



## Medicare Market Shares of Mail-Order Diabetes Test Strips From October Through December 2016

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) required the Centers for Medicare & Medicaid Services (CMS) to phase in a Competitive Bidding Program for durable medical equipment, prosthetics, orthotics, and supplies. In July 2013, the program was expanded to include a National Mail-Order Program for diabetes testing supplies.

### RESULTS AT A GLANCE

**OIG analyzed the types of strips provided under the National Mail-Order Program from October through December 2016. This report supplements two previous OIG reports about the types of strips provided to beneficiaries under this program. We found that during this timeframe:**

- **Sampled suppliers submitted claims for 19 types of mail-order diabetes test strips.**
- **The top two strip types accounted for 53 percent of the Medicare mail-order market.**
- **The top 10 strip types accounted for 97.5 percent of the Medicare mail-order market.**

The Medicare Improvements for Patients and Providers Act (MIPPA) prohibits CMS from awarding a contract to a supplier of diabetes test strips if the supplier's bid does not cover at least 50 percent, by volume, of all types of diabetes test strips on the market. (This is known as the "MIPPA 50-percent rule.") MIPPA requires the Office of Inspector General (OIG) to determine the market shares of the types of diabetes test strips before each round of competitive bidding.

On July 1, 2016, CMS began accepting claims for the current round of the National Mail-Order Program, which ends on December 31, 2018. This is the third of three OIG reports on the Medicare market shares of diabetes test strips in 2016. CMS will use the results from the second OIG report (OEI-04-16-00471, February 2017) to determine bidders' adherence with the MIPPA 50-percent rule for the next round of competitive bidding.

The first and third reports provide CMS with additional information on the market shares of diabetes test strips provided by the National Mail-Order Program. OIG will complete future evaluations as mandated by MIPPA or, if appropriate, as requested by CMS.

See Appendix A for information on diabetes, Medicare's coverage of diabetes test strips, the Competitive Bidding Program, and the National Mail-Order Program. See Appendix B for an overview of completed OIG work on this topic.

## RESULTS

### Sampled suppliers provided 19 types of diabetes test strips to Medicare beneficiaries via mail order; 2 types of test strips accounted for 53 percent of the mail-order market

Our representative sample included 19 types of diabetes test strips provided to Medicare beneficiaries in months 4 through 6—October through December 2016—of the current round of the National Mail-Order Program. Two types of diabetes test strips accounted for 53 percent of the Medicare mail-order market. Five types of diabetes test strips accounted for 81.5 percent of the market, and 10 types accounted for 97.5 percent.

Exhibit 1 lists the top 10 types (model and manufacturer) of mail-order diabetes test strips associated with Medicare claims for the 3-month period of October through December 2016. See Appendix C for a complete alphabetical listing of all 19 strip types. Appendix C also provides the model, manufacturer, and market share for each type of diabetes test strip provided.

#### Exhibit 1: Top 10\* Mail-Order Diabetes Test Strip Types Associated With Medicare Claims for the 3-Month Period of October Through December 2016

Model	Manufacturer	Market Share
Prodigy	Prodigy Diabetes Care	30.6%
TRUEmetrix	Trividia Health, Inc.	22.2%
Embrace	Omnis Health	12.9%
CareSens N	i-Sens, Inc.	8.8%
OneTouch Ultra	LifeScan, Inc.	6.9%
Advocate Redi-Code+	BroadMaster Bio-Tech Corp.	6.2%
CONTOUR	Panasonic Healthcare Holdings Co., Ltd.	2.4%
Gmate	Philosys	2.3%
On Call Plus	ACON Laboratories	2.2%
On Call Express*	ACON Laboratories	1.5%
Rightest GS 300*	Bionime Corporation	1.5%
Total**		97.5%

Source: OIG analysis of supplier documentation and Medicare claims containing Healthcare Common Procedure Coding System (HCPCS) code A4253 KL for the 3-month period of October through December 2016.

\* This list of the top 10 strip types consists of 11 types, because the last 2 strip types—On Call Express and Rightest GS 300—tied for the 10th-highest market share. If only 1 of these 2 strip types were to be included among the top 10, the market share for the top 10 strip types would be 96.0%, with a 95% confidence interval of 94.7%–97.1%.

\*\* Totals do not sum to 100 percent because these strip types are only the top 10 types, not a list of all strip types provided.

## CONCLUSION

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This report provides CMS with information on the types of diabetes test strips provided to beneficiaries for months 4 through 6—October through December 2016—of the current round of the National Mail-Order Program. We found that during this timeframe, sampled suppliers provided 19 types of diabetes test strips via mail order. The top two strips accounted for about half of the mail-order market, and the top 10 types accounted for almost all of the mail-order market.

On July 1, 2016, CMS began accepting claims for the current round of the National Mail-Order Program, which ends on December 31, 2018. This is the third of three OIG reports to determine the Medicare market shares of diabetes test strips for the periods April through June 2016, July through September 2016, and October through December 2016, respectively. CMS will use the results from the second OIG report (OEI-04-16-00471, February 2017) to determine bidders' adherence with the MIPPA 50-percent rule for the next round of competitive bidding. As requested by CMS, the first and third reports provide additional information on the market shares of diabetes test strips supplied through the National Mail-Order Program.

See Appendix B for an overview of OIG's completed work on this topic. OIG will conduct future reviews of the market shares of the various types of mail-order diabetes test strips as required by MIPPA and/or, if appropriate, as requested by CMS.

## METHODOLOGY

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### Data Collection

Using CMS’s National Claims History file, we identified the population of Medicare Part B claims for diabetes test strips that were provided by mail order and had dates of service that started between October 1, 2016, and December 31, 2016. There were 438,872 claims during this period. We then selected a simple random sample of 1,210 of these 438,872 claims. These 1,210 claims in the sample corresponded to a total of 12 suppliers. These 12 suppliers accounted for 438,763 claims—or 99.98 percent—of the population of claims from which we selected the sample.

To identify the beneficiaries associated with each claim in our sample, we matched the beneficiary numbers in the claims with beneficiary numbers in the CMS Beneficiary Enrollment Database. We sent documentation requests to the 12 suppliers associated with our sampled claims. For each claim, we asked the supplier to (1) indicate the type (model and manufacturer) of diabetes test strips it provided to the Medicare beneficiary we identified and (2) submit relevant documentation (such as packing slips or invoices) for the strips. We received responses from all 12 suppliers documenting all 1,210 claims in our sample, a 100-percent response rate for these claims.

### Data Analysis

We reviewed claims data, supplier responses, and supplier documentation 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 16 boxes, and data for the 1,210 claims provide information for a total of 4,937 boxes of strips.

We categorized types of diabetes test strips by model and manufacturer. We calculated each strip type’s share of the Medicare mail-order market by determining the total number of 50-count boxes of each strip type provided to beneficiaries in our sample and dividing that number by the total number of boxes across all strip types in our sample. To estimate the Medicare market share of each type of diabetes test strip provided by mail order, we projected our sample data to the population of diabetes test strips provided by mail order during the timeframe we reviewed. In our findings, we present the market share for the top 10 types of diabetes test strips to the first decimal. See Appendix C for the market shares of the 19 strip types in our sample.

### Limitations

Suppliers have 1 year to submit claims to CMS. Our study did not include any claims submitted after February 1, 2017, the date we collected our Medicare claims data. Therefore, our sample may not include all types of mail-order diabetes test strips reimbursed by Medicare.

### 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.

## APPENDIX A

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### Information on Diabetes, Medicare's Coverage of Diabetes Test Strips, the Competitive Bidding Program, and the National Mail-Order Program

*Diabetes and Blood Glucose Monitoring.* Diabetes is a chronic disease in which a person has a high blood sugar (glucose) level either because the body does not produce enough insulin, or because cells do not respond properly to the insulin the body does produce.<sup>1</sup> Diabetes may be managed through a variety of methods, including healthy eating, physical activity, and insulin injections to prevent medical complications (e.g., hypoglycemia or cardiovascular disease).<sup>2</sup>

A person with diabetes can use a hand-held meter to test the concentration of glucose in his or her blood. To do so, the individual pricks his or her skin with a lancet and places the resulting drop of blood on a diabetes test strip, which is a small piece of plastic meant for one-time use. The individual then inserts the strip into a meter that reads the blood sample's glucose level, providing information necessary for the individual to manage his or her diabetes. People with diabetes may need to perform glucose tests several times a day to assist them in maintaining an appropriate glucose level.

*Medicare Coverage of Diabetes Test Strips.* Medicare covers testing supplies, such as diabetes test strips, to help beneficiaries with diabetes manage their condition.<sup>3</sup> To be eligible for Medicare coverage of diabetes test strips, Medicare beneficiaries with diabetes must be under the treatment of a physician for the condition. The physician's order for diabetes test strips specifies the frequency at which the beneficiary should use the strips. Each box contains 50 strips. Because some beneficiaries need to test their glucose levels more frequently than others, the number of boxes per claim varies.<sup>4</sup>

For each beneficiary, the supplier submits a single claim that can cover up to 3 months of diabetes test strips. The claim indicates the *number* of boxes provided to the beneficiary for the applicable time period, but it does not indicate the *type* of strips provided. The modifier KL designates diabetes test strips provided via mail order.<sup>5</sup>

*Purchasing Diabetes Test Strips.* Medicare beneficiaries may purchase their diabetes test strips via mail order suppliers or via non-mail-order purchases from local pharmacies or supplier storefronts. CMS considers all diabetes test strips that are either shipped or delivered to a beneficiary's residence as mail order, regardless of the method of delivery.<sup>6</sup> Non-mail-order diabetes test strips are those that a beneficiary or caregiver picks up in person at a local pharmacy or supplier storefront. For both mail-order and non-mail-order purchases, Medicare pays 80 percent of allowed charges for diabetes test strips, and the beneficiary is responsible for the remaining 20 percent.

*Competitive Bidding Program.* The MMA requires CMS to phase in, through several rounds of bidding, a Competitive Bidding Program for selected DMEPOS items (including diabetes test strips).<sup>7</sup> The program includes high-cost and high-volume items or those with significant savings potential. Suppliers submit bids that CMS evaluates based on the suppliers' eligibility, their financial stability, and the bid price. Generally, CMS awards contracts to the suppliers that offer lower bid prices and meet applicable quality standards and financial standards. The payment

amounts resulting from winning bids replace the Medicare fee-schedule amounts for the selected items. Generally, contract awards and payment amounts expire every 3 years, and suppliers must re compete to remain contract suppliers.<sup>8</sup>

MIPPA further qualified the competition for diabetes test strips. MIPPA requires that in rounds subsequent to the first round, mail-order suppliers demonstrate in their bids that they can provide at least 50 percent, by volume, of the types of diabetes test strips provided to Medicare beneficiaries. Suppliers do this by declaring in their bids the types of diabetes test strips they intend to provide. The MIPPA 50-percent rule did not apply to suppliers' bids in Round 1 or the Round 1 Rebid described below.<sup>9</sup>

*Round 1 of the Competitive Bidding Program and the Round 1 Rebid.* Contracts between CMS and suppliers became effective in 10 selected Competitive Bidding Areas (CBAs) on July 1, 2008.<sup>10</sup>

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

- terminate contracts awarded to suppliers in Round 1;
- repeat the Round 1 competition in 2009; and
- institute the MIPPA 50-percent requirement for mail-order diabetes test strips in all rounds following the repeat of the Round 1 competition.<sup>11</sup>

The repeat of the Round 1 competition is known as the Round 1 Rebid. The Round 1 Rebid was in nine CBAs (the same areas as in Round 1, but this time excluding Puerto Rico).<sup>12</sup> The competition for contracts in the Round 1 Rebid began in October 2009, and suppliers began providing competitively bid DMEPOS items to beneficiaries in the nine selected CBAs on January 1, 2011.<sup>13</sup> This round ended in December 2013, with competitions for mail-order diabetes testing supplies expiring on December 31, 2012, in these areas. Subsequent rounds include implementation of the Round 1 Re compete (January 2014 through December 2016) for the 9 selected CBAs and Round 1 2017 (January 2017 through December 2018) for 13 selected CBAs.<sup>14</sup>

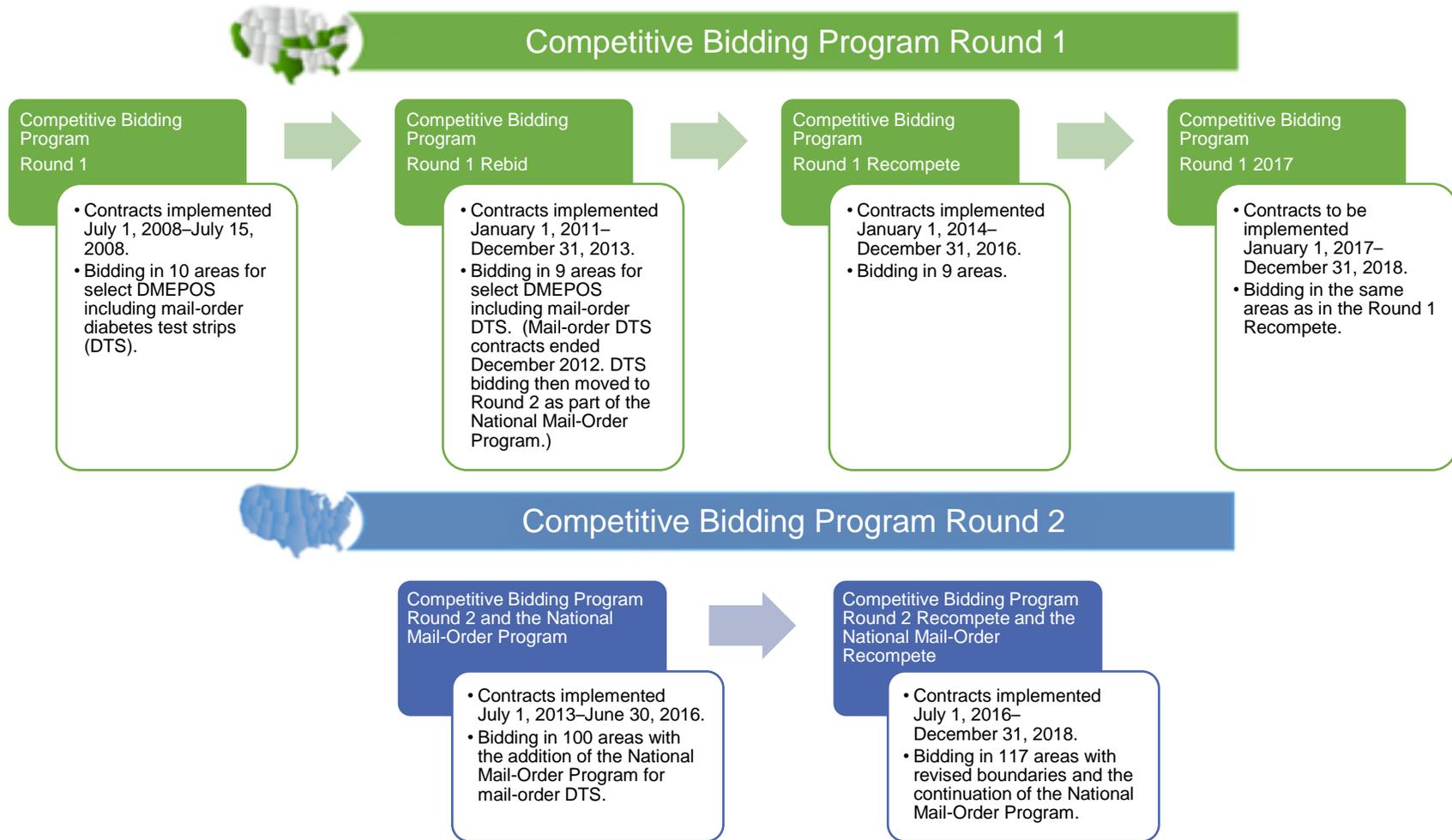
Before 2011, Medicare reimbursed all suppliers of diabetes test strips on the basis of fee-schedule amounts that were updated annually and varied by State. As a result of the Round 1 Rebid, the average Medicare payment for 2011 mail-order diabetes test strips provided to beneficiaries in CBAs was \$14.62 per 50-count box.<sup>15</sup> In contrast, the national average Medicare payment for mail-order strips in non-CBA areas was \$32.47, and the national average payment for non-mail-order diabetes test strips was \$37.67.<sup>16</sup> CMS reported that the first round of the Competitive Bidding Program saved Medicare \$51.3 million for diabetes supplies provided via mail order.<sup>17</sup>

*Round 2 of the Competitive Bidding Program and Start of the National Mail-Order Program.* MIPPA required competition for Round 2 of the Competitive Bidding Program to occur in 70 additional Metropolitan Statistical Areas (MSAs) and authorized the National Mail-Order

Program.<sup>18</sup> The Patient Protection and Affordable Care Act (ACA) further expanded the number of MSAs to 91, resulting in 100 CBAs, and required CMS to either expand the DMEPOS Competitive Bidding Program nationwide or adjust payment rates using competitively bid rates by 2016.<sup>19</sup> Round 2 of the Competitive Bidding Program and the initial round of the National Mail-Order Program began on July 1, 2013, and ended on June 30, 2016. In accordance with the requirement to equalize Medicare payments for diabetic testing supplies set out by the American Taxpayer Relief Act of 2012 (ATRA), CMS set a single payment amount at \$10.41 per box of diabetes test strips—both for those obtained via mail order and those obtained by other means.<sup>20</sup> CMS reported that Medicare saved approximately \$3.6 billion during the first 2 years of the DMEPOS contracts (i.e., from July 1, 2013, to June 30, 2015) after the start of Round 2 of the Competitive Bidding Program.<sup>21</sup>

*Start of the Round 2 Recompete of the Competitive Bidding Program and the National Mail-Order Recompete.* On July 15, 2014, CMS announced that it would conduct a recompetition of contracts that had been awarded in Round 2 of the Competitive Bidding Program and the National Mail-Order Program. This recompetition is known as the Round 2 Recompete and the National Mail-Order Recompete. The Round 2 Recompete and the National Mail-Order Recompete occurred in the same geographical locations as the previous round; however, CMS expanded the number of CBAs from 100 to 117.<sup>22</sup> Contracts for the Round 2 Recompete and National Mail-Order Recompete became effective on July 1, 2016, and will expire on December 31, 2018.<sup>23</sup> Under this program, diabetes test strips are again reimbursed at the same competitive bidding payment rate whether they are provided by mail order or by other means, and this rate was reduced to \$8.32 per 50-count box.<sup>24</sup> See Exhibit A on the next page for a timeline of the Competitive Bidding Program and National Mail-Order Program.

## Exhibit A: Timeline of the Competitive Bidding Program and the National Mail-Order Program



## APPENDIX B

### OIG's Past and Current Work on Medicare Diabetes Test Strips Market Share

MIPPA section 154(d)(3)(B) requires OIG to determine the market shares of types of diabetes test strips provided by mail order in the Competitive Bidding Program before each new round of bidding. For Round 2, CMS requested that OIG complete an additional report for the 3-month period before implementation of a new round and another report for months 4 through 6 after implementation of a new round. CMS requested these additional reports to evaluate the effect of the National Mail-Order Program on the types of diabetes test strips provided to beneficiaries. For the current Round 2 Recompete, CMS has again requested this series of reports. See Exhibit B-1 for a timeline of OIG work on the Medicare market shares of diabetes test strips.

### Exhibit B-1: OIG Work on the Medicare Market Shares of Diabetes Test Strips

#### Completed Before Round 2 (Contract Period January 1, 2011, to December 31, 2013)

*Release Date*  
December 2010

Report number: OEI-04-10-00130  
Mandated by MIPPA (to help evaluate bids for July 2013 implementation)  
Time period covered: October through December 2009  
Results: 75 total types—top 7 types had a 50% share of the market; top 10 types had 62%

#### Completed Before Round 2 Recompete (Contract Period July 1, 2016, to December 31, 2018)

*Release Date*  
June 2014

Report number: OEI-04-13-00680  
Mandated by MIPPA (to help evaluate bids for July 2016 implementation)  
Time period covered: July through September 2013  
Results: 43 total types—top 3 types had a 59% share of the market; top 10 types had 90%

*Release Date*  
June 2014

Report number: OEI-04-13-00681  
Requested by CMS for additional information  
Time period covered: April through June 2013  
Results: 62 total types—top 4 types had a 51% share of the market; top 10 types had 75%

*Release Date*  
November 2014

Report number: OEI-04-13-00682  
Requested by CMS for additional information  
Time period covered: October through December 2013  
Results: 41 total types—top 3 types had a 58% share of the market; top 10 types had 91%

#### Completed Before Next Round (Current Contracts Expire December 31, 2018)

*Release Date*  
November 2016

Report number: OEI-04-16-00470  
Requested by CMS for additional information  
Time period covered: April through June 2016  
Results: 30 total types—top 2 types had a 51% share of the market; top 10 types had 93%

*Release Date*  
February 2017

Report number: OEI-04-16-00471  
Mandated by MIPPA (to help evaluate bids for the post-December 2018 implementation)  
Time period covered: July through September 2016  
Results: 18 total types—top 2 types had a 60% share of the market; top 10 types had 98%

*Release Date*  
May 2017

Report number: OEI-04-16-00473  
Requested by CMS for additional information  
Time period covered: October through December 2016  
Results: 19 total types—top 2 types had a 53% share of the market; top 10 types had 97.5%

## APPENDIX C

### Exhibit C-1: Model, Manufacturer, and Market Share Estimates for Mail-Order Diabetes Test Strips, October Through December 2016

Model	Manufacturer	Market Share	95-Percent Confidence Interval
Advocate Redi-Code+	BroadMaster Bio-Tech Corp.	6.22%	4.85–7.94%
CareSens N	i-Sens, Inc.	8.81%	7.12–10.85%
Clever Choice	Simple Diagnostics	0.04%	0.01–0.29%
CONTOUR	Panasonic Healthcare Holdings Co., Ltd.	2.41%	1.61–3.58%
CONTOUR NEXT	Panasonic Healthcare Holdings Co., Ltd.	0.20%	0.06–0.74%
Easy Talk	Home Aide Diagnostics	0.51%	0.21–1.20%
EASYMax	Oak Tree International Holdings, Inc.	1.07%	0.59–1.95%
Embrace	Omnis Health	12.94%	10.93–15.26%
Glucocard Expression	ARKRAY	0.32%	0.11–0.97%
Glucocard Vital	ARKRAY	0.04%	0.01–0.29%
Gmate	Philosys	2.27%	1.52–3.36%
NovaMax	Nova Biomedical	0.04%	0.01–0.29%
On Call Express	ACON Laboratories	1.46%	0.87–2.45%
On Call Plus	ACON Laboratories	2.23%	1.35–3.67%
OneTouch Ultra	LifeScan, Inc.	6.89%	5.34–8.84%
Prodigy	Prodigy Diabetes Care	30.59%	27.56–33.61%
Rightest GS 300	Bionime Corporation	1.46%	0.87–2.43%
TRUEmetrix	Trividia Health, Inc.	22.22%	19.69–24.97%
Unistrip1	Unistrip Technologies, LLC	0.28%	0.12–0.66%
<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 October through December 2016.

**Exhibit C-2. Medicare Market Share Estimates for Top 2, Top 5, and Top 10\* Types of Mail-Order Diabetes Test Strips, October Through December 2016**

<b>Groupings of Strip Types with Largest Market Share</b>	<b>Model Names</b>	<b>Combined Market Share</b>	<b>95-Percent Confidence Interval</b>
Top 2 Strip Types	Prodigy TRUEmetrix	52.81%	49.56–56.05%
Top 5 Strip Types	Prodigy TRUEMetrix Embrace CareSens N OneTouch Ultra	81.45%	78.82–83.81%
Top 10* Strip Types	Prodigy TRUEMetrix Embrace CareSens N OneTouch Ultra Advocate Redi-Code+ CONTOUR Gmate On Call Plus On Call Express Rightest GS300	97.49%	96.37–98.27%

Source: OIG analysis of supplier documentation and Medicare claims containing HCPCS code A4253 KL for the 3-month period of October through December 2016.

\*There are 11 strip types in the top 10 because the last 2 strip types tied for the 10th-highest market share. If only 1 of these 2 strip types were to be included among the top 10, the market share for the top 10 strip types would be 96.0%, with a 95% confidence interval of 94.7%–97.1%.

## **ACKNOWLEDGMENTS**

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Office of Evaluation and Inspections staff from the Atlanta regional office who conducted the study include Lauren Buss, Lori Jouty, and Lucio Verani. Office of Evaluation and Inspections staff who provided support include Joe Chiarenzelli, Kevin Farber, and Christine Moritz.

## ENDNOTES

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<sup>1</sup> National Institutes of Health (NIH), *Causes of Diabetes*. Accessed at <https://www.niddk.nih.gov/health-information/diabetes/causes> on November 3, 2016.

<sup>2</sup> NIH, *Managing Diabetes: 4 Steps to Manage Your Diabetes for Life*. Accessed at <https://www.niddk.nih.gov/health-information/diabetes/manage-monitoring-diabetes> on November 3, 2016.

<sup>3</sup> Other diabetes testing supplies may include batteries, lancets, and control solution.

<sup>4</sup> CMS, *MLN Matters Number SE1008 Revised. Medicare Coverage of Blood Glucose Monitors and Testing Supplies*. Accessed at <http://www.cms.gov/MLNMattersArticles/downloads/SE1008.pdf> on July 1, 2016. Medicare covers up to 100 test strips per month (i.e., two 50-count boxes) for insulin-dependent beneficiaries with diabetes and up to 100 test strips every 3 months for non-insulin-dependent beneficiaries with diabetes. Medicare allows additional test strips if they are deemed medically necessary and documented in physician records. *Medicare LCD for Glucose Monitors (L33822 for DME MAC Jurisdictions A, B, C, and D)*.

<sup>5</sup> 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 be followed by the KL modifier (A4253 KL). CMS, *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 36, §§ 20.5.4.1 and 50.6. A modifier is a code on Medicare claim that further describes the services performed or supplies provided to a beneficiary.

<sup>6</sup> 42 CFR § 414.402 (defining “mail-order item”).

<sup>7</sup> MMA, P.L. No. 108-173 § 302(b)(1).

<sup>8</sup> CMS must recompetete contracts at least once every 3 years. Social Security Act, § 1847(b)(3)(B), 42 U.S.C. § 1395w-3(b)(3)(B).

<sup>9</sup> MIPPA, P. L. No. 110-275 § 154(d)(3)(B) (adding new paragraph Social Security Act, § 1847(b)(10)(A), 42 U.S.C. § 1395w-3(b)(10)(A)).

<sup>10</sup> The CBAs define the geographic coverage areas of the program according to specific ZIP Codes. A CBA that is identified with a specific Metropolitan Statistical Areas (MSA) may be concurrent with, larger than, or smaller than the related MSA. CMS, *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 36, § 20.2. The 10 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. CMS, *MLN Matters Number MM6112 Revised. Payment for Complex Rehabilitative Power Mobility (PMD) Services that Span the Implementation Dates of DMEPOS Competitive Bidding Programs in Competitive Bidding Areas*. Accessed at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6112.pdf> on November 16, 2016.

<sup>11</sup> MIPPA, P.L. No. 110-275 § 154(a)(1) and (d)(3)(B).

<sup>12</sup> *Competitive Bidding Areas (CBAs)*. Accessed at [http://dmecompetitivebid.com/Palmetto/Cbic.Nsf/files/Fact Sheet Competitive Bidding Areas.pdf/\\$File/Fact Sheet Competitive Bidding Areas.pdf](http://dmecompetitivebid.com/Palmetto/Cbic.Nsf/files/Fact Sheet Competitive Bidding Areas.pdf/$File/Fact Sheet Competitive Bidding Areas.pdf) on November 16, 2016.

<sup>13</sup> CMS, *Important Dates, Round 1 Rebid Timeline*. Accessed at <http://dmecompetitivebid.com/palmetto/cbicrd1rebid.nsf/docsCat/Round%201%20Rebid~Important%20Dates~Timeline?open&expand=1&navmenu=Important^Dates> on November 16, 2016.

<sup>14</sup> The 13 selected CBAs included in Round 1 2017 are composed of the same 9 areas included in the Round 1 Recompete. However, CBAs were defined so that there would be no multi-State CBAs. For example, the single CBA of “Kansas City, MO-KS” in the Round 1 Recompete was changed to two separate CBAs in Round 1 2017, one in Kansas and the other in Missouri. As a result, the number of CBAs increased to 13 for Round 1 2017. CMS, *Facts About the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), Competitive Bidding Program, Round 1 2017: Competitive Bidding Areas*. Accessed at [http://www.dmecompetitivebid.com/Palmetto/Cbicrd12017.Nsf/files/14 Fact Sheet Competitive Bidding Areas.pdf/\\$File/14 Fact Sheet Competitive Bidding Areas.pdf](http://www.dmecompetitivebid.com/Palmetto/Cbicrd12017.Nsf/files/14 Fact Sheet Competitive Bidding Areas.pdf/$File/14 Fact Sheet Competitive Bidding Areas.pdf) on April 28, 2017.

<sup>15</sup> Palmetto GBA and CMS, *Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), Competitive Bidding Program – Round 1 Rebid: Single Payment Amounts Per CBA*. Accessed at [https://dmecompetitivebid.com/palmetto/cbicrd1rebid.nsf/files/SPA All Product Categories.pdf/\\$File/SPA All Product Categories.pdf](https://dmecompetitivebid.com/palmetto/cbicrd1rebid.nsf/files/SPA All Product Categories.pdf/$File/SPA All Product Categories.pdf) on May 5, 2017.

- <sup>16</sup> CMS, *Durable Medical Equipment, Prosthetics/Orthotics, and Supplies Fee Schedule: Details for title: DME11\_C*. Accessed at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/DMEPOS-Fee-Schedule-Items/CMS1248611.html?DLPage=3&DLEntries=10&DLSort=2&DLSortDir=descending> on May 2, 2017.
- <sup>17</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 May 3, 2017.
- <sup>18</sup> MIPPA, P.L. No. 110-275 § 154(a)(1)(A)(ii) and (iii) (amending Social Security Act, § 1847(a)(1)(B)(i)(II) and (III), and 42 U.S.C. § 1395w-3(a)(1)(B)(i)(II) and (III)).
- <sup>19</sup> ACA, P.L. No. 111-148 § 6410(a)(1) and (b). The ACA expanded the number of Round 2 MSAs from 70 to 91. 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, there were 100 CBAs in Round 2. CMS, *DMEPOS Competitive Bidding Program, Round 2 & National Mail-Order*. Accessed at <http://dmecompetitivebid.com/palmetto/cbicrd2.nsf/DocsCat/Home> on May 8, 2017.
- <sup>20</sup> ATRA, P.L. No. 112-240 § 636 (adding a new subparagraph to Social Security Act, § 1834(a)(1)(H), 42 U.S.C. § 1395m(a)(1)(H)). CMS, *DMEPOS Competitive Bidding Program: Single Payment Amounts, National Mail-Order Diabetic Supplies* (effective July 1, 2013). Accessed at [http://dmecompetitivebid.com/Palmetto/Cbicrd2.Nsf/files/NMO\\_SPA\\_Chart.pdf/\\$File/NMO\\_SPA\\_Chart.pdf](http://dmecompetitivebid.com/Palmetto/Cbicrd2.Nsf/files/NMO_SPA_Chart.pdf/$File/NMO_SPA_Chart.pdf) on September 23, 2016.
- <sup>21</sup> CMS, *Competitive Bidding Program Continues to Maintain Access and Quality While Saving Medicare Billions*. Accessed at <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-03-15.html> on July 11, 2016.
- <sup>22</sup> In addition to the three largest MSAs (i.e., Chicago, Los Angeles, and New York) that CMS subdivided into multiple CBAs during Round 2, for the Round 2 Recompete, CMS redefined CBAs in multi-State MSAs so that there are no multi-State CBAs. CMS, *Round 2 Recompete and National Mail-Order Recompete*. Accessed at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Round-2-Recompete-and-National-Mail-Order-Recompete/Overview.html> on September 23, 2016.
- <sup>23</sup> CMS, *DMEPOS Competitive Bidding Program*. Accessed at <http://www.dmecompetitivebid.com/palmetto/cbicrd2recompete.nsf/vMasterDID/9KJQN52683> on September 20, 2016.
- <sup>24</sup> CMS, *Public Use File V0817*. Accessed at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/DMEPOS-Fee-Schedule-Items/DME16-C.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending> on June 29, 2016.