



DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



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TO: Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services

/S/

FROM: Brian P. Ritchie
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SUBJECT: Memorandum Report: *Medicare Market Shares of Mail Order Diabetes Test Strips From July–September 2013*, OEI-04-13-00680

This report provides information on the types of mail order diabetes test strips associated with Medicare claims for the 3-month period of July to September 2013. Section 154(d)(3)(B) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) requires the Office of Inspector General (OIG) to complete a study to determine market shares of diabetes test strips before each round of competitive bidding following Round 1 of the Competitive Bidding Program. This report fulfills the MIPPA requirement for the pending third round of competitive bidding; a 2010 OIG report fulfilled the MIPPA requirement to complete a study determining market shares of diabetes test strips before 2011.

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 the Centers for Medicare & Medicaid Services (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 competition for mail order diabetes testing supplies (hereinafter referred to as the National Mail Order Program).¹ CMS implemented the National Mail Order Program on July 1, 2013.

MIPPA prohibits CMS from awarding Competitive Bidding Program contracts for mail order diabetes test strips to suppliers that 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 July to September 2013. Our sample of 1,210 claims was drawn from a population of approximately 505,000 claims for mail order diabetes test strips provided to beneficiaries during this period. To estimate the Medicare market shares, we projected our sample data to the population of mail order diabetes test strips.

We found that 22 suppliers submitted at least 43 types of mail order diabetes test strips for the 3-month period of July to September 2013. 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. CMS may consider these data when determining whether subsequent rounds of suppliers' mail order diabetes test strip bids comply with the MIPPA 50-percent requirement.

BACKGROUND

Diabetes is a chronic disease in which a person has a high level of blood sugar (i.e., glucose) because either the body does not produce enough insulin, or cells do not respond properly to the insulin that the body does produce.² Diabetes may be managed through a variety of methods, including healthy eating, physical activity, and insulin injections.³ 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 in the United States report having diabetes, whereas the reported percentage in the overall population is 8 percent.⁴ Medicare covers services and testing supplies to help beneficiaries with diabetes manage the condition.

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

² 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.

³ 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.

⁴ The Centers for Disease Control and Prevention. *Diabetes Self Management Overview*. Accessed at 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.⁵ The physician must prescribe the frequency of use for diabetes test strips.⁶ Because some beneficiaries should test their glucose more frequently than others, the number of boxes of diabetes test strips per Medicare claim varies.⁷ 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).⁸

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.⁹ 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 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.¹⁰ The selected DMEPOS items are generally high-cost and high-volume items that have a high savings potential

⁵ Other diabetes testing supplies may include batteries and control solution.

⁶ 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).

⁷ 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 for Durable Medical Equipment Medicare Administrative Contractor Jurisdictions A, B, C, and D respectively).

⁸ 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.

⁹ 42 C.F.R. § 414.402 (defining "mail order item").

¹⁰ 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.¹¹ CMS uses bids submitted by DMEPOS suppliers to determine the payment amounts under the program. Bids are evaluated based on suppliers' eligibility, their financial stability, and the bid price.¹² Contracts are awarded to the suppliers that generally offer lower prices and meet applicable quality and financial standards.¹³

MIPPA also requires mail order suppliers to demonstrate in their bids that they provide at least 50 percent, by volume, of all types of diabetes test strips.¹⁴ This 50-percent requirement is intended to ensure that most beneficiaries can receive their preferred type of diabetes test strips. Further, the MIPPA section 154(d)(3)(B) requires the OIG to complete a study to determine market shares of mail order diabetes test strips in the Competitive Bidding Program before each round of bidding following Round 1.¹⁵

Round 1 of the Competitive Bidding Program. Before 2011, Medicare reimbursed all diabetes test strips suppliers on the basis of fee-schedule amounts, which were updated annually and varied by State. In January 2011, CMS implemented Round 1 of its Competitive Bidding Program for selected DMEPOS in nine Competitive Bidding Areas (CBAs).¹⁶ Competitive bidding payment amounts replaced the fee schedule amounts for mail order diabetes test strips in

¹¹ 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).

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

¹³ 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.

¹⁴ 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 § 154(d)(3)(A). The 50-percent requirement did not apply to suppliers' bids in Round 1 of the Competitive Bidding Program.

¹⁵ 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)).

¹⁶ MMA, P.L. No. 108-173 § 302(b)(1), as amended by MIPPA, P. L. No. 110-275 § 154. CBAs are defined by specific ZIP Codes related to Metropolitan Statistical Areas (MSAs). 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. 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).

these CBAs. Mail order diabetes test strips were included in Round 1 of the Competitive Bidding Program, but non-mail order test strips were not.¹⁷

As a result of Round 1 of the Competitive Bidding Program, the average Medicare payment in 2011 for 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 diabetes test strips in non-CBAs (i.e., areas that were not a part of the Competitive Bidding Program) was \$32.47, and the national average payment for non-mail order diabetes test strips was \$37.67. See Appendix A for more information about Round 1 of the Competitive Bidding Program.

Round 2 of the Competitive Bidding Program and the National Mail Order Program. MIPPA required competition for Round 2 of the Competitive Bidding Program to occur in 2011 in 70 additional CBAs.¹⁸ 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 2016.¹⁹

MIPPA authorized a National Mail Order Program for mail order diabetes testing supplies, expanding the Competitive Bidding Program from the nine CBAs in Round 1 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.²⁰ CMS implemented both the National Mail Order Program and Round 2 of the Competitive Bidding Program on July 1, 2013.²¹ 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

This report fulfills OIG's MIPPA requirement for the pending third round of competitive bidding and is part of a body of work on the Medicare market share of diabetes test strips. CMS requested two additional reports—one that determines the market share of diabetes test strips for the 3-month period of April to June 2013, immediately preceding the National Mail Order

¹⁷ During Round 1 of the Competitive Bidding Program, mail order diabetes test strips were defined as items ordered remotely (that is, by telephone, email, Internet, or mail) and delivered to a beneficiary's residence by common carriers (for example, U.S. Postal Service, Federal Express, United Parcel Service). It did not include items obtained by beneficiaries from local storefronts. After Round 1 of the Competitive Bidding Program, CMS expanded the definition of mail order to include "any item (for example, diabetes testing supplies) shipped or delivered to the beneficiary's home, regardless of the method of delivery." 75 Fed. Reg. 73170, 73570, and 73623 (Nov. 29, 2010) (revising the definition of "mail order item" in 42 CFR 414.402 and explaining why the new definition will not apply to Round 1).

¹⁸ MIPPA, P.L. No. 110-275 § 154(d)(3)(A).

¹⁹ 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.

²⁰ ATRA, P.L. No. 112-240 § 636 (adding Social Security Act, § 1834(a)(1)(H), 42 U.S.C. § 1395m(a)(1)(H)).

²¹ 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.

Program, and another that determines the market share of diabetes test strips for the 3-month period of October to December 2013, several months after the National Mail Order Program began.²² CMS requested these additional reports for informational purposes and to evaluate the impact of competitive bidding on brand selection.

Additionally, in 2010, OIG published the first report to fulfill its MIPPA requirement to complete a study determining market shares of diabetes test strips before 2011. OIG found that 171 suppliers submitted claims for at least 75 types of mail order diabetes test strips for the 3-month period of October to December 2009.²³ Of these strips, two types accounted for approximately 26 percent of the Medicare mail order market share, 7 types accounted for approximately 50 percent of the Medicare mail order market share, and 19 types accounted for approximately 81 percent.

METHODOLOGY

Data Collection

We identified the population of Medicare claims for mail order diabetes test strips from CMS's National Claims History file with a beginning date of service from July through September 2013. In this file, there were 504,916 claims submitted by 80 suppliers. We then selected a simple random sample of 1,210 of these 504,916 claims 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 22 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).²⁴ We received responses from 22 suppliers associated with 1,190 claims in our sample, a 98-percent response rate.

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. The 1,190 claims each covered from 1 to 19 boxes of strips, and data for these claims provide information for a total of 4,656 such boxes.²⁵

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 strip and the percentage 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 strip types.

²² OEI-04-13-00681 and OEI-04-13-00682, in progress.

²³ OIG, *Medicare Market Shares of Mail Order Diabetic Testing Strips* (OEI-04-10-00130), December 2010.

²⁴ We contacted suppliers up to three times to obtain this information.

²⁵ Most claims (91 percent) were for 1 to 6 boxes.

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 July through September 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.

RESULTS

Suppliers Submitted Claims for at Least 43 Types of Mail Order Diabetes Test Strips for the 3-Month Period of July to September 2013

Twenty-two suppliers submitted at least 43 types of mail order diabetes test strips for the 3-month period of July to September 2013. 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.

Table 1 lists the top 10 types of mail order diabetes test strips associated with Medicare claims for the 3-month period of July to September 2013. See Appendix B for a complete alphabetical listing of all 43 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 Strip Types Associated With Medicare Claims for the 3-Month Period of July to September 2013

Model	Manufacturer	Percentage of Market Share
Prodigy AutoCode	Prodigy Diabetes Care	23.9%
OneTouch Ultra Blue	LifeScan, Inc.	20.7%
TRUEtest	Nipro Diagnostics, Inc.	14.8%
Embrace	Omnis Health	8.5%
Solus V2	BioSense Medical Devices	6.9%
Advocate Redi-Code +	Diabetic Supply of Suncoast, Inc.	4.6%
Nova Max	Nova Biomedical	4.5%
CONTOUR	Bayer HealthCare LLC	2.2%
ACCU-CHEK Smartview*	Roche Diagnostics	2.1%
ACCU-CHEK Aviva Plus	Roche Diagnostics	2.1%
Total		90.3%

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

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

CONCLUSION

Twenty-two suppliers submitted at least 43 types of mail order diabetes test strips for the 3-month period of July to September 2013. 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. CMS may choose to consider these data when determining whether subsequent rounds of suppliers' mail order diabetes test strip bids comply with the MIPPA 50-percent requirement.

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-04-13-00680 in all correspondence.

Appendix A

Round 1 of the Competitive Bidding Program

The MMA 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 CBAs on July 1, 2008.²⁶

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.)²⁷

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.²⁸ This reduction resulted in an average 2009 fee-schedule amount of \$32.50 per 50-count 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 CBAs on January 1, 2011. 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 \$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.²⁹

²⁶ 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 on November 5, 2013. For a list of CBAs in Round 1, see footnote 16.

²⁷ The 50-percent requirement did not apply to suppliers' bids in Round 1 or the Round 1 Rebid.

²⁸ 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.

²⁹ 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.

Appendix B**Market Share Estimates for 43 Types of Mail Order Diabetes Test Strips, and the 95-Percent Confidence Intervals for Those Estimates**

Market Share Estimates for 43 Types of Mail Order Diabetes Test Strips, and the 95-Percent Confidence Intervals for Those Estimates			
Model	Manufacturer	Percentage of Market Share	95-Percent Confidence Interval for Market Share
ACCU-CHEK Aviva	Roche Diagnostics	0.71%	0.47–0.95%
ACCU-CHEK Aviva Plus	Roche Diagnostics	2.10%	1.69–2.52%
ACCU-CHEK Compact	Roche Diagnostics	0.30%	0.14–0.46%
ACCU-CHEK Compact Plus	Roche Diagnostics	0.45%	0.26–0.64%
ACCU-CHEK Smartview*	Roche Diagnostics	2.13%	1.71–2.54%
Advocate	Diabetic Supply of Suncoast, Inc.	0.34%	0.18–0.51%
Advocate Redi-Code	Diabetic Supply of Suncoast, Inc.	0.17%	0.05–0.29%
Advocate Redi-Code +	Diabetic Supply of Suncoast, Inc.	4.64%	4.04–5.24%
BREEZE 2	Bayer HealthCare LLC	0.37%	0.19–0.54%
CONTOUR	Bayer HealthCare LLC	2.19%	1.77–2.61%
CONTOUR NEXT	Bayer HealthCare LLC	0.04%	0.00–0.10%
CareSens N	i-Sens, Inc.	0.47%	0.28–0.67%
Clever Chek	Simple Diagnostics	0.26%	0.11–0.40%
Clever Choice Pro	Simple Diagnostics	0.04%	0.00–0.10%
Clever Choice Voice	Simple Diagnostics	0.26%	0.11–0.40%
EASYMAX V	Oak Tree International Holdings	0.30%	0.14–0.46%
Easy Plus II	Home Aide Diagnostics	0.17%	0.05–0.29%
Easy Step	Home Aide Diagnostics	0.17%	0.05–0.29%
Easy Talk	Home Aide Diagnostics	0.21%	0.08–0.35%
Easy Trak	Home Aide Diagnostics	0.34%	0.18–0.51%
Element	Infopia USA	0.69%	0.45–0.92%
Embrace	Omnis Health	8.46%	7.66–9.26%
FreeStyle Lite	Abbot Diabetes Care	0.47%	0.28–0.67%

continued on next page

Market Share Estimates for 43 Types of Mail Order Diabetes Test Strips, and the 95-Percent Confidence Intervals for Those Estimates (continued)			
Model	Manufacturer	Percentage of Market Share	95-Percent Confidence Interval for Market Share
GE 100	Bionime USA Corporation	0.21%	0.08–0.35%
GLUCOCARD Expression	ARKRAY USA	0.13%	0.03–0.23%
GLUCOCARD Vital	ARKRAY USA	0.56%	0.34–0.77%
GlucoNavii	SD Biosensor, Inc.	0.15%	0.04–0.26%
Gmate	Philosys, Inc.	0.26%	0.11–0.40%
INFINITY	US Diagnostics	0.04%	0.00–0.10%
Nova Max	Nova Biomedical	4.45%	3.85–5.04%
On Call Plus	ACON Laboratories, Inc.	0.13%	0.03–0.23%
On Call Vivid	ACON Laboratories, Inc.	0.09%	0.00–0.17%
OneTouch Ultra 2	LifeScan, Inc.	0.04%	0.00–0.10%
OneTouch Ultra Blue	LifeScan, Inc.	20.70%	19.54–21.87%
Perfect 3	Gluco Perfect	0.17%	0.05–0.29%
Prodigy AutoCode	Prodigy Diabetes Care	23.88%	22.66–25.11%
GM100	Bionime USA Corporation	0.30%	0.14–0.46%
Solo V2	BioSense Medical Devices	1.33%	1.00–1.66%
SolusV2	BioSense Medical Devices	6.94%	6.21–7.67%
TRUEbalance	Nipro Diagnostics, Inc.	0.09%	0.00–0.17%
TRUEtest	Nipro Diagnostics, Inc.	14.84%	13.82–15.86%
TRUEtrack	Nipro Diagnostics, Inc.	0.26%	0.11–0.40%
Vocal Point	Specialty Medical Supplies	0.13%	0.02–0.23%
Total		100.00%**	

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

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

**The percentages in this column do not sum to the total because of rounding.