	FAIL	2	NO	319	285	89%
Bayer	Contour Classic	Contour	108	95%	PASS	106	85%	FAIL	106	86%	FAIL	1	NO	320	284	89%
Omnis Health	Embrace	Embrace No Code	102	87%	FAIL	114	93%	PASS	103	84%	FAIL	1	NO	319	282	88%
HDI/Nipro	True Result	True Result	101	94%	PASS	114	83%	FAIL	103	86%	FAIL	1	NO	318	279	88%
HDI/Nipro	True Track	TrueTrack	102	83%	FAIL	103	80%	FAIL			FAIL*	0	NO	205	167	81%
BioSense Medical	SolusV2	SOLUS	108	56%	FAIL	106	84%	FAIL	106	89%	FAIL	0	NO	320	244	76%
Diabetic Supply of Suncoast	Advocate Redi-Code +	Advocate	102	88%	FAIL	114	71%	FAIL	103	68%	FAIL	0	NO	319	241	76%
Philosys, Inc.	Gmate Smart	Gmate	108	61%	FAIL	106	79%	FAIL	106	72%	FAIL	0	NO	320	226	71%

* No Study 3 data for HDI/Nipro TrueTrack because of test strip recall.

† Within 15% of reference value if 100 mg/dl or 15 mg/dl of reference value if s 100 mg/dl. ‡

In Studies 1, 2, and 3, each of the 18 blood glucose monitoring systems (BGMSs) was tested at 3 different sites. Over the 3 studies each BGMS was tested once by each site. The number of compliant readings needed to pass depends on the number of trials. For 100 trials, at least 91 readings must be within 15% or 15 mg/dl of the reference value. Full methodology of the study will be published.

Persons with diabetes rely on these systems to test their blood sugar levels, sometimes many times during the day. Even though a disturbing number of patients have reduced or eliminating testing altogether, testing should not be viewed as optional. Blood sugar testing helps patients maintain their health and avoid getting sick from blood sugar levels that are too low or too high. Because insulin, while life-saving for persons who manage their diabetes with this drug, can be harmful, even fatal, if mis-dosed, Medicare beneficiaries must be able to rely on accurate test systems to help manage their insulin therapy.

Immediate Action Needed

While its intentions behind the CBP are admirable, Congress could not have foreseen the scope and impact of the unintended consequences of reduced testing, increased morbidities, and lessened accuracy of the systems being made available to Medicare beneficiaries.

While Congress did include a number of beneficiary protections in the original CBP statute, these protections are not having the intended effect and continue to leave beneficiaries are vulnerable to harm.

Congress has the opportunity now to take steps that address these deficiencies.

Enhance Beneficiary Protections

On July 17, 2017, Congresswoman Diana DeGette, Congressman Tom Reed and Congresswoman Susan Brooks introduced H.R. 3271, the “Protecting Access to Diabetes Supplies Act.” This bill reflects lessons learned from the first rounds of the CBP, and ensures that as CMS embarks on future rounds, beneficiaries have access to preferred and familiar test systems. These protections should be enacted as soon as possible.

1. Strengthen the 50 Percent Rule

Under the CBP, suppliers are paid the same amount by Medicare for DTS regardless of which brand of DTS they supply to a beneficiary. As such, suppliers have a powerful economic incentive to maximize profits by offering the least expensive supplies obtainable. Congress was concerned that this incentive would lead suppliers to significantly restrict the brands and models of DTS available and to no longer offer many of the test systems commonly used by beneficiaries. Under this scenario, beneficiaries might not be able to find replacement supplies for their current test systems. Congress enacted the “50 Percent Rule” to ensure that beneficiaries would continue to have access to the same test systems that they used prior to implementation of the CBP by requiring that mail order suppliers make available at least 50 percent of all types of diabetes test supplies on the market before implementation of the CBP.

Unfortunately, the manner in which CMS has implemented the 50 Percent Rule has rendered this statutory protection inadequate. CMS interpreted the statute as applying only to brands included in a supplier’s bid; not to the inventory maintained and offered by the supplier once awarded a CBP contract. Under CMS’ interpretation a supplier was able to submit a bid that included a wide range of DTS brands yet only maintain in their inventory a small subset of those brands (typically the least expensive brands).

Moreover, CMS gave suppliers 10 percent credit toward satisfying the 50 percent requirement merely for selecting “Other—Not Listed,” a catch-all designation not associated with a particular test system or product.

The Inspector General found that in 2013, after implementation of the Round 1 of the CBP program, 22 suppliers submitted claims for 43 different types of DTS.¹² This report shows a dramatic decrease in the range of brands being made available. The OIG report also showed that three types of DTS accounted for more than one-half of the total volume of DTS provided under the CBP in 2013. By comparison, the OIG found that in 2009, 7 types of DTS accounted for 52 percent of the total volume.¹³ The report highlights a dramatic shift in the mix of types of DTS available after implementation of the CBP. Indeed, the top 7

¹² *Supra.* OEI-04-13-00680.

¹³ *Supra.* OEI-04-10-00130.

types of DTS in 2009 were not even included in the 2013 findings, indicating that these popular brands were no longer being made available.

H.R. 3271 would strengthen the 50 Percent Rule by making the following changes:

- Authorizes the Secretary to terminate a supplier contract if the Secretary finds that the supplier is not offering the products listed in its bid, unless the reason for not offering such products is because the products are no longer available from the manufacturer or there is a market-wide shortage of the product;
- Requiring bidding suppliers to demonstrate an ability to obtain an inventory of strips by volume consistent with the inventory mix provided in that supplier's bid;
- Establishing and maintaining a surveillance program to ensure that suppliers comply with the 50 Percent Rule;
- Requiring CMS to use multiple sources of data, and data that measures consumption and utilization of DTS by individuals other than just those Medicare beneficiaries who purchase DTS through Medicare-participating mail order suppliers, for purposes of measuring compliance with the 50 Percent Rule; and
- Barring CMS from giving bidding suppliers additional percentage credit toward satisfying the 50 Percent Rule by selecting "Other—Not Listed."

2. Strengthen the Anti-switching Rule

CMS established the Anti-switching Rule to protect beneficiary and physician choice of glucose meters. This rule requires suppliers to furnish the test system requested by the beneficiary, and prohibits contract suppliers from influencing or incentivizing beneficiaries to switch their current glucose monitor and testing supplies brand to another brand.

CMS has likewise rendered this protection inadequate. The Inspector General reports we have discussed clearly show a significant and dramatic shift in the types of DTS made available to and purchased by Medicare beneficiaries through the CBP. Shifts as dramatic as those identified by the Inspector General are wholly inconsistent with a program that is intended to protect a Medicare beneficiary's access to their preferred type of equipment. In fact, the reports suggest that mail order suppliers may be switching beneficiaries in spite of the rule.

Beyond the clinical implications, once a beneficiary is switched, it becomes administratively difficult, if not impossible, for the beneficiary to purchase additional supplies from another supplier, like a retail pharmacy, in order to continue to use their preferred type of DTS. When a mail order supplier sends unwanted supplies to a Medicare beneficiary and submits a claim for payment for those supplies, claims for additional supplies (*e.g.*, if the beneficiary were to go to a retail pharmacy seeking preferred supplies), will be denied because the beneficiary's supply benefit has already been exhausted for that period. If the supplier continues to send supplies and submit claims, the beneficiary cannot break the cycle and is unable to "switch back" to their preferred type of DTS system.

H.R. 3271 would strengthen the Anti-switching Rule by making the following changes:

- Codifying the Anti-switching Rule;
- Allowing beneficiaries to break the claims cycle by requiring suppliers to contact and receive a refill order from the beneficiary not more than 14 days prior to dispensing a refill; and
- 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 right to reject unwanted DTS.

While this bill is too new to have received a Congressional Budget Office score, it is expected that this bill would impose no additional cost on the Medicare program.

This bills' predecessor, H.R. 771 was cosponsored by a bipartisan group of 28 Representatives and was endorsed by the American Association of Clinical Endocrinologists and the American Association of Diabetes Educators, among other organizations.

The DPAC strongly urges the Subcommittee to take swift and decisive action on this bill in order to assure that the Medicare CBP does not result in irreparable harm to Medicare beneficiaries with diabetes across the country.

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Please contact Christel Marchand Aprigliano at caprigliano@diabetespac.org for additional information.