



Competitive Bidding Program for Mail-  
Order Diabetes Testing Supplies:  
Product Availability Survey

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## EXECUTIVE SUMMARY

Since implementation of the competitive bidding program (CBP) for mail-order diabetes testing supplies (DTS) in January 2011, anecdotal reports have surfaced suggesting that beneficiaries have limited choice of products. To study these reports, AADE conducted a study in August 2011. In that study, diabetes educators surveyed contract suppliers to determine the range of products offered and the accuracy of information supplied by CMS via its website, Medicare.gov. Through that study, AADE found that contract suppliers in Round 1 were not offering most of the products said to be offered on Medicare.gov, and most of the products available to Medicare beneficiaries before implementation of Round 1 were no longer available to through the Competitive Bidding Program.

In light of the expanded CBP for DTS, the American Association of Diabetes Educators decided to repeat its study. AADE conducted this second study to determine the range of DTS offered by contract suppliers to Medicare beneficiaries.

AADE remains concerned that the CBP is harming persons with diabetes by limiting access to and choice of DTS products. If beneficiaries have difficulty finding replacements for familiar products, they may be inappropriately influenced to switch test systems. Product switching can have negative health and economic consequences. When a beneficiary is forced to switch to a testing system that is unsuitable, unknown, confusing, or unreliable, testing compliance may diminish or even cease. Poor blood glucose management can increase the risk of complications such as blindness, kidney damage, cardiovascular disease, lower-limb amputations, and hospital readmission rates.

In this study, 7 diabetes educators contacted 23 suppliers<sup>1</sup>, and found

- None of the suppliers offer products reflecting greater than 50% of the market, as intended by Congress; and
- Only 3 suppliers carry each brand of DTS they reported as carrying to Medicare.

These findings demonstrate that as a result of the Competitive Bidding Program, Medicare beneficiaries have fewer choices and limited access to the DTS most commonly used. As a result, beneficiaries participating in the Competitive Bidding Program are effectively being made to either switch to different testing systems or purchase DTS through non-mail order settings. This study also demonstrates that the information on Medicare's website continues to be inaccurate and that information from suppliers themselves is inconsistent.

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<sup>1</sup> Attachment A includes a list of 23 suppliers contacted for this survey. However, because of industry changes which have occurred since the start of the NMO program a number of these suppliers have either consolidated or ceased operation. As of October 1, 2013, only 20 suppliers are currently listed by Medicare as eligible mail order suppliers of DTS.

## **ABOUT THE AMERICAN ASSOCIATION OF DIABETES EDUCATORS**

Founded in 1973, AADE is a multi-disciplinary professional membership organization dedicated to improving diabetes care through self-management education. With more than 13,000 professional members including nurses, dietitians, pharmacists, and others, AADE has a vast network of practitioners involved in the daily treatment of diabetes patients.

Diabetes educators are licensed health care professionals—registered nurses, registered dietitians and pharmacists, among others—who specialize in helping people with diabetes understand how to best manage their health.

## **BACKGROUND**

On January 1, 2011, the Centers for Medicare and Medicaid Services (CMS) implemented the Competitive Bidding Program (CBP) for certain items of Durable Medical Equipment and Supplies in 9 geographic areas. Diabetes testing supplies (DTS), such as blood glucose testing strips, purchased through mail order, were one of the initial product categories subject to the CBP.

In 2012 CMS, through the National Mail Order (NMO) competition, expanded the scope of the CBP for DTS to include the entire nation. Beginning July 1, 2013, any Medicare beneficiary wishing to purchase DTS via a mail order supplier must use one of 20 winning contract suppliers. Beneficiaries choosing to purchase their supplies from a “brick and mortar” retailer or pharmacy could continue to do so at any Medicare-certified supplier.

Since implementation of the CBP, there have been anecdotal reports of beneficiaries having limited choice of products, misleading advertising by the contract suppliers, inaccurate information on Medicare’s website, and abusive practices by contract suppliers actively trying to switch beneficiaries to different testing systems.

To study these reports, AADE conducted a study in August 2011. In that study, diabetes educators surveyed contract suppliers – *i.e.*, suppliers authorized by the Centers for Medicare and Medicaid Services to furnish DTS to Medicare beneficiaries in the 9 Competitive Bidding Areas – to determine the range of products offered and the accuracy of information supplied by CMS via its website, Medicare.gov. AADE found that contract suppliers, on average, offered only 38% of the products said to be offered on Medicare.gov. Of the 9 brands that the Inspector General for the U.S. Department of Health and Human Services identified in a December 2010 report as the top mail order DTS brands by percent of market share, contract suppliers offered an average of 1.44 brands (16%).

In light of the expanded CBP for DTS, AADE decided a new study was warranted to determine if the process flaws were corrected. . AADE sought to once again examine the range of products available to Medicare beneficiaries and the accuracy of information provided to beneficiaries by Medicare, but also to test the CMS’s enforcement of a new statutory provision requiring CMS to ensure that bids submitted by mail order suppliers represent that the supplier will make available at least 50% of

all types of DTS by volume. This protection is intended to ensure that suppliers offer a range of products, and that beneficiaries have choices when purchasing DTS through mail order suppliers. AADE believes that CMS is implementing this rule in a manner that is inconsistent with congressional intent. CMS allowed bidders to satisfy this requirement simply by representing that they will furnish even a limited amount of products that comprise 50% of the volume of such supplies in the marketplace outside of competitive bidding. However, CMS did not require suppliers to demonstrate that these products will account for any substantial volume of the inventory maintained and offered by the supplier. AADE expanded its original study to see whether and how this provision intended to protect beneficiaries during the transition to CBP is actually functioning.

## OBJECTIVE

The American Association of Diabetes Educators conducted this study to assess beneficiary access to diabetes blood glucose test systems through CMS's National Mail Order (NMO) Competitive Bidding Program.

## METHODOLOGY

Members of the American Association of Diabetes Educators surveyed winning suppliers listed on the [www.medicare.gov](http://www.medicare.gov) website as of August 1, 2013, one month after the expanded program was launched. Surveys were conducted during the period September 4<sup>th</sup> through the 23<sup>rd</sup>. Surveyors were furnished with a list of contract suppliers and contact information. The list of suppliers surveyed may be found at Appendix A to this report.<sup>2</sup>

On Medicare.gov, beneficiaries can identify Contract Suppliers authorized to furnish DTS, and identify the products purported to be offered by and available through the suppliers. For purposes of the survey, we tallied the specific brands and models listed on Medicare.gov in the Medicare Supplier Database ("MSD") as of August 1<sup>st</sup> as being offered by each supplier. We used this listing as a baseline against which we compared the brands and models actually being offered by each supplier, and noted discrepancies.

Each supplier was contacted by 7 different surveyors. For each survey, the surveyor contacted the contract supplier, identified himself/herself as a diabetes educator, and inquired about the availability of the blood glucose test supplies listed as being offered on Medicare.gov as available. If the supplier confirmed that the product was available, the surveyor noted that on the survey. If the supplier reported that the product was not available, the surveyor inquired about reasons why that product was not available, whether the product might be available to be purchased at a later date, and if so, when they would be available to be purchased. In this way, surveyors sought to discern whether certain products might be temporarily out-of-stock and available again at a later date, or whether they are not available at all. Surveyors sought to validate product availability by asking whether a product is available for immediate shipment, and if not when the product would be available to be

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<sup>2</sup> *Ibid.*

shipped. Surveyors also asked if product other than that listed on Medicare.gov was available. The survey instrument can be found at Appendix B to this report.

Responses were documented using a Microsoft Excel spreadsheet that contained fields for surveyors to populate for each supplier. Surveyors recorded open-ended responses in separate fields in the spreadsheet.

Because a supplier's responses to the 7 different surveyors were not always uniformly consistent, we counted as a positive response to any question one where at least 4 surveyors were given the same answer. For example, if more than half of the surveyors were told that a particular DTS product was available, that product was counted as available. By contrast, if fewer than half of the surveyors were told that a product was available, that product was counted as not available. We used the threshold of 4 matching answers throughout this analysis.

## FINDINGS

### Many suppliers do not offer brands covering 50% of the market

In December 2010, the Department of Health and Human Services, Office of Inspector General published its report, "Medicare Market Shares of Mail Order Diabetic Testing Strips"<sup>3</sup>. The OIG was required to determine the market shares of diabetes testing strips available in the marketplace so that CMS could determine if such strips available in the NMO program cover 50% of the volume of strips previously available to beneficiaries before implementation of the CBP.<sup>4</sup> When estimating the relative market share of suppliers for this study, AADE relied on the data contained in the OIG report. In this manner, the information reviewed in this report should be consistent with the information used by CMS to select winning contractors.

As a condition of bid acceptance, suppliers were required to agree to provide a sufficient mix of brands of DTS such that their individual product mix reflects at least 50% of the market coverage for DTS supplies. Congress established this "50% rule" to ensure that Medicare beneficiaries continue to have access to a wide range of diabetes test systems, and to diabetes test systems historically available before implementation of the national CBP program.

However, the 50% rule is not a condition of on-going participation in the national CBP. As such, while a supplier was required to tell CMS that the supplier intended to offer a

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<sup>3</sup> "Memorandum Report: *Medicare Market Shares of Mail Order Diabetic Testing Strips*", OIG-04-10-00130, December 2, 2010; downloaded from <http://oig.hhs.gov/oei/reports/oei-04-10-00130.pdf>; last accessed November 10, 2013

<sup>4</sup> The Medicare Improvements for Patients and Providers Act of 2008, section 154(d)(3)(b) required the OIG to "conduct a study to determine the types of diabetic testing strip products by volume that could be used to make determinations" as to whether a potential contract supplier's bid covers products that account for at least 50% of the market share for such products.

wide range of product, because of the manner in which CMS has interpreted and implemented this rule, there is no ongoing obligation on the supplier to actually make available the range of products reported to CMS, or any range of product.

Through our survey, AADE found that, by the end of only the first quarter of the NMO program, beneficiary access to familiar test systems has been compromised. According to Medicare.gov, only 5 suppliers offer more than 50% of the test systems available to beneficiaries before implementation of the CBP. Even more troubling, according to our survey, no supplier actually offers more than 50% of the test systems available to beneficiaries before implementation of the CBP.

Chart 1

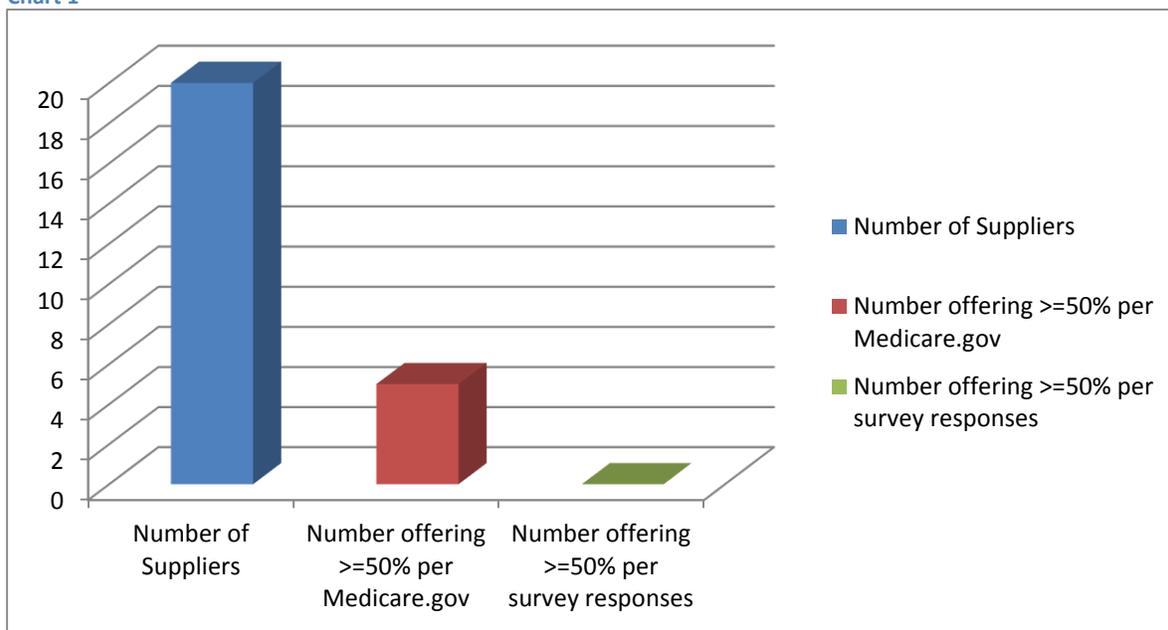
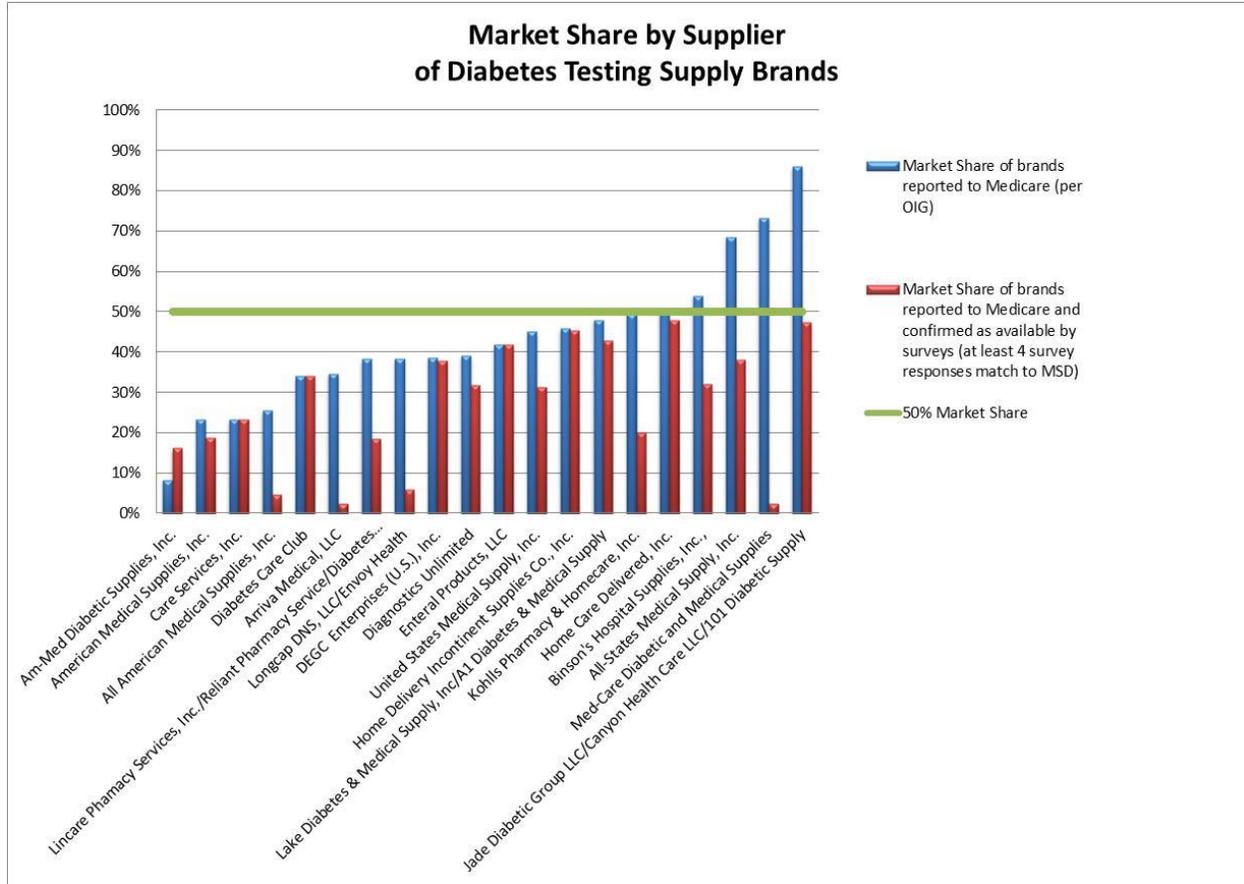


Chart 2 shows the combined market share of products available from each supplier in the NMO program. This chart highlights the differences between the market share of each supplier's products according to Medicare and those products that were confirmed as available from the supplier by our surveyors.

Chart 2



Although Congress clearly intended the 50% rule to ensure that beneficiaries would have access to the brands offered before the NMO program, CMS is failing to ensure that beneficiaries continue to have access to familiar test systems.

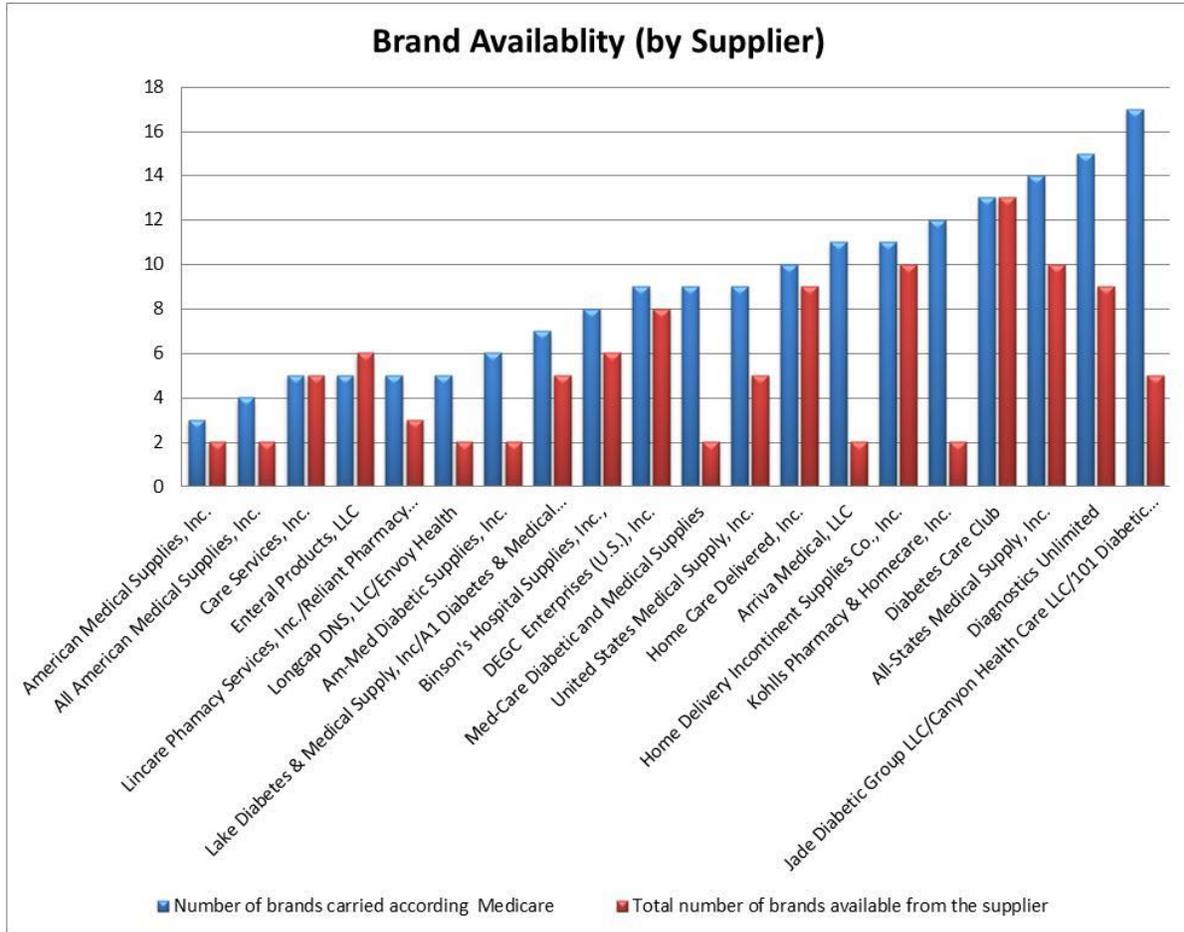
**Information provided via Medicare.gov is inaccurate and misleading.**

The NMO program reduced the number of mail order suppliers of diabetes testing supplies to 20. This substantial reduction in the number of mail order suppliers has, in many cases, forced Medicare beneficiaries to select new suppliers for their products. Medicare created the Medicare Supplier Directory as a tool for beneficiaries to identify, compare, and ultimately select a supplier of DTS. Most beneficiaries select a supplier based on their reported product offerings. The website is intended to provide users with a list of mail order suppliers and the DTS products available from each supplier, so that beneficiaries can efficiently find a supplier who carries a preferred brand of replacement items.

AADE tested the accuracy of the information on the website and found that the information on Medicare.gov is generally inaccurate. We compared survey responses to information available from Medicare and found that the information from Medicare generally does not correlate with survey responses. Medicare often indicates that certain brands and models of DTS are available from particular suppliers; however surveyors found that they are frequently unavailable.

Based on our review, the information available from Medicare completely matched AADE survey responses for only 3 suppliers. These 3 suppliers were the only suppliers for which the information available from Medicare accurately reflects the supplier’s current product offerings. In one particular instance, Medicare indicated that a supplier carried 12 brands; our surveyors found that only 2 brands were actually available from the supplier.

Chart 3



### Information gathered from suppliers is inconsistent

AADE also evaluated the consistency of the information provided by suppliers to surveyors.

In order to determine the consistency of the information available from NMO suppliers, 7 surveyors queried each supplier asking if particular brands of DTS were actually available for purchase from the supplier. We counted the number of times each surveyor was told by each supplier that a specific brand was available. Counts ranged from 7, where all 7 surveyors were told by the supplier that a brand was available, to 1 where the supplier told only a single surveyor that a brand was available. We repeated this for each brand and each supplier.

In order to determine how often suppliers provided accurate information, we counted the

number of times that 4 out of 7 surveyors (more than half of the responses) were told that a brand was available from a supplier, and the number of times all 7 surveyors were told that a brand was available. Ideally, suppliers would give surveyors and beneficiaries consistent responses to basic questions like which brands are available for purchase 100% of the time. However, to recognize that there might be some surveyor recording error or supplier-surveyor miscommunication, we provided response accuracy percentages for both 100% accuracy and more than 50% accuracy rates.

Table 1

Suppliers	Total Number of Brands Available from this Supplier	Number of times 4 of 7 surveyors were told a brand was available	Percentage of times 4 of 7 surveyors were told a brand was available	Number of times 7 out of 7 surveyors were told a brand was available	Percentage of times 7 out of 7 surveyors were told a brand was available
All American Medical Supplies, Inc.	9	2	22%	0	0%
All-States Medical Supply, Inc.	11	10	91%	2	18%
Am-Med Diabetic Supplies, Inc.	10	1	10%	0	0%
American Medical Supplies, Inc.	3	1	33%	0	0%
Arriva Medical, LLC	5	2	40%	1	20%
Binson's Hospital Supplies, Inc.,	8	6	75%	6	75%
Care Services, Inc.	7	3	43%	3	43%
DEGC Enterprises (U.S.), Inc.	8	8	100%	2	25%
Diabetes Care Club	13	13	100%	6	46%
Diagnostics Unlimited	14	9	64%	0	0%
Enteral Products, LLC	6	6	100%	0	0%
Home Care Delivered, Inc.	11	9	82%	0	0%
Home Delivery Incontinent Supplies Co., Inc.	11	10	91%	0	0%
Jade Diabetic Group LLC/Canyon Health Care LLC/101 Diabetic Supply	9	5	56%	0	0%
Kohl's Pharmacy & Homecare, Inc.	6	2	33%	0	0%

Lake Diabetes & Medical Supply, Inc/A1 Diabetes & Medical Supply	8	5	63%	0	0%
Lincare Pharmacy Services, Inc./Reliant Pharmacy Service/Diabetes Experts of America	5	3	60%	0	0%
Longcap DNS, LLC/Envoy Health	5	2	40%	0	0%
Med-Care Diabetic and Medical Supplies	9	2	22%	0	0%
United States Medical Supply, Inc.	8	5	63%	4	50%

Table 1 illustrates that when a supplier is queried on different occasions about the brands available, the information received from the supplier is inconsistent and unreliable. In only a very few occasions were all 7 surveyors given consistent responses about the brands available. Even with the lower “more than half” standard, accuracy rates are distressing.

These data suggest that if a beneficiary were to call on different occasions or if multiple beneficiaries were to call the same supplier, they are likely to receive conflicting information about product availability. This is especially disturbing given that beneficiaries must be able to rely on product related information from the supplier when ordering DTS. Providing inconsistent information to callers should not be considered acceptable.

**CONCLUSIONS**

This study shows that the NMO program is limiting access to DTS. Limited availability of products from suppliers is compounded by inconsistent and inaccurate information from Medicare and the suppliers themselves. These two factors serve to make it difficult for beneficiaries to find selected products and to remain with familiar test systems.

Physicians, diabetes educators and other health care practitioners recommend, and patients select testing systems on the basis of medical necessity, the needs of individual patients, and their experiences with the reliability and performance of specific products. For example, some beneficiaries need audible readings or large displays because of poor vision. Testing systems are not interchangeable. When a beneficiary is forced to use a testing system that is unknown, difficult, confusing, or unreliable, adherence to testing may diminish, increasing the risk of complications which can be costly for Medicare and its beneficiaries. For example, diabetic retinopathy which is one of the most common microvascular complications of diabetes and one of the major causes of blindness and low vision.

Effective and consistent self-monitoring of blood glucose levels is essential to diabetes control. Increased risk of devastating and costly complications – such as blindness,

kidney damage, cardiovascular disease, and lower-limb amputations – are associated with inadequate blood glucose control. If beneficiary access to the most appropriate or familiar glucose monitoring systems is disrupted, patient compliance with monitoring regimens may decrease, and adverse health complications may increase.

Unfortunately, the lack of product availability and the lack of consistent accurate information about product availability are leading to the unintended consequence of beneficiaries switching to different brands of testing supplies. AADE believes that Medicare beneficiaries should not feel pressured or have their choice of DTS compromised by suppliers' switching them from the testing systems with which they are familiar. However, the restrictions placed on the availability of supplies due to limited suppliers and the inaccurate information is doing just that.

## **RECOMMENDATIONS**

This study demonstrates the need for Congress and CMS to immediately address a number of flaws in the NMO program.

1) CMS should improve the information that it makes available to beneficiaries by:

- Developing a process whereby the information on Medicare.gov is regularly updated and accurately reflects a listing of currently participating suppliers and each supplier's currently available mix of products.
- Regularly and routinely communicating with Medicare beneficiaries with diabetes, using a variety of media including electronic and written means, so that beneficiaries are continuously reminded of their rights under the competitive bidding program.
- Creating standardized language for suppliers to use when addressing beneficiary questions regarding competitive bidding, particularly addressing product availability. Such language must include a reminder to the beneficiary that they are not required to change products if a preferred brand is not available from a particular supplier.

2) CMS should strengthen beneficiary protection requirements for future rounds of competitive bidding by requiring as a condition of continued participation in the competitive bidding program and not just as a condition of bid acceptance, that all suppliers continue to provide the same mix of brands and models as that which their bid acceptance was based upon.

3) CMS should regularly audit competitive bidding suppliers to ensure that they continue to meet all DME supplier standards for accreditation and quality. Audits must also include an evaluation of the supplier's continued adherence to program rules. CMS should also develop a corrective action plan program for suppliers who fail to adhere to statutory and regulatory requirements. Such plan should include removal from the program for suppliers with egregious and/or continued violation of programmatic rules.

## CONTACTS

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## Appendix A

<b>Suppliers Surveyed</b>
A-1 Diabetes & Medical Supply (*Note: supplier merged with Lake)
Discount Diabetic (No longer listed on MSD)
Mystic Medical (No longer listed on MSD)
All American Medical Supplies, Inc.
All-States Medical Supply, Inc.
American Medical Supplies, Inc.
Am-Med Diabetic Supplies, Inc.
Arriva Medical, LLC
Binson's Hospital Supplies, Inc.,
Care Services, Inc.
DEGC Enterprises (U.S.), Inc.
Diabetes Care Club
Diagnostics Unlimited
Enteral Products, LLC
Home Care Delivered, Inc.
Home Delivery Incontinent Supplies Co., Inc.
Jade Diabetic Group LLC/Canyon Health Care LLC/101 Diabetic Supply
Kohlls Pharmacy & Homecare, Inc.
Lake Diabetes & Medical Supply, Inc/A1 Diabetes & Medical Supply
Lincare Pharmacy Services, Inc./Reliant Pharmacy Service/Diabetes Experts of America
Longcap DNS, LLC/Envoy Health
Med-Care Diabetic and Medical Supplies
United States Medical Supply, Inc.

## Appendix B

### Medicare Competitive Bidding Program Supplier/Product Survey

#### BACKGROUND:

On July 1, 2013, the Centers for Medicare and Medicaid Services (CMS) implemented a National Mail Order (NMO) Medicare Competitive Bidding Program for certain items of durable medical equipment and supplies, including diabetes test strips (DTS). Under the new program, beneficiaries wishing to purchase DTS from a mail order supplier must do so from a winning bidder, known as a contract supplier.

The AADE is concerned that because of the payment amount established by CMS, contract suppliers are limiting the range of DTS available to Medicare beneficiaries, and actively trying to switch beneficiaries to less expensive product. The AADE wishes to know what products contract suppliers are making available to Medicare beneficiaries, whether Medicare beneficiaries can get replacement strips for preferred and familiar test systems, and whether contract suppliers have made accurate representations about which replacement strips are available to Medicare beneficiaries through CMS's website, Medicare.gov.

#### OBJECTIVE:

1. Determine whether the diabetes blood glucose test systems (meters/strips) advertised as available on the Medicare.gov website to Medicare beneficiaries from contract suppliers under the NMO Medicare Competitive Bidding Program are actually available.
2. Identify diabetes blood glucose test systems (meters/strips) actually available to Medicare beneficiaries from contract suppliers under the NMO program.

#### METHODOLOGY:

Surveyors will be furnished with a list of the 21 contract suppliers selected to participate in the NMO program and a list of DTS brands/models claimed to be available from each supplier according to the Medicare.gov supplier directory. Five surveyors will independently contact each of the 21 contract suppliers, and present the questions described below. Responses will be documented.

**KEY:**

Red = Question from surveyor

Black = Scripted language for surveyor

Blue = Action to be taken by surveyor.

**Survey Script**

Action:

Locate in the survey spreadsheet the name of the company with whom you are speaking. Answers to the survey will be documented in this spreadsheet. It is important that the information be entered in the correct places. All documentation of interviews must be done using the spreadsheet.

Prompt 1:

Hello, my name is \_\_\_\_\_ and I am a diabetes educator. I work with a large number of patients who routinely test their blood glucose level. Because Medicare is transitioning to a nation-wide competitive bidding program, I am trying to educate myself on the products that are going to be available so that I can in turn help these patients find what they need. I see on the CMS website that you carry a range of different brands and models of supplies. This may take a few minutes, but can I run through the list with you just to confirm that you do still carry all those products? This information is going to help me advise patients on where they can find their replacement strips.

If negative response:

Is there a better time that I can call to speak with someone? It's very important to our research that we speak with a representative of your company.

Prompt 2:

Thank you, may I have your name please? (Repeat the name), this won't take more than about 15 minutes of your time, if even that long. Your responses are very important and I promise to not waste your time.

Action:

Document the persons name with whom you are speaking.

Prompt 3:

Your company is listed as an eligible supplier of diabetes testing supplies, like monitors, lancets and test strips, under Medicare's competitive bidding program. Is this correct?

If positive response:

Document in the spreadsheet that the company is still participating in the NMO program.

If negative response:

Do you know why Medicare has your company listed as an eligible supplier?

Prompt 4:

Great, now I'd like to confirm that your company carries the brands and models that are listed on the Medicare.gov website. I'll go through these one brand at a time. Please tell me if you carry that particular brand and model. **Are you ready?**

Action:

Surveyors should locate the company name in the attached spreadsheet. Reading down the left most two columns of the spreadsheet, read off the brand and model name of each supply, allowing adequate time for the respondent to indicate an answer. Repeat prompts for each brand and model listed on the spreadsheet. Indicate the answers where shown on the spreadsheet.

Prompt 5:

Do you carry this product (product name) yes or no?

If positive response:

Document in spreadsheet

Continue to prompt 6

If negative response:

Document in spreadsheet

Did you every carry this product yes or no?

If positive response:

Why don't you carry it anymore?

Document answer in spreadsheet.

If negative response:

Document in spreadsheet.

Prompt 6:

Is this product currently available for purchase, yes or no?

If positive response:

[Document in spreadsheet](#)

[Continue to prompt 7](#)

If negative response:

Why is this product not available for purchase?

Prompt 7:

Is this product available to be shipped today?

If positive response:

[Document in spreadsheet](#)

[Continue to prompt 8](#)

If negative response:

When will this product be available to be shipped?

Prompt 8:

Are there any other diabetes testing brands and models that you carry that we haven't already talked about?

If positive response:

[Document in spreadsheet](#)

If negative response:

[Continue to prompt 9](#)

Prompt 9:

Thank you very much for your time. I greatly appreciate that you took the time to talk with me. Your answers will be most helpful.