



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

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TO: Marilyn Tavenner
Administrator
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/S/ by E. Bliss for

FROM: Suzanne Murrin
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SUBJECT: Memorandum Report: *Medicare Market Shares of Mail Order Diabetes Test Strips 3–6 Months After the Start of the National Mail Order Program*,
OEI-04-13-00682

This report provides information on the types of mail order diabetes test strips associated with Medicare claims for the 3-month period of October to December 2013 (i.e., the 3-month period beginning 3 months after July 1, 2013, the start of the National Mail Order Program for diabetes test strips). The Centers for Medicare & Medicaid Services (CMS) asked the Office of Inspector General (OIG) to conduct this study to determine Medicare market shares of diabetes test strips for this 3-month period.

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 or caregiver 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 on and after the date of implementation of a national program 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.

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.) Section 154(d)(3)(B) of MIPPA 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 the repeat of Round 1, known as the Round 1 Rebid. By issuing a report in June 2014 covering the period of July–September 2013, OIG fulfilled this mandate for the upcoming recompetes of the National Mail Order Program, scheduled to begin on July 1, 2016.² Additionally, CMS requested two other reports so that it could have market share data from different 3-month time periods in 2013 for informational purposes. OIG released one of these reports, covering the period of April–June 2013, in June 2014.³ The current report covers the period of October–December 2013 and will be the final report on the Medicare market shares of diabetes test strips that OIG releases in 2014.

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 October to December 2013, 3 months after the start of the National Mail Order Program. Our sample of 1,210 claims was drawn from a population of 1,031,913 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 for the 3-month period of October to December 2013, suppliers submitted claims for at least 41 types of mail order diabetes test strips. Two types of diabetes test strips accounted for 44 percent of the Medicare mail order market share. Three types of diabetes test strips accounted for 58 percent of the Medicare mail order market share, and 10 types accounted for 91 percent.

We are providing this information for CMS’s use in evaluating the effect of the National Mail Order Program on the types of diabetes test strips available to beneficiaries. CMS may also find this information useful in assessing whether bidders have met the MIPPA 50-percent requirement.

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

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

³ OIG, *Medicare Market Shares of Mail Order Diabetes Test Strips Immediately Prior to the National Mail Order Program* (OEI-04-13-00681), June 2014.

that the body does produce.⁴ Diabetes may be managed through a variety of methods, including healthy eating, physical activity, and insulin injections.⁵ 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.⁶ Medicare covers services and testing supplies to help beneficiaries with diabetes manage the condition.

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.⁷ The physician must prescribe the frequency of use for diabetes test strips.⁸ Because some beneficiaries should test their glucose more frequently than others, the number of boxes of diabetes test strips per Medicare claim varies.⁹ 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).¹⁰

⁴ National Institutes of Health (NIH), *Diabetes Overview: What is Diabetes?* Accessed at <http://www.diabetes.niddk.nih.gov/dm/pubs/overview/index.htm> on April 17, 2014.

⁵ NIH, *Diabetes Overview: How is Diabetes Managed?* Accessed at <http://www.diabetes.niddk.nih.gov/dm/pubs/overview/index.htm#managed> on April 17, 2014.

⁶ The Centers for Disease Control and Prevention, *Diabetes Self Management Overview*. Accessed at http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2011.pdf on April 15, 2014.

⁷ Other diabetes testing supplies may include batteries and control solution.

⁸ 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).

⁹ CMS, *MLN Matters Number SE1008. An Overview of Medicare Covered Diabetes Supplies and Services*. Accessed at <http://www.cms.gov/MLNMattersArticles/downloads/SE1008.pdf> on April 22, 2014. 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).

¹⁰ 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.

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.¹¹ 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.¹² The selected DMEPOS items are generally high-cost and high-volume items that have a high savings potential under the Competitive Bidding Program.¹³ 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.¹⁴ Contracts are awarded to the suppliers that generally offer lower prices and meet applicable quality and financial standards.¹⁵ The Round 1 Rebid of the Competitive Bidding Program began on January 1, 2011. Round 2 began on July 1, 2013. See Appendix A for more information about the Competitive Bidding Program.

MIPPA required that—after the Round 1 Rebid of the Competitive Bidding Program—mail order suppliers must demonstrate in their bids that they provide at least 50 percent, by volume, of all types of diabetes test strips.¹⁶ 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 round of competitive bidding following the Round 1 Rebid.¹⁷

MIPPA authorized a National Mail Order Program, expanding the Competitive Bidding Program for mail order diabetes testing supplies 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 on and after the date of implementation of the National Mail Order Program.

¹¹ 42 CFR § 414.402 (defining “mail order item”).

¹² MMA, P.L. No. 108-173 § 302(b)(1) (amending Social Security Act, § 1847, 42 U.S.C. § 1395w-3).

¹³ 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 April 24, 2014; 73 Fed. Reg. 17992, 18010 (Apr. 10, 2007).

¹⁴ Palmetto GBA, *Overview of the DMEPOS Competitive Bidding Program*. Accessed at <http://www.dmecompetitivebid.com/palmetto/cbic.nsf/vMasterDID/79NTSG0132> on April 23, 2014.

¹⁵ 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.

¹⁶ 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)).

¹⁷ 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)).

CMS implemented both the National Mail Order Program and Round 2 of the Competitive Bidding Program on July 1, 2013.¹⁸ 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. CMS used this report to evaluate bids for Round 2 of the Competitive Bidding Program. In this 2010 report, OIG found that suppliers submitted claims for at least 75 types of mail order diabetes test strips for the 3-month period ending December 2009.¹⁹ Of these strips, two types accounted for approximately 26 percent of the Medicare mail order market share, seven types accounted for approximately 50 percent, and 19 types accounted for approximately 81 percent.

OIG released two additional reports that determined the Medicare market shares of diabetes test strips for two different 3-month periods in 2013—one immediately preceding and one immediately following the implementation of Round 2 of the Competitive Bidding Program and the National Mail Order Program, i.e., the periods of April–June 2013 and July–September 2013, respectively. CMS asked OIG to produce the report for the period of April to June 2013 so that it would have benchmark market share data for the period immediately prior to the implementation of the National Mail Order Program. OIG found that for this 3-month period, suppliers submitted claims for at least 62 types of mail order diabetes test strips.²⁰ 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.

In the other report, OIG reviewed claims for the 3-month period of July to September 2013, immediately following the start of the National Mail Order Program. OIG found that suppliers submitted claims for at least 43 types of mail order diabetes test strips.²¹ 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. The report covering the period of July to September 2013 fulfilled OIG's MIPPA requirement 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 the Round 1 Rebid. We are also providing this information for CMS's use in evaluating the effect of the National Mail Order Program on the types of diabetes test strips available to beneficiaries.

¹⁸ 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.

¹⁹ OIG, *Medicare Market Shares of Mail Order Diabetic Testing Strips* (OEI-04-11-00130), December 2010.

²⁰ OIG, *Medicare Market Shares of Mail Order Diabetes Test Strips Immediately Prior to the National Mail Order Program* (OEI-04-13-00681), June 2014.

²¹ OIG, *Medicare Market Shares of Mail Order Diabetes Test Strips From July–September 2013*, (OEI-04-13-00680), June 2014.

METHODOLOGY

Data Collection

We identified the population of Medicare mail order diabetes test strips claims with a beginning date of service from October 1 to December 31, 2013 from CMS's National Claims History file. There were 1,031,913 claims submitted by 74 suppliers in this file. We then selected a simple random sample of 1,210 of the 1,031,913 Medicare claims for mail order diabetes test strips within our range of dates of service. 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).²² We received responses from 21 suppliers associated with 1,190 of 1,210 claims in our sample, a 98-percent response rate for these claims.²³

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 18 boxes, and data for the 1,190 claims provide information for a total of 4,696 boxes of diabetes test strips.²⁴

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. Our study did not include diabetes test strips that were provided during our time period (i.e., those with beginning dates of service in the months of October through December 2013) but for which claims were not submitted until after March 1, 2014, the date we collected our Medicare claims.

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.

²² We contacted suppliers up to three times to obtain this information.

²³ One supplier went out of business in fall 2013 and did not respond to our information request, despite repeated attempts to reach this supplier.

²⁴ Most claims (91 percent) were for 1 to 6 boxes.

RESULTS

Suppliers Submitted Claims for at Least 41 Types of Mail Order Diabetes Test Strips for the 3-Month Period of October to December 2013.

For the 3-month period of October to December 2013, suppliers submitted claims for at least 41 types of mail order diabetes test strips. Two types of diabetes test strips accounted for 44 percent of the Medicare mail order market share. Three types of diabetes test strips accounted for 58 percent of the Medicare mail order market share, and 10 types accounted for 91 percent.

Table 1 lists the top 10 types of mail order diabetes test strips associated with Medicare claims for the 3-month period of October to December 2013. See Appendix B for a complete alphabetical listing of all 41 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 October to December 2013

Model	Manufacturer	Percentage of Market Share
Prodigy Autocode	Prodigy Diabetes Care	26.9%
TRUEtest	Nipro Diagnostcs, Inc.	16.9%
OneTouch Ultra Blue	LifeScan, Inc.	14.3%
Embrace	Omnis Health	11.4%
Gmate	Philosys, Inc.	10.6%
OneTouch Ultra	LifeScan, Inc.	4.0%
Advocate Redi-Code +	Diabetic Supply of Suncoast Inc.	2.3%
SolusV2	BioSense Medical Devices	2.1%
CONTOUR	Bayer Healthcare LLC	1.6%
Clever Choice Voice	Simple Diagnostics	1.3%
Total		91.4%

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

CONCLUSION

This is the third of three reports OIG has released in 2014 that determine the Medicare market shares of diabetes test strips for three different 3-month periods in 2013. One of these reports fulfilled OIG's reporting requirement to assist CMS in ensuring that winning bidders meet the MIPPA 50-percent requirement. CMS requested the other two reports so that it could have additional market share data from different 3-month periods of service for informational purposes. Across all three reports, OIG found that a total of 15 diabetes test strip types accounted for the majority (i.e., 75 percent or greater) of the Medicare mail order market share.

The first requested report found that for the 3-month period 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.

The second required report found that during the first three months of the National Mail Order Program, 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.

Finally, data from the current requested report show that the percentages of market share for the top 2, 3, and 10 types of strips each changed by approximately 1 percent between the July–September and the October–December reporting periods. We are providing this information for CMS's use in evaluating the effect of the National Mail Order Program on the types of diabetes test strips available to beneficiaries. CMS may also find this information useful in assessing whether bidders have met the MIPPA 50-percent requirement.

OIG will conduct future reviews of the market share of mail order diabetes test strips as required by MIPPA and/or requested by CMS.

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-04-13-00682 in all correspondence.

Appendix A

The Competitive Bidding Program, Establishment of Competitive Bidding Areas (CBAs), and Reduced Reimbursement for Mail Order Diabetes Test Strips

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, 2008.²⁵

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.)²⁶

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.²⁷ 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 previously selected CBAs, except for San Juan–Caguas–Guaynabo (Puerto Rico).²⁸ 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. 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

²⁵ CMS, MLN Matters Number SE0805. *Overview of New Medicare Competitive Bidding Program for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)*. Accessed at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE0805.pdf> on October 1, 2014. 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), Riverside–San Bernardino–Ontario (California), and San Juan–Caguas–Guaynabo (Puerto Rico). CBAs are defined by specific ZIP Codes related to Metropolitan Statistical Areas (MSAs).

²⁶ The 50-percent requirement did not apply to suppliers' bids in Round 1 or the Round 1 Rebid.

²⁷ 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 April 11, 2014.

²⁸ 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 April 11, 2014.

payment for 2011 mail order diabetes test strips provided to beneficiaries in CBAs was \$14.62 per 50-count box.²⁹ 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 reported that the Competitive Bidding Program saved the Medicare program nearly \$202.1 million in the first year of implementation.³⁰

Round 2 of the Competitive Bidding Program and Expansion of CBAs

MIPPA required competition for Round 2 of the Competitive Bidding Program to occur in 2011 in 70 additional CBAs.³¹ The Patient Protection and Affordable Care Act further expanded the number of CBAs to 91 and required CMS to expand the DMEPOS competitive bidding program nationwide or to adjust payments to suppliers using competitively bid rates by 2016.³² Round 2 of the Competitive Bidding Program began on July 1, 2013, in 100 CBAs.³³

Round 2 Recompete of the Competitive Bidding Program and the National Mail Order Program To Begin July 1, 2016

On July 15, 2014, CMS announced that it will recompetete contracts awarded to suppliers in Round 2 of the Competitive Bidding Program and National Mail Order Program, which are set to expire on June 30, 2016. The Round 2 Recompetete will occur in the same geographical locations as Round 2; however, the boundaries of some CBAs will be revised to account for large MSAs and to ensure there are no multi-State CBAs.³⁴ The bidding schedule for the Round 2 Recompetete was slated to be announced in fall 2014, and contracts for the Round 2 Recompetete will become effective on July 1, 2016.

²⁹ During the Round 1 Rebid, 42 CFR § 414.402 defined “mail order contract supplier” to mean “a contract supplier that furnishes items through the mail” See 72 Fed. Reg. 17992, 18085 (Apr. 10, 2007). However, CMS deleted that definition and added new definitions for “mail order” and “non-mail order,” effective after the Round 1 Rebid. See 75 Fed. Reg. 73170, 73570, and 73623 (Nov. 29, 2010).

³⁰ 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 April 17, 2014.

³¹ 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)).

³² P. L. No. 111-148, § 6410.

³³ 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. Therefore, Round 2 was implemented in 100 CBAs. CBIC, *Round 2 & Mail Order Home*. Accessed at <http://www.dmecompetitivebid.com/palmetto/cbicrd2.nsf/vMasterDID/8TARZW7500> on April 17, 2014.

³⁴ As a result, the number of CBAs will rise to 117, an increase of 17 from Round 2. CMS, *Round 2 Recompetete and National Mail-Order Recompetete*. Accessed at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Round-2-Recompetete-and-National-Mail-Order-Recompetete/Overview.html> on July 17, 2014.

Appendix B

Market Share Estimates and Their 95-Percent Confidence Intervals for 41 Types of Mail Order Diabetes Test Strips for the 3-Month Period of October to December 2013			
Model	Manufacturer	Percentage of Market Share	95-Percent Confidence Interval for Market Share
ACCU-CHEK Aviva	Roche	0.04%	0.01–0.17%
ACCU-CHEK Aviva Plus	Roche	1.21%	0.94–1.57%
ACCU-CHEK Compact Plus	Roche	0.83%	0.61–1.13%
ACCU-CHEK Nano Smartview*	Roche	0.38%	0.24–0.61%
Advocate	Diabetic Supply of Suncoast, Inc.	0.98%	0.73–1.31%
Advocate Redi-Code +	Diabetic Supply of Suncoast, Inc.	2.34%	1.95–2.82%
BREEZE 2	Bayer HealthCare LLC	0.09%	0.03–0.23%
Care Sens	i-Sens	0.17%	0.09–0.34%
Care Sens N	i-Sens	0.17%	0.09–0.34%
Clever Choice Pro	Simple Diagnostics	0.04%	0.01–0.17%
Clever Choice Voice	Simple Diagnostics	1.28%	0.99–1.64%
Clever Choice Voice Plus	Simple Diagnostics	0.13%	0.06–0.28%
CONTOUR	Bayer HealthCare LLC	1.55%	1.24–1.95%
Easy Plus II	Home Aide Diagnostics	0.09%	0.03–0.23%
Easy Step	Home Aide Diagnostics	0.09%	0.03–0.23%
Easy Talk	Home Aide Diagnostics	0.13%	0.06–0.28%
Easy Trak	Home Aide Diagnostics	0.13%	0.06–0.28%
Element	Infopia USA	0.09%	0.03–0.23%
Element Compact	Infopia USA	0.09%	0.03–0.23%
Embrace	Omnis Health	11.37%	10.49–12.31%
FreeStyle Lite	Abbott Diabetes Care	0.13%	0.06–0.28%
GLUCOCARD Expression	ARKAY	0.17%	0.09–0.34%
GLUCOCARD Vital	ARKAY	0.30%	0.18–0.50%
GM100	BIONIME USA Corporation	0.04%	0.01–0.17%
Gmate	Philosys, Inc.	10.63%	9.78–11.54%
GS300	BIONIME USA Corporation	0.77%	0.55–1.06%
INFINITY	US Diagnostics	0.26%	0.15–0.45%
Liberty Autocode	AgaMatrix, Inc.	0.13%	0.06–0.28%

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Appendix B

Market Share Estimates and Their 95-Percent Confidence Intervals for 41 Types of Mail Order Diabetes Test Strips for the 3-Month Period of October to December 2013 (continued)			
Model	Manufacturer	Percentage of Market Share	95-Percent Confidence Interval for Market Share
NovaMax	Nova Biomedical	0.77%	0.55–1.06%
On-Call Vivid	ACON Laboratories, Inc.	0.04%	0.01–0.17%
OneTouch Ultra	LifeScan, Inc.	4.02%	3.50–4.63%
OneTouch Ultra Blue	LifeScan, Inc.	14.31%	13.34–15.34%
OneTouch Verio	LifeScan, Inc.	0.28%	0.16–0.48%
Perfect 3	Gluco Perfect	0.43%	0.27–0.66%
Prodigy AutoCode	Prodigy Diabetes Care	26.92%	25.65–28.19%
Solo V2	BioSense Medical Devices	0.47%	0.31–0.71%
SolusV2	BioSense Medical Devices	2.13%	1.75–2.58%
TRUEtest	Nipro Diagnostics, Inc.	16.91%	15.86–18.01%
TRUEtrack	Nipro Diagnostics, Inc.	0.04%	0.01–0.17%
V10/D20	ForaCare, Inc.	0.04%	0.01–0.17%
WaveSense Presto	AgaMatrix, Inc.	0.04%	0.01–0.17%
Total		100.00%**	

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

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

**Because of rounding, the percentages in this column do not sum to the total.