

**Department of Health and Human Services**

**OFFICE OF  
INSPECTOR GENERAL**

**ROUND 2 COMPETITIVE BIDDING FOR  
ENTERAL NUTRITION: CONTINUED  
ACCESS FOR VAST MAJORITY OF  
BENEFICIARIES**



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## Round 2 Competitive Bidding for Enteral Nutrition: Continued Access for Vast Majority of Beneficiaries

### What OIG Found

The vast majority of beneficiaries who received enteral nutrition supplies in 2013 continued to do so after Round 2 of the Competitive Bidding Program for durable medical equipment (DME) began in July 2013. (In this report, we use the term “enteral nutrition supplies” to refer to daily feeding supply kits, tubes, and nutrients.)

Medicare payments for enteral nutrition supplies continued for 91 percent of beneficiaries in Round 2 competitive bidding areas (CBAs) and for 94 percent of beneficiaries in areas that were not CBAs (which we refer to as non-CBAs) after Round 2 began. These rates are only slightly lower than the percentage of beneficiaries—95 percent—for whom Medicare payments for enteral nutrition supplies continued over the same timeframe in 2012, 1 year prior to Round 2 of competitive bidding.

Our surveys of physicians and beneficiaries provided some insights for a sample of beneficiaries for whom payments for enteral nutrition supplies stopped.

For example, physicians largely told us that beneficiaries without continued payments still had a prescribed need for the nutrients or supplies, and three of the six responding beneficiaries reported continuing to receive them even though Medicare payments stopped.

### What OIG Concludes

The Competitive Bidding Program aims to combat fraud, waste, and abuse; improve the methods for setting payments for DME; and create cost savings for Medicare and its beneficiaries, all while maintaining beneficiary access to needed DME. Our analysis for this report supports the conclusion that the vast majority of beneficiaries had continued access to enteral nutrition supplies after Round 2 began. However, we did find that the percentage of beneficiaries for whom Medicare payments for enteral nutrition supplies did not continue was slightly higher in Round 2 CBAs than in non-CBAs. This difference may or may not indicate disruptions in receiving needed enteral nutrition supplies. For example, this difference may indicate that the program reduced the provision of unnecessary enteral nutrition supplies, as the Centers for Medicare & Medicaid Services determined to be the case with Round 1 of the program.

### Key Takeaway

Round 2 of the Competitive Bidding Program does not appear to have disrupted access to enteral nutrition supplies for the vast majority of beneficiaries. Among beneficiaries who received enteral nutrition supplies in 2013 before bidding began, 91 percent continued to do so after Round 2 began. This rate is only slightly lower than the 94-percent continuation rate in nonbidding areas after Round 2 began and the 95-percent continuation rate before Round 2 took effect.

### Why OIG Did This Review

The Competitive Bidding Program changed the way Medicare pays for DME and it is important to understand how this change may have affected beneficiary access to needed DME. Medicare established the program to combat fraud, waste, and abuse in the provision of DME. The program replaced a fee schedule with a competitive bidding process to set Medicare reimbursement amounts for certain types of DME.

In a letter to the Office of Inspector General (OIG), Members of Congress expressed concerns about the program’s effect on access to DME and requested that OIG study this issue.

### How OIG Did This Review

We used Medicare claims to identify a population of beneficiaries for whom Medicare paid claims for enteral nutrition supplies before Round 2 of the Competitive Bidding Program began in 2013. Using discontinued payments after Round 2 began as a proxy for disrupted access, we compared the rates of discontinued payments in Round 2 CBAs and non-CBAs. We also analyzed Medicare claims data from 2012 to determine the percentage of beneficiaries receiving enteral nutrition supplies for whom Medicare payments stopped in the last full year prior to Round 2 of the program. We then surveyed the physicians who had ordered the enteral nutrition supplies for a sample of these beneficiaries. In cases in which physicians reported a continued beneficiary need, we surveyed those beneficiaries to learn about their experiences after Round 2 began.

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## OBJECTIVE

To determine whether Round 2 of the Competitive Bidding Program (CBP) appeared to disrupt beneficiary access to enteral nutrition supplies.

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## BACKGROUND

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 mandated the establishment of the CBP as one of several efforts aimed at combating fraud, waste, and abuse.<sup>1</sup> For selected categories of durable medical equipment (DME), this program replaces a fee-schedule payment methodology with a competitive bidding process in certain areas of the country. The goal of the program is to improve the methodology for setting DME payment amounts in a way that creates cost savings for Medicare and its beneficiaries while maintaining beneficiary access to quality items and services. The Centers for Medicare & Medicaid Services (CMS) has reported that the CBP is a success; however, Congress and other stakeholders have raised concerns about the program's impact on beneficiary access to DME.

In a July 2014 letter to the Office of Inspector General (OIG), 138 Members of Congress expressed concerns about the CBP's effect on Medicare beneficiary access to DME. The letter suggested that noncompliance of contracted suppliers in the CBP is affecting the quality and choice of DME available to beneficiaries and requested that OIG study the CBP's effect on access to DME.

In a report issued in May 2016, CMS concluded that the CBP was saving money for Medicare and its beneficiaries without compromising access to DME. In that report, CMS stated that the CBP had saved about \$3.6 billion and had not had any negative impact on beneficiary health outcomes.<sup>2</sup> CMS conducts real-time data analysis to monitor the health status of beneficiaries served by the CBP, and as of the end of June 2017, CMS reported that it had not observed any negative changes in beneficiary

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

<sup>2</sup> CMS, *Providing Quality, Affordable Durable Medical Equipment for Beneficiaries*. Accessed at <https://wayback.archive-it.org/2744/20161207130006/https://blog.cms.gov/2016/05/17/providing-quality-affordable-durable-medical-equipment-for-beneficiaries/> on April 26, 2017.

health outcomes.<sup>3</sup> For its real-time data analysis, CMS monitors health outcomes such as deaths, hospitalizations, and emergency room visits, as well as average number of days spent hospitalized, among other data. In addition, CMS estimated in 2012 that Round 1 of competitive bidding had reduced Medicare spending on enteral nutrients, equipment, and supplies by nearly \$19 million.<sup>4</sup>

### **Overview of the Competitive Bidding Program**

Under the CBP, DME suppliers compete to contract with Medicare to supply selected DME items within specific geographic areas known as Competitive Bidding Areas (CBAs). CMS and its Competitive Bidding Implementation Contractor evaluate a supplier's bid on the basis of the bid amount and several other criteria, including the supplier's eligibility and financial stability.<sup>5</sup>

Pursuant to the Medicare Modernization Act, CMS established bidding in rounds, which CMS must recompetes at least once every 3 years.<sup>6</sup> Each round involves certain DME product categories and CBAs. Each product category includes a group of related products that are used to treat a similar medical condition. In January 2016, CMS began using pricing data from the CBP to set reimbursement rates for DME in areas of the country not subject to the CBP.<sup>7</sup> (In this report, we refer to areas not subject to the CBP as “non-CBAs.”) See Exhibit 1 below for details on the rounds of the CBP.

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<sup>3</sup> CMS, *Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Bidding Program—Health Status Monitoring: Summary of Findings thru the Second Quarter of 2017*. Accessed at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Downloads/DME-Summary-of-Findings.pdf> on November 16, 2017.

<sup>4</sup> CMS, *Competitive Bidding Update—One Year Implementation Update, April 17, 2012*. Accessed at <https://www.cms.gov/medicare/medicare-fee-for-service-payment/dmeposcompetitivebid/downloads/competitive-bidding-update-one-year-implementation.pdf> on October 26, 2016.

<sup>5</sup> CMS, *DMEPOS Competitive Bidding – Home*. Accessed at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/index.html?redirect=/dmeposcompetitivebid/> on May 5, 2015.

<sup>6</sup> Social Security Act, § 1847(b)(3)(B), 42 U.S.C. § 1395w-3(b)(3)(B); 42 CFR § 414.422(b).

<sup>7</sup> 42 CFR § 414.210(g).

## Exhibit 1: CBP Round Effective Dates, CBAs, and Product Categories

CBP Round	Effective Dates	CBAs	Product Categories*
<b>Round 1</b>	<p><b>Round 1 Rebid:</b><sup>8</sup> Jan. 1, 2011 – Dec. 31, 2013</p> <p><b>Round 1 Recompete:</b><sup>9</sup> Jan. 1, 2014 – Dec. 31, 2016</p> <p><b>Round 1 2017:</b> Jan. 1, 2017 – Dec. 31, 2018</p>	9 to 13 CBAs – For the Round 1 Rebid and Round 1 Recompete, 9 CBAs covering the largest metropolitan statistical areas by population that did not span multiple Medicare Administrative Contractor jurisdictions, <sup>10</sup> but not including New York City, Los Angeles, and Chicago. For Round 1 2017, to prevent multi-State CBAs, CMS split 3 of the original 9 CBAs into multiple CBAs, for a total of 13 CBAs.	<p><u>All Effective Dates:</u> Oxygen; CPAP/RAD devices and supplies; enteral nutrition; standard power wheelchairs; scooters; walkers; hospital beds</p> <p><u>Some Effective Dates:</u> Complex rehabilitative wheelchairs, standard manual wheelchairs, support surfaces, mail-order diabetes supplies, commode chairs, patient lifts, seat lifts, transcutaneous electrical nerve stimulation, external infusion pumps, nebulizers, negative pressure wound therapy pumps</p>
<b>Round 2</b>	<p>July 1, 2013 – June 30, 2016</p> <p><b>Recompete:</b> July 1, 2016 – December 31, 2018</p>	100 to 117 CBAs – For Round 2, 100 CBAs, covering the next 91 largest metropolitan statistical areas and including New York City, Los Angeles, and Chicago, with each subdivided into multiple CBAs. For the Round 2 Recompete, 117 CBAs to prevent multi-State CBAs.	Oxygen; CPAP/RAD devices and supplies; enteral nutrition; standard wheelchairs; walkers; hospital beds; support surfaces; negative pressure wound therapy pumps
<b>National Mail Order Program</b>	<p>July 1, 2013 – June 30, 2016</p> <p><b>Recompete:</b> July 1, 2016 – December 31, 2018</p>	1 CBA – All parts of the United States, including the 50 States, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Guam, and American Samoa.	Diabetes testing supplies

\*Some product categories were renamed and combined from one contract cycle to the next.

### Medicare Coverage of Enteral Nutrition

To be covered by Medicare, an item or service must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body part.<sup>11</sup> Enteral nutrition provides

<sup>8</sup> Round 1 was implemented in 2008 and discontinued 2 weeks later by the passage of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). As required by MIPPA, the supplier competition was held again in 2009. This 2009 competition is referred to as the Round 1 Rebid.

<sup>9</sup> The Round 1 Rebid included contracts for mail-order diabetes testing supplies, but those contracts ended in December 2012, and bidding for diabetes testing supplies moved to the National Mail Order Program. CMS, *Round 1 Rebid Mail-Order Diabetic Supply Contracts Ending on December 31, 2012*. Accessed at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Downloads/2012-12-14-DMEPOS.pdf> on January 12, 2017.

<sup>10</sup> CMS, *General Overview of the Final Rule for Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies*, April 10, 2007. Accessed at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Downloads/DMEPOSRegSumm.pdf> on May 5, 2015.

<sup>11</sup> Social Security Act § 1862(a)(1)(A), 42 U.S.C. § 1395y(a)(1)(A).

nutrients through a tube into the stomach or small intestine.<sup>12</sup> Medicare considers enteral nutrition reasonable and necessary for beneficiaries who have a permanent nonfunction or disease of the structures that normally permit food to reach the small intestine (e.g., if a beneficiary cannot swallow because of a permanent medical problem) or who have a disease of the small intestine that impairs digestion and absorption of nutrients.<sup>13</sup> In addition, the beneficiary must require tube feedings to provide sufficient nutrients to maintain weight and strength commensurate with the beneficiary’s overall health status. Medicare pays for enteral nutrition as long as medically necessary.<sup>14</sup>

Enteral nutrients may be administered to beneficiaries by syringe, gravity, or pump.<sup>15</sup> For enteral nutrients and supplies such as dressings, tape, and syringes, Medicare pays for no more than 1 month’s supply at a time. Medicare pays to replace certain more durable supplies every 3 months.<sup>16</sup>

In this report, we use the term “enteral nutrition supplies” to refer to daily feeding supply kits, tubes, and nutrients.

### **Program Integrity Concerns with Enteral Nutrition**

Medicare’s Comprehensive Error Rate Testing (CERT) program has long found high error rates in DME, including enteral nutrition. In 2012, the year before Round 2 of the CBP started, the CERT found a 66-percent error rate in DME overall and a 57-percent error rate in enteral

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<sup>12</sup> CMS, *The Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program: Enteral Nutrition*. Accessed at [https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/DME\\_Enteral\\_Factsheet\\_ICN901005.pdf](https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/DME_Enteral_Factsheet_ICN901005.pdf) on April 26, 2017.

<sup>13</sup> CMS, *National Coverage Determinations Manual*, Pub. No. 100-03, ch. 1, pt. 3, § 180.2. See also *Local Coverage Determination (LCD): Enteral Nutrition (L33783) for DME MAC Jurisdictions A, B, C, and D*. Accessed at <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33783&ver=9&DocID=L33783&bc=gAAAABAAAA&> on January 18, 2018. Prior to October 1, 2015, the DME MACs had separate but identical LCDs for enteral nutrition (i.e., LCDs L5041, L27214, L11553, and L11568 for DME MAC Jurisdictions A, B, C and D, respectively), available online at [https://localcoverage.cms.gov/mcd\\_archive/](https://localcoverage.cms.gov/mcd_archive/).

<sup>14</sup> Ibid.

<sup>15</sup> Ibid.

<sup>16</sup> Ibid.

nutrition.<sup>17, 18</sup> In 2016, the CERT found a 46-percent error rate in DME overall and a 50-percent error rate in enteral nutrition.<sup>19</sup>

### **Related OIG Work**

OIG has a long history of identifying fraud, waste, and abuse in the provision of DME devices and supplies. Since passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which established the CBP, OIG has opened more than 2,000 investigative cases involving DME suppliers. Over the last several years, OIG investigations have contributed to several fraud cases by the Department of Justice against suppliers of enteral nutrition supplies.<sup>20, 21, 22, 23</sup>

OIG audits and evaluations have examined implementation of the CBP and market trends for specific types of DME.<sup>24</sup> A November 2017 OIG audit found that CMS generally met requirements in Round 2 of the CBP.<sup>25</sup> However, because of inconsistency in how CMS followed its procedures, CMS awarded a small number of Round 2 contracts to suppliers that did not meet program requirements. OIG has also released three

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<sup>17</sup> CMS, *Medicare Fee-For-Service 2012 Improper Payments Report*, p. 31. Accessed at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/CERT/Downloads/Medicare-Fee-for-Service-2012-Improper-Payments-Report.pdf> on November 2, 2016.

<sup>18</sup> CMS, *Medicare Fee-For-Service 2012 Improper Payments Report*, p. 8. Accessed at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/CERT/Downloads/AppendicesNovember2012CERTReport.pdf?agree=yes&next=Accept> on May 2, 2017.

<sup>19</sup> CMS, *Medicare Fee-For-Service 2016 Improper Payments Report*, pp. 9 and 21. Accessed at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/CERT/Downloads/AppendicesMedicareFee-for-Service2016ImproperPaymentsReport.pdf> on November 16, 2017.

<sup>20</sup> U.S. Department of Justice, *Healthcare Company Executives Sentenced to Prison for Fraud and Kickbacks*, February 2015. Accessed at <https://www.justice.gov/usao-mdla/pr/healthcare-company-executives-sentenced-prison-fraud-and-kickbacks> on April 26, 2017.

<sup>21</sup> U.S. Department of Justice, *Operators Of Healthcare Company Convicted Of Fraud And Kickbacks*, July 2014. Accessed at <https://www.justice.gov/usao-mdla/pr/operators-healthcare-company-convicted-fraud-and-kickbacks> on April 26, 2017.

<sup>22</sup> U.S. Department of Justice, *DME Owner Convicted On All Counts*, April 2014. Accessed at <https://www.justice.gov/usao-sdtx/pr/dme-owner-convicted-all-counts> on April 26, 2017.

<sup>23</sup> U.S. Department of Justice, *DME Owner Arrested In 21-Count Health Care Fraud Indictment*, March 2013. Accessed at <https://www.justice.gov/usao-sdtx/pr/dme-owner-arrested-21-count-health-care-fraud-indictment> on April 26, 2017.

<sup>24</sup> OIG, *CMS Generally Met Requirements in the DME Competitive Bidding Round 1 Rebid Program*, A-05-12-00067, April 2014.

<sup>25</sup> OIG, *CMS Generally Met Requirements in Round 2 of the DMEPOS Competitive Bidding Program*, A-05-14-00049, November 2017.



memorandum reports evaluating the market shares of different types of diabetes test strips.<sup>26, 27, 28</sup>

This report is one of a series on how the launch of Round 2 of the CBP has affected continued access to DME. It examines beneficiary access to enteral nutrition supplies, which in 2013 made up 5 percent of paid claims in Round 2 of the CBP. The other reports in this series examine CPAP/RAD devices (i.e., continuous positive airway pressure devices and respiratory assist devices) and related supplies and oxygen equipment and contents. The former found that the launch of Round 2 of the CBP did not likely disrupt beneficiary access to CPAP/RAD devices but it was inconclusive as to whether Round 2 had affected access to related supplies.<sup>29</sup> The latter, *Round 2 Competitive Bidding for Oxygen: Continued Access for Vast Majority of Beneficiaries*, OEI-01-15-00041, which is being issued simultaneously with this report, found that Round 2 of the CBP did not likely disrupt beneficiary access to oxygen equipment and contents.

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## METHODOLOGY

This inspection analyzes a population of Medicare beneficiaries over two different time spans to determine whether Round 2 of the CBP appeared to disrupt access to enteral nutrition supplies. This population includes beneficiaries using enteral nutrition supplies and covers the 3 months before and the 6 months after Round 2 contracts became effective on July 1, 2013. For ease of presentation in this report, we refer to July 1, 2013—the date when Round 2 contracts went into effect—as the date that Round 2 began.

We used Medicare claims data to identify our population. The population includes beneficiaries who resided in Round 2 CBAs and non-CBAs, which enabled us to make comparisons to look for evidence of potential disruptions in access. This population includes beneficiaries for whom there was at least one claim for enteral nutrition supplies from April through June 2013.

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<sup>26</sup> OIG, *Memorandum Report: Medicare Market Shares of Mail Order Diabetes Test Strips from July-September 2013*, OEI-04-13-00680, June 2014.

<sup>27</sup> OIG, *Memorandum Report: Medicare Market Shares of Mail Order Diabetes Test Strips Immediately Prior to the National Mail Order Program*, OEI-04-13-00681, June 2014.

<sup>28</sup> OIG, *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, November 2014.

<sup>29</sup> OIG, *Round 2 Competitive Bidding for CPAP/RAD: Disrupted Access Unlikely for Devices, Inconclusive for Supplies*, OEI-01-15-00040, June 2017.

Using Medicare claims data, we determined the extent to which beneficiaries in our population appeared to have their access to enteral nutrition supplies disrupted by Round 2 of the CBP. Specifically, we used the absence of paid claims for beneficiaries in the population after Round 2 began as a marker of potential disruption in access. We calculated the percentages of beneficiaries in the population for whom Medicare payments stopped and compared them between beneficiaries residing in Round 2 CBAs and non-CBAs. As a comparison, we analyzed Medicare claims data from 2012 to determine the percentage of beneficiaries receiving enteral nutrition supplies for whom Medicare payments stopped in the last full year prior to Round 2 of the CBP.

To learn more about the experience of beneficiaries with a potential disruption in access after Round 2 began, we selected a sample of beneficiaries in our population for whom Medicare payments stopped. We stratified this sample by whether the beneficiaries resided in Round 2 CBAs or non-CBAs. To determine whether the sampled beneficiaries continued to need the items after Round 2 began, we separately surveyed the physicians who ordered their enteral nutrition supplies. Each physician we surveyed ordered nutrients or supplies for one of our sampled beneficiaries. When a physician told us that the beneficiary had a continued need for the items and Medicare records indicated that the beneficiary was still living in 2016, we considered that beneficiary to be eligible for our survey, which asked beneficiaries to describe their experiences after Round 2 began. Exhibit 2 provides details on these samples and surveys.

**Exhibit 2: Surveys Regarding Enteral Nutrition Supplies**

	<b>Round 2 CBAs</b>	<b>Non-CBAs</b>	<b>Total</b>
<b>Total Physicians in Sample</b>	150	150	300
<b>Physicians Surveyed<sup>1</sup></b>	114	94	208
<b>Physicians Responding With Usable Data<sup>2</sup></b>	64	54	118
<b>Physician Response Rate</b>	<b>43%</b>	<b>36%</b>	<b>39%</b>
<b>Beneficiaries Eligible for Survey</b>	25	12	37
<b>Beneficiaries Responding With Usable Data</b>	5	1	6
<b>Beneficiary Response Rate</b>	<b>20%</b>	<b>8%</b>	<b>16%</b>

Source: OIG analysis of physician and beneficiary responses to survey, 2017.

<sup>1</sup> We did not survey a physician if the beneficiary was deceased when Round 2 began, if the physician was under investigation, or if the physician was no longer in business.

<sup>2</sup> In some cases, physicians cooperated by responding to our survey, but their responses included no usable information.

## **Limitations**

This review has two limitations. First, we use continued Medicare payment as a proxy for continued access to enteral nutrition supplies. Continued Medicare payment is a measure of *potential* continued access but we understand that it is not a direct measure of continued access to enteral nutrition supplies. Without a determination of continued need, the lack of continued Medicare payments does not necessarily indicate a disruption in access to enteral nutrition supplies.

Secondly, the response rate for our survey was too low to project the results to all beneficiaries for whom claims did not continue. Therefore, we present our survey responses as testimonial evidence to provide potential insights into these individual beneficiaries' experiences in accessing enteral nutrition supplies. We did not independently verify responses from physicians and beneficiaries, nor did we conduct a medical review of beneficiaries' medical need for these supplies. See Appendix A for a detailed description of our methodology.

## **Standards**

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

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## **FINDING**

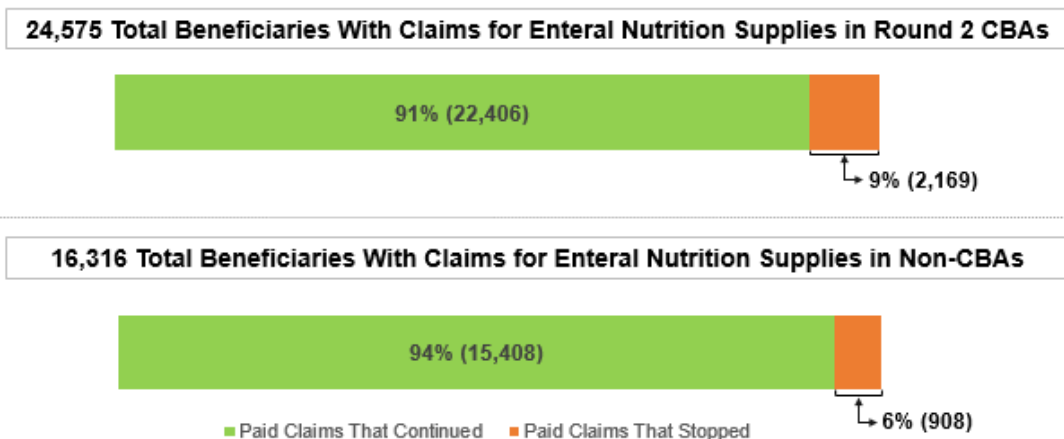
### **The start of Round 2 did not appear to disrupt access to enteral nutrition supplies for the vast majority of beneficiaries**

During the 3 months before Round 2 began (i.e., April through June 2013), 40,891 beneficiaries used enteral nutrition supplies in Round 2 CBAs and non-CBAs. The proportions of beneficiaries for whom Medicare made continued payments for enteral nutrition supplies after Round 2 began were similar in Round 2 CBAs and non-CBAs. Additionally, the rate at which Medicare payments continued for beneficiaries between the period of April through June 2013 and later in 2013 was similar to the continuation rate for the corresponding months in 2012.

#### ***In 2013, Medicare payments continued for 91 percent of beneficiaries in Round 2 CBAs and 94 percent of beneficiaries in non-CBAs***

After Round 2 began, 91 percent of beneficiaries in Round 2 CBAs and 94 percent in non-CBAs had one or more paid claims for enteral nutrition supplies. After Round 2 began, Medicare paid (on average) 13 claims per beneficiary for beneficiaries in Round 2 CBAs and 12 claims for beneficiaries in non-CBAs. This suggests that in the months after Round 2 began, beneficiaries continued to receive enteral nutrition supplies both in Round 2 CBAs and non-CBAs. However, we note that the slightly higher proportion of beneficiaries without continued Medicare payments in Round 2 CBAs compared to beneficiaries in non-CBAs may suggest disruptions in receiving needed enteral nutrition supplies for a small proportion of beneficiaries. Alternatively, it may indicate that Round 2 of the CBP reduced the provision of unnecessary enteral nutrition supplies, similar to what CMS analysis found after Round 1 of the CBP. See Exhibit 3 for additional detail on the numbers and percentages of beneficiaries with continued or stopped paid claims for enteral nutrition supplies.

**Exhibit 3: Numbers and Percentages of Beneficiaries For Whom Paid Claims for Enteral Nutrition Supplies Continued or Stopped After Round 2 Began**



Source: OIG analysis of Medicare claims data, 2017.

In addition, Medicare claims suggest that a majority of these beneficiaries likely continued to receive enteral nutrition supplies without interruption. In the first half of 2013, suppliers billed Medicare every 24 to 30 days, on average, for beneficiaries’ enteral nutrients and daily feeding supply kits and less frequently for more durable supplies such as tubing. On average, beneficiaries with continuing payments for these items in Round 2 CBAs went 30 days and beneficiaries in non-CBAs went 29 days between their last claim before Round 2 began and their first claim after Round 2 began. This suggests that beneficiaries with continued Medicare payments largely received their enteral nutrition supplies without interruption after Round 2 began.

***In 2012, Medicare payments continued for 95 percent of beneficiaries who received enteral nutrition supplies in April through June of that year***

We also examined Medicare payments in 2012, the last full year prior to Round 2, and found that 95 percent of beneficiaries with Medicare payments for enteral nutrition supplies in April through June 2012 continued to have payments for enteral nutrition supplies in the second half of that year. This continuation rate for 2012 is slightly higher than the continuation rate for the corresponding period in 2013, which was 91 percent in Round 2 CBAs.

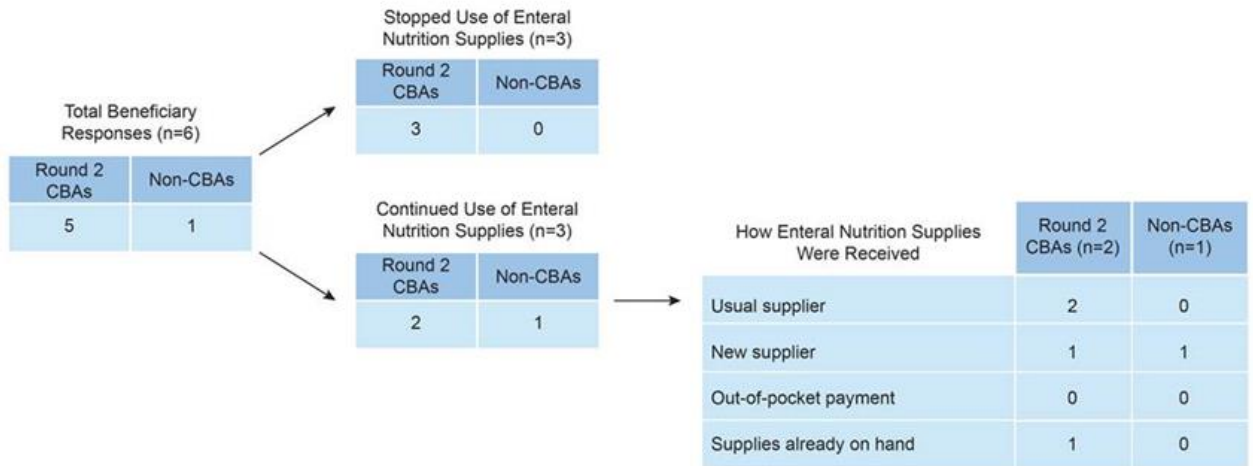
***In their survey responses, over 80 percent of physicians told us that beneficiaries without continued payments still had a prescribed need for the nutrients or supplies, and three of the six responding beneficiaries reported continued use of the nutrients or supplies***

Our surveys provide some insights, albeit limited, to the experiences of these beneficiaries for whom payments stopped after Round 2 began—an indicator of a potential disruption in access. Physicians who responded to our survey largely reported that beneficiaries for whom they ordered enteral nutrition supplies still had a prescribed need for them after Round 2 began. This was the case both in Round 2 CBAs and non-CBAs. In Round 2 CBAs, 46 of 51 physicians who provided usable data reported that the beneficiaries for whom they ordered nutrients or supplies still had a prescribed need for those nutrients or supplies. This compares to 37 of 45 physicians in non-CBAs.

Finally, responding beneficiaries provided some insights into their experiences with enteral nutrition supplies. For example, three of the six beneficiaries reported continued use of enteral nutrition supplies, even though Medicare stopped paying for them. Specifically, two of the five responding beneficiaries from Round 2 CBAs and the one responding beneficiary from a non-CBA reported continued use of enteral nutrition supplies. One beneficiary from each population reported having started getting enteral nutrition supplies from a new supplier, while two beneficiaries from Round 2 CBAs reported that they received supplies from their usual respective suppliers. One beneficiary from a Round 2 CBA reported using nutrients or supplies that he or she already had on hand. None reported having paid out of pocket for their needed nutrients or supplies. Having to pay out of pocket could limit access to needed items.

Also, of the three beneficiaries in Round 2 CBAs who reported that they stopped using enteral nutrition supplies, one reported doing so because of being able to eat again after removal of the feeding tube. See Exhibit 4 for additional detail on survey responses from beneficiaries.

**Exhibit 4: Survey Responses From a Subset of Beneficiaries For Whom Paid Claims for Enteral Nutrition Supplies Stopped**



Note: Each category is not mutually exclusive. Respondents can answer "Yes" to more than one category, "No," or not respond to the survey question.

Source: OIG analysis of beneficiary responses to survey, 2017.

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## CONCLUSION

This study is one in a series that determines whether Round 2 of the CBP appeared to disrupt access to certain types of DME when it began in 2013. In this study, we examined enteral nutrition supplies, which accounted for 5 percent of paid Medicare claims under Round 2 in 2013.

According to our claims analysis, the start of Round 2 of the CBP did not appear to disrupt access to enteral nutrition supplies for the vast majority of beneficiaries.

Another report in this series examines beneficiary access to CPAP/RAD and found that Round 2 did not likely disrupt beneficiary access to CPAP/RAD devices but was inconclusive as to whether Round 2 had affected access to related supplies. Additionally, a report on oxygen equipment and contents found that Round 2 of the CBP did not appear to disrupt access to oxygen equipment and supplies for the vast majority of beneficiaries.

Taken together, the three types of DME we examined in this series comprise just over 70 percent of DME subject to bidding under Round 2. The CBP aims to combat fraud, waste, and abuse; improve the methods for setting DME payments; and create cost savings for Medicare and its beneficiaries, all while maintaining access for beneficiaries who need DME. With respect to the DME we examined in this report, our analysis supports the conclusion that the vast majority of beneficiaries had continued access to enteral nutrition supplies after Round 2 began. However, we did find a slightly higher proportion of beneficiaries in Round 2 CBAs in 2013 without continued Medicare payments compared to beneficiaries in non-CBAs and compared to beneficiaries in 2012. This decline may suggest disruptions in receiving needed supplies for a small proportion of beneficiaries. Alternatively, it may indicate that Round 2 of the CBP reduced the provision of unnecessary enteral nutrition supplies, similar to CMS's findings after Round 1 of the CBP.



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## **AGENCY COMMENTS AND OIG RESPONSE**

CMS wrote that it appreciates our close review of the CBP's effect on beneficiary access to DME. CMS stated that it continues to review the and will take our findings and methods into account.

OIG appreciates CMS's review of and comments to this report.

## APPENDIX A

### Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

200 Independence Avenue SW  
Washington, DC 20201

**DATE:** FEB 26 2018

**TO:** Daniel R. Levinson  
Inspector General

**FROM:** Seema Verma *SV*  
Administrator

**SUBJECT:** Office of Inspector General (OIG) Draft Report: Round 2 Competitive Bidding for Enteral Nutrition: Continued Access for Vast Majority of Beneficiaries (OEI-01-15-00042)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report. CMS welcomes the OIG's review in this area and is committed to ensuring the success of the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program for patients, suppliers, and providers.

The Medicare DMEPOS Competitive Bidding Program was established by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and later modified by the Medicare Improvements for Patients and Providers Act of 2008, the Patient Protection and Affordable Care Act of 2010, and the Medicare Access and CHIP Reauthorization Act of 2015. Section 1834(a)(1)(F)(i) of the Social Security Act requires that Medicare replace the fee schedule payment methodology for selected DMEPOS items and services furnished within competitive bidding areas with the payment amounts determined under the Competitive Bidding Program.

CMS appreciates the OIG's close review of the Competitive Bidding Program's effect on access to DMEPOS items. We believe it is important to consider various methods of detecting impacts on beneficiaries and suppliers. As OIG is aware, CMS is closely reviewing the Competitive Bidding Program, including ways to analyze potential impacts on access outside of claims data. CMS continues to independently review the program and will take OIG's findings and methods into account.

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## **APPENDIX B**

### **Detailed Methodology**

#### **Scope**

This inspection analyzes a population of Medicare beneficiaries over two different time spans to determine the effect of Round 2 of the CBP on access to enteral nutrition supplies. This population includes beneficiaries using enteral nutrition supplies and covers the 3 months before and the 6 months after Round 2 contracts became effective on July 1, 2013. For ease of presentation in this report, we refer to July 1, 2013, as the date when Round 2 began. This inspection does not examine beneficiary access to enteral nutrition infusion pumps or intravenous poles.

We used Medicare claims data to identify the population. The population includes beneficiaries who resided in Round 2 CBAs and non-CBAs, which enabled us to make comparisons to look for evidence of potential disruptions in access. This population includes beneficiaries for whom there was at least one claim for enteral nutrition supplies from April through June 2013.

#### **Data Sources**

Our data sources for this evaluation were Medicare claims and administrative data and survey responses we collected from a sample of beneficiaries and the physicians who ordered their enteral nutrition supplies. We used the continuation of paid claims as a marker for continued access after Round 2 began. We surveyed physicians and beneficiaries to learn about the experience of beneficiaries for whom Medicare stopped paying for supplies after Round 2 began. Because we did not receive sufficiently high response rates to our surveys, we did not project the survey responses we received to our population of beneficiaries.

#### **Identification of Beneficiaries Using Supplies**

We identified beneficiaries who used enteral nutrition supplies in 2013 using data from Medicare's National Claims History File and CMS's Competitive Bidding Implementation Contractor. As a comparison, we also identified beneficiaries who used enteral nutrition supplies in 2012 using data from Medicare's National Claims History File.

We first created files of claims for enteral nutrition supplies. To do so, we downloaded a list of Healthcare Common Procedure Coding System (HCPCS) codes for enteral nutrition supplies subject to bidding from the Competitive Bidding Implementation Contractor's website. We then used these HCPCS codes to extract paid claims for enteral nutrition supplies

from Medicare’s National Claims History File. We created one claim file for 2012 and another for 2013. Next, we matched ZIP Codes from Medicare’s Competitive Bidding Implementation Contractor to the beneficiary ZIP Code on the claim to identify each claim as being for a beneficiary in a Round 2 CBA, Round 1 CBA, or non-CBA.

To identify beneficiaries using enteral nutrition supplies, we used our 2013 claims file to select all beneficiaries for whom there was at least one paid claim for supplies from April through June 2013. This identified 40,891 beneficiaries. We used this criterion because enteral nutrition supplies include a wide range of items, some of which may need to be replaced once a month and others every several months. See Exhibit A-1 for additional detail on beneficiary selection criteria.

**Exhibit A-1: Selection Criteria for Sample of Beneficiaries Using Enteral Nutrition Supplies**

Characteristics of Supply-Using Beneficiaries in Sample	Beneficiaries in Round 2 CBAs	Beneficiaries in Non-CBAs	Total
<p><b>HCPCS:</b>  <b>B4034–B4036: Enteral Feeding Supply Kit</b>  <b>B4081–B4083: Tubing</b>  <b>B4087, B4088: Gastrostomy/Jejunostomy Tube</b>  <b>B4149, B4150, B4152–B4155: Enteral Formula</b></p> <p><b>Payment History</b>  <b>At least 1 paid claim</b>  <b>April-June 2013</b></p>	24,575	16,316	40,891

Source: OIG analysis of Medicare claims data, 2017

**Identification of Populations of Beneficiaries For Whom Medicare Payments Stopped**

Next, for each group of beneficiaries we identified, we identified the population of those for whom there were no paid Medicare claims after Round 2 began. For enteral nutrition supplies, we identified 3,077 beneficiaries for whom there were claims for supplies from April 1 through June 30, 2013, only. See Exhibit A-2 for additional detail on beneficiary claims data.

### Exhibit A-2: Beneficiaries With Paid Claims for Enteral Nutrition Supplies

Status of Beneficiaries Who Used Enteral Nutrition Supplies Before Round 2 Began	Beneficiaries in Round 2 CBAs	Beneficiaries in Non-CBAs	Total
Medicare payments stopped after Round 2 began	2,169	908	3,077
Percentage of beneficiaries for whom Medicare payments stopped after Round 2 began	9%	6%	8%
Medicare payments continued after Round 2 began	22,406	15,408	37,814
Percentage of beneficiaries for whom Medicare payments continued after Round 2 began	91%	94%	92%

Source: OIG analysis of Medicare claims data, 2017.

We also analyzed Medicare claims data from 2012 to determine the percentage of beneficiaries receiving enteral nutrition supplies for whom Medicare payments stopped in the last full year prior to Round 2 of the CBP.

#### Sample Selection

From the population of beneficiaries for whom Medicare payments stopped after Round 2 began, we drew a statistical sample of 300 beneficiaries. We stratified this sample by whether the beneficiaries were in Round 2 CBAs or non-CBAs. See Exhibit A-3 for a description of beneficiary sample sizes.

### Exhibit A-3: Samples of Beneficiaries Using Enteral Nutrition Supplies

Type of Beneficiary	Beneficiaries in Round 2 CBAs	Beneficiaries in Non-CBAs	Total
Beneficiaries using enteral nutrition supplies	150	150	300
<b>Total</b>	150	150	300

Source: OIG analysis of Medicare claims data, 2017.

#### Physician Survey

To determine whether beneficiaries in our sample still had a prescribed need for supplies, we surveyed the physicians who were the ordering physician on the beneficiaries' final enteral nutrition claims and who were still living. The surveys asked physicians if the beneficiary for whom they ordered supplies had a prescribed need for them during the period from July 1 through December 31, 2013.

We made at least three attempts to reach physicians with our survey. We sent the surveys using a trackable delivery service and accepted survey responses by mail and by fax to a secure fax server. We received responses from 148 of the 208 physicians we surveyed. In 96 of those responses, physicians were able to answer our key question as to whether or not the beneficiary still needed supplies after Round 2 began. See Exhibit A-4 for information on physician survey sampling and responses.

**Exhibit A-4: Results From Survey of Physicians for Beneficiaries Using Enteral Nutrition Supplies**

Characteristics of Physicians	Round 2 CBAs	Non-CBAs	Total
A) <b>Total Physicians in Sample</b>	150	150	300
B) <b>Physicians Surveyed<sup>1</sup></b>	114	94	208
C) <b>Physicians Responding With Usable Data<sup>2</sup></b>	64	54	118
D) <b>Physicians Answering Key Question</b>	51	45	96
<b>Physician Response Rate (Row C/Row A)</b>	<b>43%</b>	<b>36%</b>	<b>39%</b>

Source: OIG analysis of data from survey of physicians, 2017.

<sup>1</sup> We did not survey a physician if the beneficiary was deceased when Round 2 began, if the physician was under investigation, or if the physician was no longer in business.

<sup>2</sup> In some cases, physicians cooperated by responding to our survey, but their responses included no usable information.

**Beneficiary Survey**

To learn about beneficiaries’ experiences in the 6 months immediately after Medicare stopped paying for their enteral nutrition supplies, we sent a brief survey to beneficiaries. Specifically, we surveyed the beneficiaries who were still living and whose physicians told us in the physician survey that they had a prescribed need for supplies after Round 2 began. In the surveys, we asked beneficiaries if they continued to use enteral nutrition supplies after Round 2 began and, if so, how they managed given that Medicare did not pay for their supplies.

We made at least three attempts to reach beneficiaries with our survey. We used a trackable delivery service to send the surveys to beneficiaries and provided them with postage-paid business reply mail envelopes for returning the surveys directly to the Office of Inspector General. We received responses from 6 of the 37 beneficiaries we surveyed. We did not survey beneficiaries when Medicare records indicated that they were no longer living. See Exhibit A-5 for information on beneficiary survey eligibility and responses.

**Exhibit A-5: Response Rates for Survey of Beneficiaries Using Enteral Nutrition Supplies**

Status of Beneficiaries	Beneficiaries in Round 2 CBAs	Beneficiaries in Non-CBAs	Total
<b>Beneficiaries Eligible for Survey</b>	25	12	37
<b>Beneficiaries Responding With Usable Data</b>	5	1	6
<b>Beneficiary Response Rate</b>	<b>20%</b>	<b>8%</b>	<b>16%</b>

Source: OIG analysis of survey data, 2017.

**Data Analysis**

*All-Beneficiary Analysis Using Medicare Claims*

We analyzed claims data to determine the extent to which beneficiaries experienced a potential disruption in access to supplies. To do so, we calculated the percentage of supply-using beneficiaries for whom there were no paid claims for supplies after Round 2 began. We used these percentages as the basis of our lead findings for supplies.

We analyzed claims data to determine two aspects of Medicare payments for supply-using beneficiaries for whom there were continued payments after Round 2 began. First, we counted the number of paid claims for supplies for these beneficiaries after Round 2 began to determine whether payments had continued for a sustained period. Second, we checked whether these beneficiaries experienced an interruption in payments immediately after Round 2 began. To do so, we calculated the days between the last paid claim for supplies before Round 2 began and the first paid claim after Round 2 began. We then determined the percentage of beneficiaries for whom this span was greater than 30 days, as Medicare covers 1 month of enteral nutrition supplies at a time.<sup>30</sup>

*Tabulation of Physician and Beneficiary Survey Responses*

We counted responses to our physician survey to determine the number of responding physicians who told us that beneficiaries in our sample still needed supplies after Round 2 began. Our denominator of responses for this analysis considered the responses in which physicians were able to tell us whether or not the beneficiary still needed supplies after Round 2 began—i.e., we did not include responses of “cannot determine.”

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<sup>30</sup> CMS, *National Coverage Determinations Manual*, Pub. No. 100-03, ch. 1, pt. 3, § 180.2.

We counted responses to our survey of supply-using beneficiaries to determine the extent to which beneficiaries reported that they continued to use enteral nutrition supplies in the 6 months after Round 2 began, and, if so, whether they needed any supplies during that time. For beneficiaries who reported that they did need supplies during that time, we counted how many reported that they got supplies from their existing supplier, found a new supplier, paid out of pocket, or used supplies that they already had on hand.

### **Limitations**

This review has two limitations. First, we use continued Medicare payment as a proxy for continued access to enteral nutrition supplies. Continued Medicare payment is a measure of *potential* continued access, but we understand that it is not a direct measure of continued access to enteral nutrition supplies. Without a determination of continued need, the lack of continued Medicare payments does not necessarily indicate a disruption in access to enteral nutrition supplies.

Secondly, the response rate for our survey was too low to project the results to all beneficiaries for whom claims did not continue. Therefore, we present our survey responses as testimonial evidence to provide potential insights into these individual beneficiaries' experiences in accessing enteral nutrition supplies. We did not independently verify responses from physicians and beneficiaries, nor did we conduct a medical review of beneficiaries' medical need for the supplies.



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## **ACKNOWLEDGMENTS**

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This report was prepared under the direction of Joyce Greenleaf, Regional Inspector General for Evaluation and Inspections in the Boston regional office, and Kenneth Price, Deputy Regional Inspector General.

To obtain additional information concerning this report or to obtain copies, contact the Office of Public Affairs at [Public.Affairs@oig.hhs.gov](mailto:Public.Affairs@oig.hhs.gov)

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