



DEPARTMENT OF HEALTH AND HUMAN SERVICES

**OFFICE OF INSPECTOR GENERAL**

WASHINGTON, DC 20201



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Administrator  
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/S/

**FROM:** Brian P. Ritchie  
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**SUBJECT:** Memorandum Report: *Medicare Market Shares of Mail Order Diabetes Test Strips Immediately Prior to the National Mail Order Program*, OEI-04-13-00681

This report provides information on the types of mail order diabetes test strips associated with Medicare claims for the 3-month period of April to June 2013, i.e., the 3-month period immediately prior to the start of a national program for mail order diabetic testing supplies on July 1, 2013. The Centers for Medicare & Medicaid Services (CMS) asked the Office of Inspector General (OIG) to conduct a study to determine market shares of diabetes test strips for this 3-month period. CMS may choose to use the results of this report for program analysis purposes and to evaluate the effect of the Competitive Bidding Program on brand choice.

**SUMMARY**

Medicare covers diabetes test strips provided by mail order suppliers and local pharmacies or supplier storefronts. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) requires CMS to phase in, with several rounds of bidding, a Competitive Bidding Program for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). Under this program, suppliers compete to become Medicare contract suppliers for selected DMEPOS items. The payment amounts resulting from the competition replace the Medicare fee-schedule amounts for these items.

The Competitive Bidding Program includes diabetes test strips provided by mail order but does not include diabetes test strips purchased at a local pharmacy or supplier storefront (i.e., non-mail order). Under the program, "mail order" includes diabetes test strips shipped or delivered to the beneficiary's home, regardless of the method of delivery. Non-mail order diabetes test strips are those that a beneficiary picks up in person at a local pharmacy or supplier storefront. The American Taxpayer Relief Act of 2012 (ATRA) established equal Medicare payment amounts for mail order and non-mail order diabetes test strips purchased after the implementation of a national program for mail order diabetes testing supplies (hereinafter

referred to as the National Mail Order Program).<sup>1</sup> CMS implemented the National Mail Order Program on July 1, 2013.

The Medicare Improvements for Patients and Providers Act (MIPPA) prohibits CMS from awarding Competitive Bidding Program contracts for mail order diabetes test strips to suppliers who do not demonstrate that their bid covers at least 50 percent, by volume, of all types of diabetes test strips. (This is referred to as the MIPPA 50-percent requirement.) Further, MIPPA section 154(d)(3)(B) requires OIG to complete a study to determine market shares of diabetes test strips in the Competitive Bidding Program before each round of competitive bidding following Round 1.

We determined the Medicare market shares for diabetes test strip types associated with a random sample of Medicare claims for the 3-month period of April to June 2013, immediately prior to implementation of the National Mail Order Program. Our sample of 1,210 claims was drawn from a population of 1,363,668 claims for mail order diabetes test strips provided to beneficiaries during this period. We projected our sample data to the population of mail order diabetes test strips to estimate the Medicare market shares.

We found that 152 suppliers submitted claims for at least 62 types of mail order diabetes test strips for the 3-month period of April to June 2013. Two types of diabetes test strips accounted for 34 percent of the Medicare mail order market share. Four types of diabetes test strips accounted for 51 percent of the Medicare mail order market share, and 10 types accounted for 75 percent. CMS may choose to consider these data for its informational purposes and to evaluate the effect of the National Mail Order Program on brand choice.

## **BACKGROUND**

Diabetes is a chronic disease in which a person has a high blood sugar (i.e., glucose) level either because the body does not produce enough insulin, or cells do not respond properly to the insulin that the body does produce.<sup>2</sup> Diabetes may be managed through a variety of methods, including healthy eating, physical activity, and insulin injections.<sup>3</sup> If people with diabetes do not properly manage their glucose levels, medical complications (e.g., hypoglycemia, cardiovascular disease, or renal disease) may occur.

Diabetes disproportionately affects older adults. Approximately 27 percent of individuals ages 65 and older report having diabetes, whereas the reported percentage in the overall population is 8 percent.<sup>4</sup> Medicare covers services and testing supplies to help beneficiaries with diabetes manage the condition.

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<sup>1</sup> ATRA, P.L. No. 112-240 § 636 (adding Social Security Act, § 1834(a)(1)(H), 42 U.S.C. § 1395m(a)(1)(H)).

<sup>2</sup> National Institutes of Health (NIH), *Diabetes Overview: What is Diabetes?* Accessed at <http://www.diabetes.niddk.nih.gov/dm/pubs/overview/index.htm> on October 11, 2013.

<sup>3</sup> NIH, *Diabetes Overview: How is Diabetes Managed?* Accessed at <http://www.diabetes.niddk.nih.gov/dm/pubs/overview/index.htm#managed> on October 11, 2013.

<sup>4</sup> The Centers for Disease Control and Prevention. *Diabetes Self Management Overview*. Accessed at [http://www.cdc.gov/diabetes/pubs/pdf/ndfs\\_2011.pdf](http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2011.pdf) on October 3, 2013.

A person with diabetes may use a hand-held meter to test the concentration of glucose in his or her blood. To do so, the individual inserts a diabetes test strip into the meter. A diabetes test strip is a small, thin, one-time-use piece of plastic on which a sample of blood is placed after pricking the skin with a lancet. The meter's reading of an individual's glucose level provides the information required for that person to manage his or her diabetes. People with diabetes may need to perform glucose tests several times a day to assist them in maintaining appropriate glucose levels.

To be eligible for Medicare coverage of diabetes test strips and other diabetes supplies, Medicare beneficiaries with diabetes must be under the treatment of a physician for the condition.<sup>5</sup> The physician must prescribe the frequency of use for diabetes test strips.<sup>6</sup> Because some beneficiaries should test their glucose more frequently than others, the number of boxes of diabetes test strips per Medicare claim varies.<sup>7</sup> Each box contains 50 strips.

Suppliers submit one Medicare claim for a beneficiary's supply of diabetes test strips for up to 3 months at a time. Each claim indicates the number of boxes provided to the beneficiary for the applicable time period. Suppliers submit claims using Healthcare Common Procedure Coding System (HCPCS) codes to receive Medicare reimbursement. Medicare claims for diabetes test strips are billed using HCPCS code A4253. For diabetes test strips provided by mail order, the HCPCS code A4253 must use the KL modifier (A4253 KL).<sup>8</sup>

Medicare beneficiaries may purchase their diabetes test strips via mail order from suppliers in the Competitive Bidding Program or via non-mail order from local pharmacies or supplier storefronts. Mail order applies to diabetes test strips shipped or delivered to a beneficiary's residence.<sup>9</sup> For both mail order and non-mail order, Medicare pays 80 percent of allowed charges for diabetes test strips and the beneficiary is responsible for the remaining 20 percent.

### **The Competitive Bidding Program and National Mail Order Program for Diabetes Test Strips**

MMA required CMS to phase in, with several rounds of bidding, the Competitive Bidding Program for selected DMEPOS items, including mail order diabetes test strips.<sup>10</sup> The selected DMEPOS items are generally high-cost and high-volume items that have a high savings potential

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<sup>5</sup> Other diabetes testing supplies may include batteries and control solution.

<sup>6</sup> Medicare Local Coverage Determinations (LCDs) for Glucose Monitors (L11530, L27231, L11520, and L196 for Durable Medical Equipment Medicare Administrative Contractor Jurisdictions A, B, C, and D respectively).

<sup>7</sup> CMS, *MLN Matters Number SE1008. An Overview of Medicare Covered Diabetes Supplies and Services*. Accessed at <http://www.cms.gov/MLN MattersArticles/downloads/SE1008.pdf> on October 25, 2013. Medicare covers up to 100 testing strips per month (i.e., two 50-count boxes) for insulin-dependent beneficiaries with diabetes and up to 100 testing strips every 3 months for noninsulin-dependent beneficiaries with diabetes. Medicare allows additional testing strips if deemed medically necessary and documented in physician records. Medicare LCDs for Glucose Monitors (L11530, L27231, L11520, and L196).

<sup>8</sup> *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 36 §§ 20.5.4.1 and 50.6. A modifier is a code on a Medicare claim that further describes the services performed or supplies provided to a beneficiary.

<sup>9</sup> 42 CFR § 414.402 (defining "mail order item").

<sup>10</sup> MMA, P.L. No. 108-173 § 302(b)(1) (amending Social Security Act, § 1847, 42 U.S.C. § 1395w-3).

under the Competitive Bidding Program.<sup>11</sup> CMS uses bids submitted by DMEPOS suppliers to determine the competitive bidding payment amounts. Bids are evaluated based on suppliers' eligibility, their financial stability, and the bid price.<sup>12</sup> Contracts are awarded to the suppliers that generally offer lower prices and meet applicable quality and financial standards.<sup>13</sup> Round 1 of the Competitive Bidding Program began on January 1, 2011. Round 2 began on July 1, 2013. See Appendix A for more information about Rounds 1 and 2 of the Competitive Bidding Program.

MIPPA required, after Round 1 of the Competitive Bidding Program, that mail order suppliers must demonstrate in their bids that they provide at least 50 percent, by volume, of all types of diabetes test strips.<sup>14</sup> Further, MIPPA section 154(d)(3)(B) requires OIG to complete a study to determine market shares of mail order diabetes test strips in the Competitive Bidding Program before each subsequent round of competitive bidding.<sup>15</sup>

*National Mail Order Program.* MIPPA authorized a National Mail Order Program beginning July 1, 2013, for mail order diabetes testing supplies, expanding the Competitive Bidding Program to all U.S. States and Territories. Additionally, ATRA established equal Medicare payment amounts for mail order and non-mail order diabetes test strips provided after implementation of the National Mail Order Program. CMS implemented both the National Mail Order Program and Round 2 of the Competitive Bidding Program on July 1, 2013.<sup>16</sup> Thus, under Round 2 of the Competitive Bidding Program, both mail order and non-mail order diabetes test strips are reimbursed at the same competitive bidding payment rate, \$10.41 per 50-count box.

### **Related OIG Work**

In December 2010, OIG completed the first report to fulfill its MIPPA requirement to determine market shares of diabetes test strips before 2011. OIG found that 171 suppliers submitted claims

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<sup>11</sup> CMS, *General Overview of the Final Rule for Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies*. Accessed at <https://www.cms.gov/DMEPOSCompetitiveBid/Downloads/DMEPOSRegSumm.pdf> on October 4, 2013; 73 Fed. Reg. 17992, 18010 (Apr. 10, 2007).

<sup>12</sup> Palmetto GBA, *Overview of the DMEPOS Competitive Bidding Program*. Accessed at <http://www.dmecompetitivebid.com/palmetto/cbic.nsf/vMasterDID/79NTSG0132> on October 16, 2013.

<sup>13</sup> Palmetto GBA, *How a Bid is Evaluated*. Accessed at [http://www.dmecompetitivebid.com/Palmetto/cbicrd2.nsf/files/Webcast\\_Transcript\\_Bid\\_Evaluation.pdf/\\$File/Webcast\\_Transcript\\_Bid\\_Evaluation.pdf](http://www.dmecompetitivebid.com/Palmetto/cbicrd2.nsf/files/Webcast_Transcript_Bid_Evaluation.pdf/$File/Webcast_Transcript_Bid_Evaluation.pdf) on February 24, 2014; CMS, *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 36, § 40.1. The payment amount for an item furnished under the competitive bidding program is equal to the median of the bids submitted by qualified suppliers whose composite bids are equal to or below the “pivotal bid” for that product category. 42 CFR § 414.416(b). The pivotal bid is the lowest composite bid based on bids submitted by suppliers that includes a sufficient number of suppliers to meet beneficiary demand for the items in a product category. 42 CFR § 414.402.

<sup>14</sup> Specifically, MIPPA stipulates that suppliers provide at least “50 percent (or such higher percentage as the Secretary may specify)” of all diabetes test strips “in the aggregate and taking into account volume for the different products.” MIPPA, P.L. No. 110-275 § 154(d)(3)(B) (adding Social Security Act § 1847(b)(10)(A), 42 U.S.C. § 1395w-3(b)(10)(A)).

<sup>15</sup> MIPPA, P.L. No. 110-275 § 154(d)(3)(B) (adding Social Security Act § 1847(b)(10)(B), 42 U.S.C. § 1395w-3(b)(10)(B)).

<sup>16</sup> CMS, *Contract Suppliers Selected Under Medicare Competitive Bidding Program*. Accessed at <http://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2013-Press-releases-items/2013-04-092.html> on February 19, 2014. Eighteen contracts were awarded to suppliers to provide diabetes testing supplies through the National Mail Order Program.

for at least 75 types of mail order diabetes test strips for the 3-month period ending December 2009.<sup>17</sup> Of these strips, 2 types accounted for approximately 26 percent of the Medicare mail order market share, 7 types accounted for approximately 50 percent, and 19 types accounted for approximately 81 percent.

In a June 2014 report, OIG determined the market share of diabetes test strips for the 3-month period of July to September 2013, beginning with implementation of the National Mail Order Program.<sup>18</sup> OIG found that 22 suppliers submitted claims for at least 43 types of mail order diabetes test strips for that period. Two types of diabetes test strips accounted for approximately 45 percent of the Medicare mail order market share. Three types of diabetes test strips accounted for 59 percent of the Medicare mail order market share and 10 types accounted for 90 percent. That report fulfilled OIG's MIPPA requirement.

Finally, OIG is working on a study to determine the market share of diabetes test strips for the 3-month period of October to December 2013, several months after implementation of the National Mail Order Program.<sup>19</sup> OIG expects to release the report for this study in December 2014. CMS asked OIG to conduct this study so that the results may be used for program analysis purposes and to evaluate the effect of the National Mail Order Program on brand selection.

## **METHODOLOGY**

### **Data Collection**

We identified the population of Medicare mail order diabetes test strips claims with a beginning date of service from April through June 2013 from CMS's National Claims History file. This timeframe represents the 3-month period immediately prior to the start of the National Mail Order Program on July 1, 2013. There were 1,363,668 claims submitted by 1,294 suppliers in this file. We then selected a simple random sample of 1,210 of the 1,363,668 Medicare claims for mail order diabetes test strips within our date-of-service range. To identify the beneficiaries associated with each claim in our sample, we matched them with the CMS Beneficiary Enrollment Database.

We sent a documentation request to 154 suppliers associated with the claims in our sample. For each claim, we asked the supplier to indicate the type (model and manufacturer) of diabetes test strips that it provided to the Medicare beneficiary associated with the claim and to submit relevant documentation (e.g., packing slips, invoices for the strips).<sup>20</sup> We received responses from 152 suppliers associated with 1,199 claims in our sample, a 99-percent response rate.

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<sup>17</sup> OIG, *Medicare Market Shares of Mail Order Diabetic Testing Strips* (OEI-04-11-00130), December 2010.

<sup>18</sup> OIG, *Medicare Market Shares of Mail Order Diabetes Test Strips From July–September 2013* (OEI-04-13-00680), June 2014.

<sup>19</sup> OEI-04-13-00682, in progress.

<sup>20</sup> We contacted suppliers up to three times to obtain this information.

### **Data Analysis**

We reviewed claims data and supplier documentation and responses to determine the quantity and type of mail order diabetes test strips associated with each claim in our sample. Each claim in our sample contained between 1 and 15 boxes, and data for the 1,199 claims provides information for a total of 4,357 boxes of diabetes test strips.<sup>21</sup>

We categorized types of diabetes test strips by model and manufacturer. We accounted for the volume of each type by determining the total number of 50-count boxes of each type of diabetes test strip and the percentage of each type across all boxes. We projected our sample data to the population of mail order diabetes test strips during our time period to estimate the Medicare market shares of mail order diabetes test strip types.

### **Limitations**

Suppliers have 1 year to submit claims to CMS. Types of diabetes test strips associated with claims during our time period (i.e., with beginning dates of service in the months of April through June 2013) submitted after November 1, 2013—the date we collected our Medicare claims—are not included.

### **Standards**

This review was conducted in accordance with the *Quality Standards for Inspections* approved by the Council of the Inspectors General on Integrity and Efficiency.

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<sup>21</sup> Most claims (93 percent) were for 1 to 6 boxes.

## RESULTS

### Suppliers Submitted Claims for at Least 62 Types of Mail Order Diabetes Test Strips for the 3-Month Period of April to June 2013

One hundred fifty-two suppliers submitted claims for at least 62 types of mail order diabetes test strips for the 3-month period of April to June 2013. Two types of diabetes test strips accounted for 34 percent of the Medicare mail order market share. Four types of diabetes test strips accounted for 51 percent of the Medicare mail order market share, and 10 types accounted for 75 percent.

Table 1 lists the top 10 types of mail order diabetes test strips associated with Medicare claims for the 3-month period of April to June 2013. See Appendix B for a complete alphabetical listing of all 62 types. Appendix B also provides the model, manufacturer, percentage of market share, and 95-percent confidence intervals for market share for each type of diabetes test strip.

**Table 1: Top 10 Mail Order Diabetes Test Strips Types Associated With Medicare Claims for the 3-Month Period of April to June 2013**

Model	Manufacturer	Percentage of Market Share
Prodigy AutoCode	Prodigy Diabetes Care	19.4%
TRUEtest	Nipro Diagnostics, Inc.	14.7%
Gmate	Philosys, Inc.	8.5%
Embrace	Omnis Health	8.2%
OneTouch Ultra Blue	LifeScan, Inc.	5.0%
SolusV2	BioSense Medical Devices	4.7%
CONTOUR	Bayer HealthCare LLC	4.6%
OneTouch Ultra	LifeScan, Inc.	4.1%
FreeStyle Lite	Abbott Diabetes Care	3.1%
Element	Infopia USA	2.2%
<b>Total</b>		<b>74.5%</b>

Source: OIG analysis of supplier documentation and Medicare claims containing HCPCS code A4253 KL for the 3-month period of April to June 2013.

## CONCLUSION

One hundred fifty-two suppliers submitted claims for at least 62 types of mail order diabetes test strips for the 3-month period of April to June 2013, immediately prior to the start of the National Mail Order Program. Two types of diabetes test strips accounted for 34 percent of the Medicare mail order market share. Four types of diabetes test strips accounted for 51 percent of the Medicare mail order market share, and 10 types accounted for 75 percent. CMS may choose to consider these data for program analysis purposes and to evaluate the effect of the Competitive Bidding Program on brand choice.

This memorandum report is being issued directly in final form because it contains no recommendations. If you have comments or questions about this report, please provide them within 60 days. Please refer to report number OEI-04-13-00681 in all correspondence.

## Appendix A

### Round 1 of the Competitive Bidding Program

The MMA of 2003 required CMS to phase in, with several rounds of bidding, a Competitive Bidding Program for DMEPOS. Suppliers began submitting bids for Round 1 of the Competitive Bidding Program on May 15, 2007. Contracts between CMS and suppliers became effective in selected Competitive Bidding Areas (CBAs) on July 1, 2008.<sup>22</sup>

Two weeks after the Round 1 contracts between CMS and suppliers became effective, Congress enacted MIPPA, which mandated the following changes to the Competitive Bidding Program:

- the termination of contracts awarded to suppliers in Round 1;
- the requirement for CMS to repeat the Round 1 competition in 2009; and
- the institution of the MIPPA 50-percent requirement for mail order diabetes test strips in all rounds following the repeat of the Round 1 competition. (The repeat of the Round 1 competition is known as the Round 1 Rebid.)<sup>23</sup>

MIPPA also reduced the 2009 fee-schedule amounts by 9.5 percent for all DMEPOS included in Round 1 to offset the estimated cost savings lost by the delayed implementation of the Competitive Bidding Program.<sup>24</sup> This reduction resulted in an average 2009 fee-schedule amount of \$32.50 per box of mail order diabetes test strips.

The Round 1 Rebid began in October 2009 and included the previous selected CBAs, except for San Juan–Caguas–Guaynabo (Puerto Rico). CMS announced the winning contract suppliers on November 3, 2010, and the suppliers began providing competitively bid DMEPOS items to beneficiaries in nine selected CBAs on January 1, 2011.<sup>25</sup> Before 2011, Medicare reimbursed all diabetes test strips suppliers on the basis of fee-schedule amounts, which were updated annually and varied by State. As a result of the Round 1 Rebid, the average Medicare payment for 2011 mail order diabetes test strips provided to beneficiaries in CBAs was \$14.62 per 50-count box. In contrast, the national average Medicare payment for mail order strips in non-CBAs was

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<sup>22</sup> CMS, *DMEPOS Competitive Bidding*. Accessed at [http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/index.html?redirect=/DMEPOSCompetitiveBid/01a\\_MSAs\\_and\\_CBAs.asp](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/index.html?redirect=/DMEPOSCompetitiveBid/01a_MSAs_and_CBAs.asp) on November 5, 2013. CBAs are defined by specific ZIP Codes related to Metropolitan Statistical Areas (MSAs). Selected CBAs in Round 1 were Charlotte–Gastonia–Concord (North Carolina and South Carolina), Cincinnati–Middletown (Ohio, Kentucky, and Indiana), Cleveland–Elyria–Mentor (Ohio), Dallas–Fort Worth–Arlington (Texas), Kansas City (Missouri and Kansas), Miami–Fort Lauderdale–Pompano Beach (Florida), Orlando–Kissimmee (Florida), Pittsburgh (Pennsylvania), and Riverside–San Bernardino–Ontario (California).

<sup>23</sup> The 50-percent requirement did not apply to suppliers' bids in Round 1 or the Round 1 Rebid.

<sup>24</sup> CMS, *MLN Matters Number MM6270: Fee Schedule Update for 2009 for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)*. Accessed at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6270.pdf> on November 20, 2013.

<sup>25</sup> MMA, P.L. No. 108-173 § 302(b)(1), as amended by MIPPA, P. L. No. 110-174 § 154. CMS, *Competitive Bidding Areas*. Accessed at [http://www.dmecompetitivebid.com/Palmetto/Cbic.nsf/files/Fact\\_Sheet\\_Competitive\\_Bidding\\_Areas.pdf/\\$File/Fact\\_Sheet\\_Competitive\\_Bidding\\_Areas.pdf](http://www.dmecompetitivebid.com/Palmetto/Cbic.nsf/files/Fact_Sheet_Competitive_Bidding_Areas.pdf/$File/Fact_Sheet_Competitive_Bidding_Areas.pdf) on November 5, 2013.

\$32.47, and the national average payment for non-mail order diabetes test strips was \$37.67. CMS also reported that the Competitive Bidding Program saved the Medicare program nearly \$202.1 million in the first year of implementation.<sup>26</sup>

### **Round 2 of the Competitive Bidding Program**

MIPPA required competition for Round 2 of the Competitive Bidding Program to occur in 2011 in 70 additional CBAs.<sup>27</sup> The Patient Protection and Affordable Care Act of 2010 further expanded the number of CBAs to 100 and required CMS to expand the DMEPOS competitive bidding program nationwide or to adjust payments to suppliers using competitively bid rates by 2016.<sup>28</sup> Round 2 of the Competitive Bidding Program began on July 1, 2013.

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<sup>26</sup> CMS, *Competitive Bidding Update—One Year Implementation Update April 17, 2012*. Accessed at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Downloads/Competitive-Bidding-Update-One-Year-Implementation.pdf> on October 7, 2013.

<sup>27</sup> MIPPA, P.L. No. 110-275 § 154(d)(3)(A).

<sup>28</sup> CMS, *DMEPOS Competitive Bidding Program*. Accessed at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/> on November 18, 2013. MIPPA allows for MSAs that have populations over 8 million to be subdivided into multiple CBAs. Most Round 2 MSAs contain only one CBA; however, the three largest MSAs—Chicago, Los Angeles, and New York—are subdivided into multiple CBAs.

**Appendix B**

<b>Market Share Estimates and Their 95-Percent Confidence Intervals for 62 Types of Mail Order Diabetes Test Strips for the 3-Month Period of April to June 2013</b>			
<b>Model</b>	<b>Manufacturer</b>	<b>Percentage of Market Share</b>	<b>95-Percent Confidence Interval for Market Share</b>
ACCU-CHEK Aviva	Roche Diagnostics	0.14%	0.03%–0.25%
ACCU-CHEK Aviva Plus	Roche Diagnostics	2.13%	1.71%–2.56%
ACCU-CHEK Comfort Curve	Roche Diagnostics	0.39%	0.21%–0.58%
ACCU-CHEK Compact	Roche Diagnostics	1.03%	0.73%–1.33%
ACCU-CHEK Compact Plus	Roche Diagnostics	0.09%	0.00%–0.18%
ACCU-CHEK SmartView*	Roche Diagnostics	1.74%	1.36%–2.13%
Advance Intuition	Arkray USA	0.05%	0.00%–0.11%
Advocate	Diabetic Supply of Suncoast, Inc.	0.46%	0.26%–0.66%
Advocate Redi-Code	Diabetic Supply of Suncoast, Inc.	1.24%	0.91%–1.57%
Advocate Redi-Code +	Diabetic Supply of Suncoast, Inc.	0.87%	0.60%–1.15%
BREEZE 2	Bayer HealthCare LLC	1.77%	1.38%–2.16%
Care Sens	i-Sens	0.37%	0.19%–0.55%
Care Sens N	i-Sens	0.23%	0.09%–0.37%
Clever Chek	Simple Diagnostics	0.18%	0.06%–0.31%
Clever Choice Pro	Simple Diagnostics	0.32%	0.15%–0.49%
Clever Choice Voice	Simple Diagnostics	0.57%	0.35%–0.80%
Clever Choice Voice Plus	Simple Diagnostics	0.05%	0.00%–0.11%
CONTOUR	Bayer HealthCare LLC	4.57%	3.95%–5.19%
CONTOUR NEXT	Bayer HealthCare LLC	1.63%	1.25%–2.01%
CONTOUR TS	Bayer HealthCare LLC	1.15%	0.83%–1.46%
EasyGluco G2	US Diagnostics	0.14%	0.03%–0.25%
EasyGluco Plus	US Diagnostics	0.48%	0.28%–0.69%
EASYMAX N	Oak Tree International Holdings	0.69%	0.44%–0.93%
EASYMAX V	Oak Tree International Holdings	0.05%	0.00%–0.11%
Easy Plus II	Home Aide Diagnostics	0.18%	0.06%–0.31%
Easy Step	Home Aide Diagnostics	0.09%	0.00%–0.18%
Easy Talk	Home Aide Diagnostics	0.23%	0.09%–0.37%
Element	Infopia USA	2.16%	1.73%–2.59%

\*This diabetes test strip may also be listed as the ACCU-CHEK Nano SmartView.

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Medicare Market Shares of Mail Order Diabetes Test Strips Immediately Prior to the National Mail Order Program (OEI-04-13-00681)

**Appendix B**

<b>Market Share Estimates and Their 95-Percent Confidence Intervals for 62 Types of Mail Order Diabetes Test Strips for the 3-Month Period of April to June 2013 (continued)</b>			
<b>Model</b>	<b>Manufacturer</b>	<b>Percentage of Market Share</b>	<b>95-Percent Confidence Interval for Market Share</b>
Embrace	Omnis Health	8.17%	7.36%–8.98%
Evencare G2	Medline Industries, Inc.	0.09%	0.00%–0.18%
V10/D20	ForaCare, Inc.	0.14%	0.03%–0.25%
V30a	ForaCare, Inc.	0.05%	0.00%–0.11%
FreeStyle	Abbott Diabetes Care	0.05%	0.00%–0.11%
FreeStyle InsuLinx	Abbott Diabetes Care	0.32%	0.15%–0.49%
FreeStyle Lite	Abbott Diabetes Care	3.12%	2.61%–3.64%
GE 100	BIONIME USA Corporation	0.14%	0.03%–0.25%
GLUCOCARD 01	Arkray USA	0.23%	0.09%–0.37%
GLUCOCARD Expression	Arkray USA	0.92%	0.63%–1.20%
GLUCOCARD Vital	Arkray USA	0.69%	0.44%–0.93%
GlucNavii	SD Biosensor, Inc.	0.14%	0.03%–0.25%
GM100	BIONIME USA Corporation	0.09%	0.00%–0.18%
GM300	BIONIME USA Corporation	1.61%	1.23%–1.98%
Gmate	Philosys, Inc.	8.54%	7.71%–9.37%
INFINITY	US Diagnostics	0.23%	0.09%–0.37%
Liberty 2	Nipro Diagnostics, Inc.	0.83%	0.56%–1.10%
Liberty Autocode	AgaMatrix, Inc.	0.46%	0.26%–0.66%
NovaMax	Nova Biomedical	0.76%	0.50%–1.01%
On-Call Plus	ACON Laboratories, Inc.	0.18%	0.06%–0.31%
OneTouch Select	LifeScan, Inc.	0.37%	0.19%–0.55%
OneTouch Ultra	LifeScan, Inc.	4.11%	3.52%–4.70%
OneTouch Ultra Blue	LifeScan, Inc.	5.03%	4.38%–5.68%
OneTouch Verio	LifeScan, Inc.	0.25%	0.10%–0.40%
OptiumEZ	Abbott Diabetes Care	0.14%	0.03%–0.25%
Perfect 3	Gluc Perfect	0.05%	0.00%–0.11%
Prodigy AutoCode	Prodigy Diabetes Care	19.44%	18.26%–20.62%

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**Appendix B**

<b>Market Share Estimates and Their 95-Percent Confidence Intervals for 62 Types of Mail Order Diabetes Test Strips for the 3-Month Period of April to June 2013 (continued)</b>			
<b>Model</b>	<b>Manufacturer</b>	<b>Percentage of Market Share</b>	<b>95-Percent Confidence Interval for Market Share</b>
Solo V2	BioSense Medical Devices	0.78%	0.52%–1.04%
SolusV2	BioSense Medical Devices	4.71%	4.08%–5.33%
SureEdge	Specialty Medical Supplies	0.05%	0.00%–0.11%
TRUEbalance	Nipro Diagnostics, Inc.	0.50%	0.29%–0.72%
TRUEtest	Nipro Diagnostics, Inc.	14.71%	13.66%–15.76%
Vero Star TK	TEMCare Medical Design & Manufacturing, Inc.	0.09%	0.00%–0.18%
WaveSense Presto	AgaMatrix, Inc.	0.05%	0.00%–0.11%
<b>Total</b>		<b>100.00%**</b>	

Source: OIG analysis of supplier documentation and Medicare claims containing HCPCS code A4253 KL for the 3-month period of April to June 2013.

\*\*Column does not sum to 100 percent because of rounding.