



## Medicare Market Shares of Non-Mail Order Diabetes Test Strips From April Through June 2018

This Office of Inspector General (OIG) report lists the Medicare market shares for diabetes test strips (DTS) provided through the non-mail order market (i.e., picked up in person at a local pharmacy or supplier storefront) from April through June 2018. A January 2019 OIG report (OEI-04-18-00440) lists the Medicare market shares for DTS provided via mail order for the same timeframe. These evaluations will inform future round(s) of the Competitive Bidding Program for DTS. All Competitive Bidding Program contracts expired on December 31, 2018, and new contracts are not expected before the end of 2020.

### RESULTS AT A GLANCE

OIG analyzed the types of strips provided via non-mail order from April through June 2018. We found that during this timeframe:

- **Sampled suppliers provided 34 types of DTS via non-mail order to Medicare beneficiaries.**
- **The top three strip types accounted for 53 percent of the Medicare non-mail order market.**
- **The top 10 strip types accounted for 93 percent of the Medicare non-mail order market.**

### Why OIG Did This Review

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) prohibits the Centers for Medicare & Medicaid Services (CMS) from awarding a Competitive Bidding Program contract to a DTS supplier if the supplier's bid does not cover at least 50 percent, by volume, of the DTS types provided to Medicare beneficiaries. This is known as the "50-percent rule." To assist CMS in ensuring that bidding suppliers meet the 50-percent rule, MIPPA requires OIG to determine the market shares of the types of DTS before each round of competitive bidding. Initially, compliance with the 50-percent rule was assessed using mail order claims only. The Bipartisan Budget Act of 2018 amended the 50-percent rule by requiring that, for bids on or after January 1, 2019, CMS must use data from the *non-mail order* Medicare market as well as the mail-order one. Since 2010, OIG has been conducting evaluations of the Medicare market shares of DTS provided via mail order. This is the first OIG evaluation of Medicare market shares for DTS provided via non-mail order.

See Appendix A for information on diabetes, Medicare's coverage of DTS, the Competitive Bidding Program, and the National Mail-Order Program. See Appendix B for an

overview of completed OIG work on this topic. OIG will conduct future evaluations of the market shares of the various types of mail-order and non-mail order DTS, as required by MIPPA and/or as requested by CMS.

## RESULTS

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### **Sampled suppliers provided 34 types of DTS via non-mail order to Medicare beneficiaries; 3 types of test strips accounted for 53 percent of the non-mail order market**

Our sample of claims included 34 types of DTS provided to Medicare beneficiaries from April through June 2018. Three types of DTS accounted for approximately 53 percent of the Medicare non-mail order market. Five types of DTS accounted for approximately 74 percent of the market, and 10 types accounted for approximately 93 percent of the market.<sup>1</sup>

Exhibit 1 lists the top 10 types of non-mail order DTS associated with Medicare claims for the 3-month period of April through June 2018. See Appendix C for a complete alphabetical listing of all 34 strip types. Appendix C also provides the model, manufacturer, market share, and 95-percent confidence interval for each type of DTS captured in our sample.

#### **Exhibit 1: Top 10 Non-Mail Order DTS Types Associated With Medicare Claims for the 3-Month Period of April Through June 2018\***

<b>Model</b>	<b>Manufacturer</b>	<b>Market Share</b>
OneTouch Ultra	LifeScan, Inc.	29.12%
CONTOUR NEXT	Panasonic Healthcare Holdings Co., Ltd.	12.61%
FreeStyle LITE	Abbott Diabetes Care, Inc.	11.03%
ACCU-CHEK Aviva Plus	Roche	10.88%
TRUEmetrix	Trividia Health, Inc.	10.31%
OneTouch Verio	LifeScan, Inc.	8.31%
CONTOUR	Panasonic Healthcare Holdings Co., Ltd.	4.14%
ACCU-CHEK Smartview	Roche	2.81%
ACCU-CHEK Compact Plus	Roche	1.90%
Prodigy	Prodigy Diabetes Care	1.68%
Total		92.79%

Source: OIG analysis of supplier documentation and Medicare claims with the Healthcare Common Procedure Coding System (HCPCS) code A4253—but without the KL modifier—for the 3-month period of April through June 2018.

## CONCLUSION

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This report provides CMS with information on the types of DTS provided to beneficiaries via non-mail order from April through June 2018. We found that during this timeframe, sampled suppliers provided 34 types of DTS via non-mail order to Medicare beneficiaries. The top 3 strip types accounted for just over half of the non-mail order market, and the top 10 strip types accounted for approximately 93 percent of the non-mail order market.

This is the second of two OIG reports providing the Medicare market shares of DTS from April through June 2018. The first report, released in January 2019, lists the Medicare market shares for DTS provided via the National Mail-Order Program for the same timeframe. These evaluations will inform future round(s) of the Competitive Bidding Program for DTS. All Competitive Bidding Program contracts expired on December 31, 2018, and new contracts are not expected before the end of 2020.

OIG will conduct future reviews of the market shares of the various types of mail-order and non-mail order DTS, as required by MIPPA and/or as requested by CMS.

## METHODOLOGY

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### Data Collection and Analysis

Using CMS's National Claims History file, we identified the population of Medicare Part B paid claims for DTS that were provided via non-mail order and had dates of service beginning between April 1, 2018, and June 30, 2018. There were 1,598,926 claims for which Medicare paid during this period. From this population of claims, we selected a simple random sample of 1,210 claims. These 1,210 claims were submitted by a total of 1,192 suppliers of non-mail order DTS for this period of time.

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 1,192 suppliers associated with our sampled claims. In some cases, we were able to aggregate individual suppliers under a large retailer chain (e.g., CVS Health and Wal-Mart Stores, Inc.). In these cases, we sent a documentation request to the large retailer for a response on behalf of all suppliers that had been aggregated under it. For each claim, we asked the large retailer or individual supplier to (1) indicate the type (model and manufacturer) of DTS that it provided to the Medicare beneficiary we identified; (2) indicate whether the DTS is sold exclusively by a single retailer; and (3) submit relevant documentation (such as prescriptions, prescription box labels, or invoices) for the strips. For every claim line in our sample, we attempted to contact the associated supplier a minimum of three times through various types of communication, including email, phone, fax, and/or hard copy letter.

Of the 1,192 suppliers associated with our sampled claims, 1,143 responded, a 96-percent response rate by supplier. These 1,143 responding suppliers provided documentation for 1,160 of the 1,210 sampled claims, a 96-percent response rate by claim.<sup>2</sup> The 49 suppliers that did not respond to our requests have been referred to CMS for potential review of their claims.

For the 1,160 claims for which suppliers responded, we reviewed claims data, supplier responses, and supplier documentation to determine the quantity of DTS associated with each claim. We also categorized types of DTS by model and manufacturer. Each of the sampled claims for which suppliers responded covered between 1 and 22 boxes of DTS, for a total of 3,187 boxes.

After we categorized types of DTS by model and manufacturer for the 1,160 sampled claims for which suppliers responded, we identified 3 types of DTS that were sold exclusively by a single retailer. These 3 types of DTS accounted for 13 claims and 25 boxes in our sample. We removed these claims from our sample to assist CMS in meeting the Bipartisan Budget Act of 2018's requirement for CMS to use multiple sources of data, including market-based data measuring sales of DTS products that are not sold exclusively by a single retailer.<sup>3</sup> This reduced our sample of claims from 1,160 to 1,147, with a corresponding total of 3,162 boxes.

We determined the market share estimates for each DTS model type that our sample captured. We calculated each strip type's share of the Medicare non-mail order market by determining the total number of strips across all boxes of that strip type in our sample and dividing that number

by the total number of strips across all strip types in our sample.<sup>4</sup> To estimate the Medicare market share of each type of DTS provided via non-mail order, we projected our sample data to the population of DTS provided via non-mail order during the timeframe we reviewed. In our results, we present the market share for each type of DTS to the second decimal place. See Appendix C for the market share point estimates and 95-percent confidence intervals for the 34 strip types that our sample captured.

### **Limitations**

Suppliers have 1 year to submit claims to CMS. Our evaluation did not include non-mail order claims submitted after August 3, 2018, the date we collected our Medicare claims data. Therefore, our analysis may not include all types of non-mail order DTS reimbursed by Medicare during our timeframe. We did not independently verify that these DTS were provided via non-mail order. Additionally, the market share analysis reflects only the suppliers that responded to our documentation request.

### **Standards**

We conducted this study in accordance with the *Quality Standards for Inspection and Evaluations* issued by the Council of the Inspectors General on Integrity and Efficiency.

## APPENDIX A

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### Information on Diabetes, Medicare's Coverage of DTS, Beneficiaries' Purchase of DTS, and the Competitive Bidding 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>5</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>6</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 DTS, 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. A person with diabetes may need to perform glucose tests several times a day to help maintain an appropriate glucose level.

*Medicare Coverage of DTS.* Medicare covers testing supplies, such as DTS, to help beneficiaries with diabetes manage their condition.<sup>7</sup> To be eligible for Medicare coverage of DTS, Medicare beneficiaries with diabetes must be under the treatment of a physician for the condition. The physician's order for DTS specifies the frequency at which the beneficiary should use the strips. Each box contains 50 or 51 strips. Because some beneficiaries need to test their glucose levels more frequently than others, the number of boxes per claim varies.<sup>8</sup>

For each beneficiary, the supplier submits a single claim that can cover up to 3 months of DTS. 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 DTS provided via mail order.<sup>9</sup> Therefore, claims without the KL modifier were provided via non-mail order.

*Beneficiaries' Purchase of DTS.* Medicare beneficiaries may purchase their DTS via non-mail order either from local pharmacies or supplier storefronts, or they may purchase their DTS via mail order from CBP suppliers. For both non-mail order and mail-order purchases, Medicare pays 80 percent of allowed charges for DTS (less any unmet Part B deductible), and the beneficiary is responsible for the remaining 20 percent. Effective for dates of service on or after July 1, 2013, Medicare adjusts the fee-schedule amounts for non-mail order DTS so that they are equal to the single payment amounts that the National Mail-Order Program establishes for mail-order DTS.<sup>10</sup>

*Competitive Bidding Program.* The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 requires CMS to phase in—through several rounds of bidding—a Competitive Bidding Program for selected durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items (including DTS).<sup>11</sup> Suppliers submit bids that CMS evaluates

based on the suppliers' eligibility, their financial stability, and their bid prices. Generally, CMS awards contracts to the suppliers that offer lower bid prices and meet applicable quality and financial standards. The payment amounts resulting from winning bids replace Medicare fee-schedule amounts for the selected items.<sup>12</sup> Generally, contract awards and payment amounts expire every 3 years, and suppliers must recompute to remain contract suppliers.<sup>13</sup>

MIPPA added further conditions to the competition for DTS. MIPPA required that in rounds subsequent to the first round, mail-order suppliers must demonstrate in their bids that they can provide at least 50 percent, by volume, of the types of DTS provided to Medicare beneficiaries via mail order. This is known as the "50-percent rule." Suppliers must attest in their bids the types of DTS they intend to provide to meet the 50-percent rule. The Bipartisan Budget Act of 2018 amended the 50-percent rule by requiring the use of data from mail order and non-mail order Medicare markets.<sup>14</sup> The Bipartisan Budget Act of 2018 also amended the attestation requirement for the 50-percent rule by requiring suppliers to demonstrate their ability to obtain the inventory of DTS in their bids. Evidence supporting this ability may consist of letters of intent (or other evidence that the Secretary may determine) or good-faith efforts to obtain such letters or other evidence.<sup>15</sup>

*Current Status of the Competitive Bidding Program.* All Competitive Bidding Program contracts expired on December 31, 2018. In October 2018, CMS issued guidance stating that there would be a temporary gap in the Competitive Bidding Program, starting January 1, 2019, and expected to last until December 31, 2020.<sup>16</sup> As a result, beginning January 1, 2019, and until new contracts are awarded under the Competitive Bidding Program, beneficiaries may receive DTS from any Medicare-enrolled DMEPOS supplier.<sup>17</sup> According to CMS's November 2018 final rule, during the temporary gap in the Competitive Bidding Program, Medicare will pay for mail-order DTS at the single payment amount that was in effect on the last day of the Competitive Bidding Program contract period (i.e., December 31, 2018), adjusted for inflation.<sup>18</sup> For non-mail order DTS, Medicare payment will continue to be the single payment amount for mail-order DTS that was in effect on December 31, 2018, and those amounts will not be adjusted for inflation.<sup>19</sup>

## APPENDIX B

### OIG's Past and Current Work on Medicare DTS Market Share

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

Release Date  
December 2010

Report Title: *Medicare Market Shares of Mail Order Diabetic Testing Strips* (OEI-04-10-00130)  
Time period covered: October 2009 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 Title: *Medicare Market Shares of Mail Order Diabetes Test Strips from July-September 2013* (OEI-04-13-00680)  
Results: 43 total types—top 3 types had a 59% share of the market; top 10 types had 90%

Release Date  
June 2014

Report Title: *Medicare Market Shares of Mail Order Diabetes Test Strips Immediately Prior to the National Mail-Order Program* (OEI-04-13-00681)  
Time period covered: April 2013 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 Title: *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)  
Time period covered: October 2013 through December 2013  
Results: 41 total types—top 3 types had a 58% share of the market; top 10 types had 91%

#### Completed Before Round 2019 (Contracts Expired December 31, 2018)

Release Date  
November 2016

Report Title: *Medicare Market Shares of Mail Order Diabetes Test Strips from April to June 2016* (OEI-04-16-00470)  
Results: 30 total types—top 2 types had a 51% share of the market; top 10 types had 93%

Release Date  
February 2017

Report Title: *Medicare Market Shares of Mail-Order Diabetes Test Strips from July Through September 2016* (OEI-04-16-00471)  
Results: 18 total types—top 2 types had a 60% share of the market; top 10 types had 98%

Release Date  
May 2017

Report Title: *Medicare Market Shares of Mail-Order Diabetes Test Strips from October Through December 2016* (OEI-04-16-00473)  
Results: 19 total types—top 2 types had a 53% share of the market; top 11 types had 97%

#### Completed Before Next Round (No Contracts as of January 1, 2019)

Release Date  
January 2019

Report Title: *Medicare Market Shares of Mail-Order Diabetes Test Strips from April Through June 2018* (OEI-04-18-00440)  
Results: 17 total types—top 2 types had a 53% share of the market; top 10 types had 98%

Release Date  
March 2019

Report Title: *Medicare Market Shares of Non-Mail-Order Diabetes Test Strips from April Through June 2018* (OEI-04-18-00441)  
Results: 34 total types—top 3 types had a 53% share of the market; top 10 types had 93%

## APPENDIX C

### Exhibit C-1: Model, Manufacturer, and Market Share Estimates for Non-Mail Order DTS, April Through June 2018

Model	Manufacturer	Market Share	95-Percent Confidence Interval
ACCU-CHEK Aviva	Roche	0.22%	0.04–1.21%
ACCU-CHEK Aviva Plus	Roche	10.88%	8.88–13.26%
ACCU-CHEK Compact Plus	Roche	1.90%	1.14–3.15%
ACCU-CHEK Guide	Roche	0.85%	0.41–1.75%
ACCU-CHEK SmartView	Roche	2.81%	1.84–4.27%
Advocate Redi-Code+	BroadMaster Bio-Tec Corp.	0.19%	0.04–0.82%
Breeze2	PHC Holdings Corporation	0.32%	0.10–0.99%
CONTOUR	PHC Holdings Corporation	4.14%	3.10–5.52%
CONTOUR NEXT	PHC Holdings Corporation	12.61%	9.92–15.91%
EASYMax	Oak Tree International Holdings, Inc.	0.44%	0.21–0.93%
EasyTouch	MHC Medical Products	0.16%	0.05–0.51%
Embrace	Omnis Health	0.25%	0.10–0.63%
EvenCare G2	Medline	0.25%	0.08–0.84%
Fora G20	ForaCare, Inc.	0.06%	0.01–0.45%
Fora V10/V12	ForaCare, Inc.	0.06%	0.01–0.45%
Fora V30/G30/PremiumV10	ForaCare, Inc.	0.03%	0.00–0.22%
FreeStyle	Abbott Diabetes Care, Inc.	1.39%	0.77–2.49
FreeStyle InsuLinX	Abbott Diabetes Care, Inc.	0.63%	0.22–1.83%
FreeStyle LITE	Abbott Diabetes Care, Inc.	11.03%	9.10–13.33%
GE100	Bionime Corporation	0.16%	0.06–0.45%
GlucoCard Expression	ARKRAY	0.32%	0.12–0.82%
GlucoCard Vital	ARKRAY	0.25%	0.08–0.84%
GlucoNavii	SD Biosensor	0.13%	0.03–0.51%

<b>Model</b>	<b>Manufacturer</b>	<b>Market Share</b>	<b>95-Percent Confidence Interval</b>
NovaMax	Nova Biomedical	0.03%	0.00–0.22%
On Call Express	ACON Laboratories	0.06%	0.01–0.45%
On Call Vivid	ACON Laboratories	0.06%	0.01–0.45%
OneTouch Ultra	LifeScan, Inc.	29.12%	25.81–32.42%
OneTouch Verio	LifeScan, Inc.	8.31%	6.30–10.90%
Prodigy	Prodigy Diabetes Care	1.68%	0.94–2.97%
TRUEbalance	Trividia Health, Inc.	0.13%	0.02–0.89%
TRUEmetrix	Trividia Health, Inc.	10.31%	8.51–12.43%
TRUEtrack	Trividia Health, Inc.	0.89%	0.44–1.78%
Ultra Trak Pro	Zenith Diagnostics	0.09%	0.02–0.41%
WaveSense Presto	AgaMatrix	0.22%	0.08–0.61%

Source: OIG analysis of supplier documentation and Medicare claims containing the Healthcare Common Procedure Coding System (HCPCS) code A4253—but without the KL modifier—for the 3-month period of April through June 2018.

**Exhibit C-2. Medicare Market Share Estimates for the Top 3, Top 5, and Top 10 Types of Non-Mail Order DTS, April Through June 2018**

<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 3 Strip Types	<ol style="list-style-type: none"> <li>1. OneTouch Ultra</li> <li>2. CONTOUR NEXT</li> <li>3. FreeStyle LITE</li> </ol>	52.76%	49.12–56.41%
Top 5 Strip Types	<ol style="list-style-type: none"> <li>1. OneTouch Ultra</li> <li>2. CONTOUR NEXT</li> <li>3. FreeStyle LITE</li> <li>4. ACCU-CHEK Aviva Plus</li> <li>5. TRUEmetrix</li> </ol>	73.94%	70.76–77.13%
Top 10 Strip Types	<ol style="list-style-type: none"> <li>1. OneTouch Ultra</li> <li>2. CONTOUR NEXT</li> <li>3. FreeStyle LITE</li> <li>4. ACCU-CHEK Aviva Plus</li> <li>5. TRUEmetrix</li> <li>6. OneTouch Verio</li> <li>7. CONTOUR</li> <li>8. ACCU-CHEK Smart-View</li> </ol>	92.79%	90.92–94.30%

Source: OIG analysis of supplier documentation and Medicare claims containing HCPCS code A4253—but without the KL modifier—for the 3-month period of April through June 2018.

## **ACKNOWLEDGMENTS**

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This report was prepared under the direction of Dwayne Grant, Regional Inspector General for Evaluation and Inspections in the Atlanta regional office, and Jaime Stewart, Assistant Regional Inspector General.

## ENDNOTES

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<sup>1</sup> This analysis does not include types of DTS that were exclusively sold by single retailers. The methodology provides additional information about which types of DTS were included in our analysis.

<sup>2</sup> We did not receive responses from 49 suppliers. Of these, 33 suppliers acknowledged receipt of the documentation request but never submitted the required documentation; 15 never responded and appear to still be doing business; and 1 never responded and appears to have stopped doing business after the claims included in our sample were submitted.

<sup>3</sup> § 50414(a)(1)(A) of the Bipartisan Budget Act of 2018, P.L. No. 115-123, revising 1847(b)(10)(A) of the Social Security Act. Accessed at <https://www.congress.gov/115/bills/hr1892/BILLS-115hr1892enr.pdf> on August 17, 2018.

<sup>4</sup> Generally, each box of DTS contains 50 strips. Some types of DTS are packaged in 51-count boxes instead of 50-count boxes, but Medicare pays for these boxes as though they were 50-count boxes. We counted these boxes of DTS as containing 51 strips in our analysis.

<sup>5</sup> National Institutes of Health (NIH), *What is Diabetes?* Accessed at <https://www.niddk.nih.gov/health-information/diabetes/overview/what-is-diabetes> on October 24, 2018.

<sup>6</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 October 24, 2018.

<sup>7</sup> Other diabetes testing supplies may include batteries, lancets, and control solution.

<sup>8</sup> CMS, *MLN [Medicare Learning Network] Matters Number SE1008 Revised. Medicare Coverage of Blood Glucose Monitors and Testing Supplies*. Accessed at <http://www.cms.gov/MLNMattersArticles/downloads/SE1008.pdf> on October 3, 2018. 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 [Local Coverage Determination] for Glucose Monitors (L33822 for DME [Durable Medical Equipment] MAC Jurisdictions A, B, C, and D)*.

<sup>9</sup> Suppliers submit claims using Healthcare Common Procedure Coding System (HCPCS) codes to receive Medicare reimbursement. Medicare claims for DTS are billed using HCPCS code A4253. For DTS provided via 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>10</sup> American Taxpayer Relief Act of 2012, P.L. No. 112-240 § 636 (added new paragraph to Social Security Act, § 1834(a)(1)(H), 42 U.S.C. § 1395m(a)(1)(H)). See also CMS, *MLN Matters Number MM8325 Revised. July Quarterly Update for 2013 Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule*. Accessed at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM8325.pdf> on December 13, 2018.

<sup>11</sup> Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. No. 108-173 § 302(b)(1).

<sup>12</sup> In November 2018, CMS revised its Competitive Bidding Program rules to change the processes for submitting bids, evaluating bids, and calculating single payment amounts. Specifically, CMS will replace the bidding method in effect through 2018—in which a supplier submits a bid for each item in the product category—with what is known as “lead item pricing.” Under lead item pricing, a bidding supplier would submit a bid for one item—known as the lead item—in the product category. The maximum winning bid for the lead item would be used to establish single payment amounts for both the lead item and all other items in the product category. 83 Fed. Reg. 56922 (Nov. 14, 2018). Accessed at <https://www.gpo.gov/fdsys/pkg/FR-2018-11-14/pdf/2018-24238.pdf> on November 16, 2018.

<sup>13</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>14</sup> § 50414(a)(1) of the Bipartisan Budget Act of 2018, P.L. No. 115-123. Accessed at <https://www.congress.gov/115/bills/hr1892/BILLS-115hr1892enr.pdf> on August 17, 2018.

<sup>15</sup> *Ibid.*

<sup>16</sup> CMS, *Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Bidding Program: Temporary Gap Period*. Accessed at <https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/Downloads/DMEPOS-Temporary-Gap-Period-Fact-Sheet.pdf> on December 13, 2018.

<sup>17</sup> Ibid.

<sup>18</sup> The single payment rate for mail-order DTS that was in effect on December 31, 2018, will be increased by the projected percentage change in the Consumer Price Index for All Urban Consumers for the 12-month period on the date after the contract period ended. 42 CFR § 414.210(g)(10) (as added by 83 Fed. Reg. 56922, 57071 (Nov. 14, 2018)). Accessed at <https://www.gpo.gov/fdsys/pkg/FR-2018-11-14/pdf/2018-24238.pdf> on November 16, 2018.

<sup>19</sup> 83 Fed. Reg. 56922, 57037 (Nov. 14, 2018). Accessed at <https://www.gpo.gov/fdsys/pkg/FR-2018-11-14/pdf/2018-24238.pdf> on November 16, 2018.