Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

CMS GENERALLY MET REQUIREMENTS IN ROUND 2 OF THE DMEPOS COMPETITIVE BIDDING PROGRAM

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November 2017
A-05-14-00049

Office of Inspector General

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Report in Brief
November 2017
Report No. A-05-14-00049

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

CMS Generally Met Requirements in Round 2 of the DMEPOS Competitive Bidding Program

Why OIG Did This Review

The Medicare Improvements for Patients and Providers Act of 2008 contains a broad mandate requiring OIG to assess, through a post-award audit, survey, or otherwise, the process used by the Centers for Medicare & Medicaid Services (CMS) to conduct the competitive bidding and subsequent pricing determinations that are the basis for the pivotal bid amounts and single-payment amounts (SPAs) under rounds 1 and 2 of the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (the Program).

Our objective was to determine whether CMS selected DMEPOS suppliers, calculated the SPAs, and monitored the suppliers for Round 2 in accordance with its established Program procedures and applicable Federal requirements.

How OIG Did This Review

We verified the calculation for a sample of 240 SPAs and reviewed CMS's supplier selection process for 215 suppliers.

To determine the effect of errors on Medicare payments, we reviewed covered paid claims data for DMEPOS items from July 1 through December 31, 2013. Specifically, we reviewed 48,298 lines of service, totaling $3.6 million, paid during the first 6-month period of the Program.

What OIG Found

We determined that CMS consistently followed its established Program procedures and applicable Federal requirements for 192 of the 215 winning suppliers associated with the sampled SPAs reviewed.

While the overall effect on Medicare payments to suppliers was relatively small, we determined that CMS did not consistently follow its established procedures and applicable Federal requirements for selecting suppliers during the bid process for 23 of the 215 winning suppliers. This affected 99 of the 240 sampled SPAs. Specifically, CMS awarded contracts to 10 suppliers that did not meet financial statement requirements and 13 suppliers that did not have the applicable license in at least one competition. Additionally, CMS did not monitor suppliers in accordance with established procedures and Federal requirements for another 31 suppliers that did not maintain the applicable license, as required by their contracts, for the last 6 months of 2013.

On the basis of our sample, we estimated that CMS paid suppliers $182,000 less than they would have received without any errors, or less than 0.03 percent of the $553.7 million paid under Round 2 during the last 6 months of 2013.

What OIG Recommends and CMS Comments

We recommend that CMS take specific actions, as described in this report, to ensure that suppliers meet financial documentation requirements and obtain and maintain the required licenses.

CMS concurred with our recommendations.

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INTRODUCTION

WHY WE DID THIS REVIEW

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) contains a broad mandate requiring the Office of Inspector General (OIG) to assess, through a post-award audit, survey, or otherwise, the process used by the Centers for Medicare & Medicaid Services (CMS) to conduct the competitive bidding and subsequent pricing determinations that are the basis for the pivotal bid amounts and single payment amounts (SPAs) under the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (the Program).[1, 2] On April 9, 2013, CMS announced the contract suppliers for Round 2 of the Program (Round 2).

In May 2016, we issued a report on supplier compliance with applicable licensure requirements under Round 2. That audit was conducted in response to specific complaints that CMS received.[3] Because that report identified suppliers without applicable licenses, we included in this audit of Round 2 a determination of the number of suppliers without required licenses.

OBJECTIVE

Our objective was to determine whether CMS selected DMEPOS suppliers, calculated the SPAs, and monitored the suppliers for Round 2 in accordance with its established program procedures and applicable Federal requirements.

BACKGROUND

CMS administers the Medicare program, which provides health insurance for people age 65 and older and those who have disabilities or permanent kidney disease. Medicare Part B covers DMEPOS items, including wheelchairs, hospital beds, diabetic test strips, walkers, and oxygen.

How Medicare Determines Payment Amounts for Some Durable Medical Equipment

Congress mandated the Program through the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)[4] and made certain revisions to the Program through MIPPA.

[1] A SPA is the allowed payment for an item furnished under a competitive bidding program (42 CFR § 414.402). It is the median of the bid amounts submitted by winning suppliers for an item under Round 2 (42 CFR § 414.416(b)).

[2] MIPPA § 154(a)(1)(A)(iv) amended the Social Security Act (the Act) by adding subparagraph (E) to § 1847(a)(1), 42 U.S.C. § 1395w-3(a)(1).

[3] *Some Suppliers in Round 2 of the Durable Medical Equipment Competitive Bidding Program Did Not Have Required Licenses*, A-05-13-00047, May 2016.

[4] MMA § 302(b)(1), amended the Act § 1847, 42 U.S.C. § 1395w-3.

The Program requires that Medicare set payment rates for selected DMEPOS items using a competitive bid process.

The intent of the Program is to use market-based prices to reduce the amount Medicare pays for certain equipment, reduce beneficiary out-of-pocket expenses, and limit fraud and abuse while ensuring beneficiary access to quality items and services. CMS is required by law to recompete contracts under the Program at least once every 3 years.

Competitive Bidding Process

Suppliers who wanted to provide DMEPOS to Medicare beneficiaries under Round 2 were required to submit a bid for selected products through a web-based application process and to submit a hardcopy of certain required documents. CMS evaluated bids using, among other factors, the supplier's eligibility, which included checking a supplier's license status, its financial stability, the bid price, and the total supplier capacity to meet beneficiary demand in a competitive bidding area (CBA).[5]

CMS offered contracts to as many winning suppliers as necessary to meet or exceed the demand in each CBA.[6] As full payment for competitively bid DMEPOS items, winning suppliers accept the SPA derived from the median of all winning bids for an item.[7] Medicare reimburses the contract suppliers at 80 percent of the SPA for each DMEPOS item, with the beneficiary responsible for the remaining 20 percent.[8]

CMS Contractors

CMS contracts with Palmetto GBA to be the Competitive Bidding Implementation Contractor (CBIC), as well as the National Supplier Clearinghouse Medicare Administrative Contractor (NSC MAC). The CBIC performs certain functions, including evaluating bids, selecting qualified suppliers, setting SPAs for all CBAs, and overseeing an education program. The NSC MAC, as the designated national enrollment contractor for DMEPOS suppliers, helps them update their records to reflect current information and helps the CBIC with verifying and validating licensure and accreditation status of bidding suppliers.

The NSC MAC uses the Provider Enrollment and Chain Ownership System (PECOS) to access and store supplier licensure information to verify that contract suppliers are properly licensed and

[5] 42 CFR §§ 414.414(a), (b), (c), (d), and (e).

[6] 42 CFR §§ 414.414(h)(1) and (2) and 42 CFR § 414.414(i). CMS also offered contracts to as many small business suppliers as necessary to meet small-supplier program requirements (42 CFR § 414.414(g)).

[7] 42 CFR §§ 414.416(b)(1) and (2).

[8] 42 CFR § 414.408(a). The Act § 1847(b)(5)(B), 42 U.S.C. 1395w-3(b)(5)(B).

reaches out to each State every 3 months to identify any applicable changes in State licensure requirements affecting currently enrolled DME suppliers. The NSC MAC revalidates supplier licenses every 3 years and investigates situations in which CMS is not certain that contract suppliers are properly licensed.[9]

Appendix A contains a more detailed history of the Program.

HOW WE CONDUCTED THIS REVIEW

We reviewed CMS's process for selecting DMEPOS suppliers and its computation of SPAs for Round 2. We used a two-stage unrestricted sample. The first stage consisted of 100 CBAs from which we selected a random sample of 8 as the primary units. For the second stage, we selected a random sample of 30 SPAs from each of the 8 selected CBAs, for a total of 240 secondary units.

Specifically, we examined the supplier selection process for the 215 winning suppliers and 37 nonwinning suppliers associated with the sample and each related payment calculation by reviewing financial documentation, bid amounts, applicable licenses, and whether winning suppliers maintained the applicable licenses for our audit period.

Our review covered all lines of service[10] on Medicare claims for all competitively bid DMEPOS items with dates of service from July 1 through December 31, 2013. During this period, Medicare paid $553,719,716 for 8,232,398 lines of service. We reviewed 48,298 lines of service, totaling $3,583,659, related to the 240 SPAs that we sampled. These lines of service were paid during the first 6 months of the Round 2 Program.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix B contains the details of our audit scope and methodology. Appendix C contains our statistical sampling methodology. Appendix D contains our mathematical calculation plan. Appendix E contains our sample results and estimates. Appendix F contains a summary of any differences between CMS's calculation of a sampled SPA and our calculation of it, and Appendix G contains a summary of the Medicare payment effect of those differences.

[9] Under the current contract, the NSC MAC is not required to validate a supplier's license after the supplier has been awarded a contract or on a continuous basis throughout the enrollment process.

[10] A Medicare DMEPOS claim could contain up to 13 lines of service.

FINDINGS

We determined that CMS usually selected DMEPOS suppliers, calculated the sampled DMEPOS SPAs, and monitored suppliers in accordance with its established procedures and applicable Federal requirements. However, of the 215 winning DMEPOS suppliers associated with the 240 SPAs in our sample, CMS's selection of 23 suppliers was not in accordance with its established procedures and applicable Federal requirements. Of those 23 suppliers, CMS awarded contracts to 10 suppliers that did not meet financial statement requirements and to 13 suppliers that did not have the applicable license in at least one competition.

As a result of not following established procedures and Federal requirements in selecting 23 of the 215 winning DMEPOS suppliers associated with our sample of 240 SPAs, CMS miscalculated 99 of the sampled SPAs. On the basis of our sample results, we estimated that CMS paid suppliers $181,980 less than they would have received because CMS awarded contracts to suppliers that did not meet requirements, or less than 0.03 percent of the $553,719,716 paid under Round 2 during the last 6 months of 2013.

After selecting the winning suppliers, CMS did not monitor all suppliers to ensure that they maintained applicable licenses. We identified 31 suppliers that did not maintain applicable licenses, as required by their contracts, for the last 6 months of 2013. (Because the SPAs were already calculated, the noncompliance of these 31 suppliers in not maintaining the applicable licenses had no effect on the SPA computations.)

CMS DID NOT SELECT SOME SUPPLIERS IN ACCORDANCE WITH ESTABLISHED PROCEDURES AND FEDERAL REQUIREMENTS

Ten Winning Suppliers Did Not Meet Financial Statement Requirements

To be eligible to participate in the Program, each supplier must meet financial statement requirements by submitting certain financial documentation specified in the Request for Bids[11] to the CBIC by a specified deadline. This documentation includes an income statement, a balance sheet, a statement of cash flow, a tax return extract, and a credit report. CMS uses this documentation to determine supplier compliance with financial standards.[12]

Round 2 bid instructions list several requirements for financial documentation, which include, but are not limited to, the following:

[11] 42 CFR § 414.414(d)(1) and 42 CFR § 414.402.

[12] Available online at https://dmecompetitivebid.com/palmetto/cbicrd2.nsf/DocsCat/Round%202~Bidding%20Suppliers~Bid%20Evaluation~8P2K5N5878?open&navmenu=Bidding%5eSuppliers|||. Accessed on November 7, 2017.

- the financial statements should be prepared in accordance with generally accepted accounting principles,

- each financial statement must correspond with related financial statements,[13] and

- data within the financial statements must accurately total.[14]

To determine whether CMS evaluated suppliers, we obtained documentation from CMS explaining its reasons for not selecting the 37 nonwinning suppliers. We noted that CMS did not offer contracts to some of these suppliers because they did not comply with the financial documentation requirements detailed above.[15]

CMS selected 10 contract suppliers that did not meet financial statement requirements. Specifically:

- nine winning suppliers submitted financial statements with data that did not accurately total and

- one winning supplier submitted financial statements that did not correspond with related financial statements.

CMS did not detect that the financial statements did not meet the requirements. CMS stated that its contractor performs a review of the suppliers' financial statements that may uncover only obvious errors.

Thirteen Winning Suppliers Did Not Have the Applicable License in at Least One Competition

To be awarded a contract, a supplier must meet all of the applicable State licensure requirements.[16] Bidding suppliers must have ensured that copies of all applicable State licenses were received by the NSC MAC on or before the May 1, 2012, licensure deadline.

[13] For example, "ending cash" on the statement of cash flows should equal "cash" on the balance sheet.

[14] Available online at http://dmecompetitivebid.com/Palmetto/cbicrd2.nsf/files/R2_RFB.pdf/$File/R2_RFB.pdf. Accessed on October 4, 2016.

[15] On the basis of our review of CMS's procedures for both winning and nonwinning suppliers and of CMS's published supplier guidelines, "Request for Bids (RFB) Instructions," we determined that CMS's review process for supplier eligibility did not detect errors in financial documentation for 10 winning suppliers. All 10 of the winning suppliers did not meet CMS requirements for what must be submitted.

[16] Licensure requirements refer to licenses, permits, or certificates that suppliers must obtain through their respective State licensing boards at the location and product-category levels to furnish supplies to beneficiaries.

The NSC MAC monitors the State licensure requirements for suppliers; however, it ultimately is the suppliers' responsibility to know which licenses they must have. To determine whether suppliers had the applicable licenses, we reviewed the NSC's PECOS, which is used to keep track of supplier licensure.

We found that of the 215 winning suppliers in our sample, 13 did not have the applicable license for the competition[17] for which they submitted a bid by the May 1, 2012, licensure deadline. Thus, these suppliers should not have been awarded a contract for these specific competitions.

CMS Miscalculated Some Sampled Single Payment Amounts, but the Financial Impact Was Immaterial

Because CMS did not follow established procedures and Federal requirements in selecting 23 of the 215 winning DMEPOS suppliers associated with our sample of 240 SPAs, it miscalculated 99 of the sampled SPAs. On the basis of our sample results, we estimated that CMS paid suppliers $181,980 less than they would have received if CMS had not awarded contracts to suppliers that did not meet requirements, or less than 0.03 percent of the $553,719,716 paid under Round 2 during the last 6 months of 2013.

Because a supplier must bid on every item in a competition, any error in determining eligibility can potentially affect SPAs for all the items in the competition. However, calculating SPAs using the median of winning bid amounts reduces the influence of each bid on the calculated SPAs when compared with a competitive bidding system in which the single winning bid determines the payment amount. The design of the SPA calculation that CMS has established for the Program creates some stability, even in the presence of minor errors, as shown in the small estimated impact on aggregate payments to winning suppliers.

CMS DID NOT MONITOR SUPPLIERS TO ENSURE THAT THEY MAINTAINED APPLICABLE LICENSES

Whether under the Program or the traditional DMEPOS fee-for-service program, suppliers are responsible for knowing the applicable licensure requirements and for ensuring that they meet those requirements for any durable medical equipment they provide to Medicare beneficiaries. To remain in good standing with Medicare and to maintain their supplier billing numbers, suppliers are required to maintain applicable licenses for the products and States in which they furnish items and services.[18]

[17] A competition is a combination of a product category and a CBA.

[18] 42 CFR § 424.57(c)(1)(ii)(A).

After suppliers are enrolled in Medicare, they are responsible for informing the NSC MAC of any changes in information supplied on their applications.[19] The NSC MAC verifies that suppliers have the required licenses in the applicable States and for the product categories and then updates each supplier's enrollment record, which contains all the licenses a supplier holds. Under competitive bidding, contracts require suppliers to maintain their licensure for the duration of the 3-year contracts that started on the July 1, 2013, contract implementation date.[20]

Of the 215 winning suppliers associated with our sampled SPAs, we determined that 31 of these suppliers did not maintain their required license for the last 6 months of 2013. These 31 suppliers did not affect the SPAs because they were properly licensed by the May 1, 2012, licensure deadline. However, we determined that these suppliers did not maintain the proper licensure from the July 1, 2013, contract implementation date to the end of our audit period, December 31, 2013.

In accordance with Round 2 guidelines, CMS verified licensure requirements as of the May 1, 2012, licensure deadline. However, CMS did not verify licensure requirements again at the July 1, 2013, contract implementation date or during the term of the contract unless a supplier was subject to a revalidation. While we recognize that the NSC MAC is required to validate licensures only at initial enrollment and revalidation, CMS did not have a system in place to identify these 31 unlicensed suppliers during our audit period. Even though these unlicensed suppliers did not affect the actual SPA computations, unlicensed suppliers should not have remained as contract suppliers serving Medicare beneficiaries.

RECOMMENDATIONS

We recommend that CMS:

- follow its established program procedures and applicable Federal requirements consistently in evaluating the financial documents of all suppliers;

- ensure that suppliers have the applicable licenses for the specific competitions in which they are submitting a bid by continuing to work with State licensing boards, as recommended in our previous report; and

- monitor supplier licensure requirements by implementing a system to identify and address potential unlicensed suppliers.

[19] 42 CFR § 424.57(c)(2).

[20] 42 CFR § 414.422(a) and individual supplier contracts.

CMS COMMENTS AND OIG RESPONSE

In written comments on our draft report, CMS concurred with our recommendations. CMS stated that it consistently applies all Program procedures and applicable Federal requirements during all phases of bid evaluation. CMS stated that it will continue to take steps to ensure that suppliers have applicable licenses for furnishing DMEPOS and that the Medicare contractor is required to validate supplier licenses at initial enrollment and revalidation. CMS also stated that it is working to establish a system that would help continuously monitor suppliers to ensure that each maintains an active license.

CMS stated that it had not received data from OIG for the suppliers deemed to have not met financial statement and State licensure requirements. We will send the requested supplier information to CMS. Finally, CMS provided technical comments on our draft report, which we addressed, as appropriate.

CMS's comments, excluding technical comments, are included as Appendix H.

APPENDIX A: HISTORY OF COMPETITIVE BIDDING FOR DURABLE MEDICAL EQUIPMENT

Historically, Medicare has paid for most DMEPOS on the basis of fee schedules.[21] Unless otherwise specified by Congress, fee schedule amounts are updated each year by a measure of price inflation. In the 5-year period before CMS implemented the Program in 2008, annual Medicare Part B expenditures for DMEPOS items ranged from $7 billion to $8 billion.

Over the years, Medicare has paid above-market prices for certain items of DME. These above-market payments may be due partly to the fee schedule mechanism of payment, which does not reflect market changes, such as new and less expensive technologies, changes in production or supplier costs, or variations in prices in comparable locations.

THE COMPETITIVE BIDDING PROGRAM PAYS SUPPLIERS A SINGLE PAYMENT AMOUNT

To address market changes and the increased Medicare Part B expenditures for DMEPOS items, Congress enacted legislation through the MMA to phase in a Medicare competitive bidding program under which prices for selected DMEPOS sold in specified areas would be determined not by a fee schedule but with a generally lower SPA determined through a competitive bidding process. Congress required CMS to establish a DMEPOS competitive bidding program as a permanent part of Medicare, beginning in 2007 with the initial phase of competition.[22] On July 1, 2008, CMS completed the process for awarding contracts for the Round 1 competition. However, on July 15, 2008, Congress terminated the Round 1 contracts and imposed additional requirements. It directed CMS to conduct a Round 1 rebid.[23]

ROUND 1 REBID

On January 1, 2011, CMS implemented the Round 1 Rebid in nine CBAs for nine product categories. CBAs are defined by specific ZIP Codes related to Metropolitan Statistical Areas (MSAs). Each combination of a product category and a CBA is referred to as a competition. There were 73 competitions in the Round 1 Rebid.[24] Each product category comprised related items, and each item was identified by a Healthcare Common Procedure Coding System (HCPCS) code or payment class.[25] The contract period for mail-order diabetic supplies ended on

[21] The Act § 1834(a)(1)(A) and 42 U.S.C. § 1395m(a)(1)(A).

[22] The Act § 1847(a)(1)(B)(i)(I) and 42 U.S.C. § 1395w-3(a)(1)(B)(i)(I) (originally enacted by the MMA § 302(b)(1)).

[23] The Act § 1847(a)(1)(D) and 42 U.S.C. § 1395w-3(a)(1)(D) (originally enacted by the MIPPA § 154(a)(1)(A)(iv)).

[24] The 73 competitions were made up of 8 product categories in 9 CBAs plus the support surfaces product category offered only in the Miami-Fort Lauderdale-Pompano Beach, Florida, CBA.

[25] HCPCS codes are used throughout the health care industry to standardize coding for medical procedures, services, products, and supplies.

December 31, 2012. The contract period for other Round 1 Rebid product categories ended on December 31, 2013. To respond to our MIPPA mandate to review CMS's competitive bidding process, we issued a report on the Round 1 Rebid in April 2014.[26]

ROUND 2

In July 2013, CMS implemented Round 2 in 100 CBAs and 8 product categories. The MIPPA required Round 2 to occur in 70 MSAs and authorized competition for national mail-order items and services after 2010. The Patient Protection and Affordable Care Act (ACA) expanded the number of Round 2 MSAs from 70 to 91 areas.[27] MIPPA allows for the subdivision of MSAs with populations of more than 8 million into multiple CBAs.[28] Most Round 2 MSAs have only one CBA. However, the three largest MSAs (Chicago, Los Angeles, and New York) were subdivided into multiple CBAs, creating a total of 100.

After Round 2 was implemented, Congress received complaints that certain suppliers that did not have applicable licenses were being awarded contracts. In response to these complaints and at the request of Congress, we conducted a review of supplier licensure and issued a report in May 2016.[29]

CMS also conducted a national mail-order competition for diabetic testing supplies at the same time as the Round 2 competition. The national mail-order CBAs include all 50 States, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Guam, and American Samoa. The contract period for Round 2 product categories ended on June 30, 2016.

ROUND 1 RECOMPETE

Federal law requires CMS to recompete contracts under each round of the Program at least once every 3 years.[30] On January 1, 2014, CMS implemented the Round 1 Recompete for six product categories in the same nine CBAs as the Round 1 Rebid. The contract period for Round 1 Recompete product categories ended on December 31, 2016.

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[26] *CMS Generally Met Requirements in the Durable Medical Equipment Competitive Bidding Round 1 Rebid Program* (A-05-12-00067).

[27] The Act § 1847(a)(1)(B)(i)(II) and 42 U.S.C. § 1395w-3(a)(1)(B)(i)(II) (originally enacted by the ACA § 6410(a)(1)).

[28] The Act § 1847(a)(1)(D)(ii)(III) and 42 U.S.C. § 1395w-3(a)(1)(D)(ii)(III) (originally enacted by the MIPPA § 154(a)(1)(A)(iv)).

[29] *Incomplete and Inaccurate Licensure Data Allowed Some Suppliers in Round 2 of the Durable Medical Equipment Competitive Bidding Program That Did Not Have Required Licenses* (A-05-13-00047).

[30] The Act § 1847(b)(3)(B) and 42 U.S.C. § 1395w-3(b)(3)(B) (originally enacted by the MMA § 302(b)(1)).

ROUND 2 RECOMPETE

On July 15, 2014, CMS announced that it would conduct a recompetition of contracts that had been awarded in Round 2 and the National Mail-Order Program. The Round 2 Recompete and the National Mail-Order Recompete occurred in the same locations as the previous round; however, CMS expanded the number of CBAs from 100 to 117.

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.[31] Contracts for the Round 2 Recompete and National Mail-Order Recompete became effective on July 1, 2016, and will expire on December 31, 2018.[32]

ROUND 1 2017

On January 1, 2017, CMS implemented Round 1 2017 for eight product categories in the same nine MSAs as the Round 1 Recompete. CBAs in multi-State MSAs have been defined so that there are no multi-State CBAs.[33] As a result, 13 CBAs are in Round 1 2017. The contract period for Round 1 2017 product categories will end December 31, 2018.[34]

[31] Available online at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Round-2-Recompete-and-National-Mail-Order-Recompete/Overview.html. Accessed on September 23, 2016.

[32] Available online at http://www.dmecompetitivebid.com/palmetto/cbicrd2recompete.nsf/vMasterDID/9KJQN52683. Accessed on September 20, 2016.

[33] Available online at https://dmecompetitivebid.com/palmetto/cbicrd12017.nsf/vMasterDID/9V5QZQ8010. Accessed on April 11, 2017.

[34] Available online at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-11-01-2.html. Accessed on April 11, 2017.

APPENDIX B: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed the Round 2 Program in 100 CBAs and covered 8 product categories. Bidding began January 30, 2012, and ended March 30, 2012. CMS granted an extension to May 1, 2012, for all bidding suppliers to ensure that they had the applicable licenses for the States they intended on servicing. In January 2013, CMS announced SPAs, and in April 2013, it announced the winning contract suppliers. On July 1, 2013, CMS implemented the contracts and prices for the Round 2 Program.

We did not review the overall internal control structure of CMS's competitive bidding program. Rather, we reviewed only those controls related to meeting our objectives.

We met with CMS officials in Baltimore, Maryland, and we performed our fieldwork at the CBIC, Palmetto GBA (Palmetto), in Columbia, South Carolina.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal statutes, regulations, and other guidance related to the Round 2 Program;
- reviewed the *Bid Evaluation Manual*, an internal CMS manual, to obtain an understanding of the process for selecting suppliers and computing SPAs from CMS and Palmetto;
- interviewed CMS and Palmetto officials to inquire about Palmetto's process for ensuring that supplier applications met basic supplier eligibility requirements and had:
    - an active NSC status,
    - a CMS-approved accreditation for the product category for which the suppliers submitted a bid,
    - applicable State licenses,
    - a bona fide bid,[35] and

[35] A bona fide bid is a bid that, when considered by itself, passes scrutiny as a rational and feasible price for furnishing the item (42 CFR § 414.414(b)(4) and pages 6 and 7 of the Request for Bids Instructions). Available online at http://dmecompetitivebid.com/Palmetto/cbicrd2.nsf/files/R2_RFB.pdf/$File/R2_RFB.pdf. Accessed on October 5, 2016.

- only one bid submitted if suppliers had common ownership;

- performed a risk assessment and identified areas of high risk based on Program implementation requirements, applicable Federal criteria, and CMS and CBIC inquiries regarding the supplier selection process;

- obtained paid claims data with dates of service from July 1 through December 31, 2013;

- selected a random sample of 8 CBAs as our primary units;

- selected a random sample of 240 SPAs as our secondary units (Appendix C);

- identified the 55 competitions related to the DMEPOS items listed in our 240 SPAs;

- identified the 215 winning suppliers, of which 194 were awarded contracts within the 55 competitions;

- verified that the 215 winning suppliers in our sample met basic eligibility requirements by determining whether each application had:

  - the necessary network documentation if the winning supplier was part of a network,

  - the proper financial documentation[36] showing that it had met financial standards,[37]

  - a bid that met the "small supplier" classification if submitting a bid as a small supplier, and

  - the applicable license for the product category on which it submitted bids for each of the States it intended on servicing;

- determined whether suppliers maintained the licenses required under their contracts for the last 6 months of 2013;

[36] From suppliers' financial documentation, we verified whether CMS identified eligible bidding suppliers.

[37] Financial standards are established to reasonably ensure that suppliers will be able to fulfill their contractual obligations and provide beneficiaries the necessary DMEPOS items.

- calculated the weighted bid[38] for each winning supplier's DMEPOS item in each competition;

- calculated the composite bid[39] by adding all the weighted bids for a winning supplier in each competition;

- verified the pivotal bid[40] calculations by:

    - arraying all of the winning supplier composite bids from smallest to largest,

    - determining the demand for each competition of our sample, and

    - computing the pivotal bid for each sampled competition by determining the accumulated supplier capacity of arrayed eligible suppliers[41] that met the demand;

- compared our calculated pivotal bid to that of CMS for any discrepancy;

- verified that the SPAs in the 240 randomly selected samples were calculated correctly by:

    - arraying the winning suppliers by their bid amounts for each item in the product category and

    - computing the sampled SPA by calculating the median bid amount for all of the winning bids in the competition;

- compared our calculated SPA to CMS's amount;

- verified that nonwinning suppliers that were not offered contracts because of reasons other than price were properly disqualified by:

[38] "Weighted bid" is a specific DME item's weight (the volume of units of service for the DME item relative to the rest of the DME items in the product category) multiplied by the supplier's bid price for an item (42 CFR § 414.402).

[39] "Composite bid" is the sum of a supplier's weighted bids for all items within a product category that allows a comparison across suppliers (42 CFR § 414.402).

[40] "Pivotal bid" is the lowest composite bid based on bids submitted by suppliers for a product category that includes a sufficient number of suppliers to meet beneficiary demand for the items in that product category (42 CFR § 414.402).

[41] The eligible suppliers whose composite bids were less than or equal to the pivotal bid were considered the winning suppliers (42 CFR § 414.414(e)(6)).

- identifying 37 suppliers in our sample that were disqualified for either not meeting financial standards or submitting unacceptable financial documentation, and

- reviewing the disqualifying decisions in the hardcopy documentation for all 37 disqualified suppliers;

- determined the impact of incorrectly calculated SPA amounts on the paid lines of service using the methodology stated in our mathematical calculation plan in Appendix D; and

- discussed the results of our reviews with CMS.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

POPULATION

The population consisted of SPAs within each CBA for the Round 2 Program from July 1 through December 31, 2013.

SAMPLING FRAME

The sampling frame contained the 100 CBAs included in the Round 2 Program. Each of the 100 CBAs contained SPAs for 202 HCPCS codes for a total of 20,200 SPAs. Medicare paid $553,719,716 for 8,232,398 lines of service from July 1 through December 31, 2013, for HCPCS codes associated with the 20,200 SPAs in Round 2.

SAMPLE UNIT

The primary sample unit was a CBA. The secondary sample unit was a SPA for an HCPCS code within each selected CBA.

SAMPLE DESIGN

We used a two-stage unrestricted sample. The first stage consisted of a random selection of eight CBAs from the sampling frame. The second stage consisted of a random selection of 30 SPAs from each of the eight selected CBAs.

SAMPLE SIZE

We selected a random sample of eight CBAs as the primary units. We then selected a random sample of 30 SPAs from each of the 8 selected CBAs as the secondary units. The total number of secondary units was 240 SPAs.

SOURCE OF RANDOM NUMBERS

We generated the random numbers using the Office of Inspector General (OIG), Office of Audit Services (OAS), statistical software.

METHOD FOR SELECTING SAMPLE ITEMS

We consecutively numbered the CBAs in our sampling frame from 1 through 100 for the first stage. After generating the eight random numbers for the primary sample, we selected the corresponding frame items. We created a list of the eight primary sample units.

We consecutively numbered the SPAs from 1 through 202 for each of the primary units. After generating 8 sets of 30 random numbers for the primary units, we selected the corresponding frame items. Finally, we created a list of the 240 sampled items.

ESTIMATION METHODOLOGY

We used the Round 2 Program paid claims data and determined the dollar amount that was paid for each sampled SPA that was calculated incorrectly. We used the calculated error amounts detailed in the mathematical calculation plan (Appendix D) as our difference value for each sampled SPA.

We used the OIG/OAS statistical software to estimate the amount that Medicare paid incorrectly for claims with SPA calculations.

APPENDIX D: MATHEMATICAL CALCULATION PLAN

DESCRIPTION OF MATHEMATICAL CALCULATION

We determined the impact of any incorrectly calculated SPAs on the paid lines of service for new items, rental items, used items, and maintenance items for Medicare's DMEPOS Round 2 Program from July 1 through December 31, 2013.

MATHEMATICAL CALCULATION METHODOLOGY

We determined the impact of any incorrectly calculated SPAs by performing the following steps:

Step 1 – We identified all lines of service from the DMEPOS Round 2 Program paid claims data for the HCPCS code associated with any sampled SPA that was incorrectly calculated.

Step 2 – We calculated the total amount that Medicare incorrectly paid for all lines of service with each type of HCPCS modifier associated with any sampled SPA that was incorrectly calculated:

- For lines of service having an HCPCS modifier code of UE (used items), we multiplied the identified SPA difference by 75 percent[42] to determine the UE modifier difference amount. We then multiplied the UE modifier difference amount by the number of lines of service having the UE modifier to determine the total amount that Medicare paid incorrectly for used items for that specific SPA.

- For lines of service having an HCPCS modifier code of RR (rental items), we multiplied the identified SPA difference by 10 percent[43] to determine the RR modifier difference amount. We then multiplied the RR modifier difference amount by the number of lines of service having the RR modifier to determine the total amount that Medicare paid incorrectly for rental items for that specific SPA. Suppliers bid on nine HCPCS codes as rental items. Any difference amount for these nine HCPCS codes was multiplied by the number of lines of service without multiplying the difference amount by 10 percent.[44]

[42] The modifier UE pays 75 percent of the base SPA amount (42 CFR § 414.408(f)(2)).

[43] The modifier RR pays 10 percent of the base SPA amount (42 CFR § 414.408(h)) for the first 3 months of rental and 7.5 percent for months 4 through 13 for all capped rental items other than power wheelchairs. For power wheelchairs, the RR modifier pays 15 percent of the base SPA for the first 3 months and 6 percent for months 4 through 13.

[44] Nine HCPCS codes (E0424, E0431, E0433, E0434, E0439, E1390, E1391, E1392, and K0738) in the oxygen product category were bid on as RR. Therefore, their base amount represents the RR monthly amount and was not multiplied by 10 percent (42 CFR § 414.408(i)(1)).

- For lines of service having an HCPCS modifier code of MS (maintenance items), we multiplied the identified SPA difference by 5 percent[45] to determine the MS modifier difference amount. We then multiplied the MS modifier difference amount by the number of lines of service having the MS modifier to determine the total amount that Medicare paid incorrectly for maintenance items for that specific SPA.

- For lines of service having an HCPCS modifier code of NU (new items), there was no need to determine a modifier difference amount. We simply multiplied the identified SPA difference by the number of lines of service to determine the total amount that Medicare paid incorrectly for the new and bid rental items for that specific SPA.

Step 3 – We added each amount that Medicare paid incorrectly from Step 2 to determine the total incorrect Medicare payment for July 1 through December 31, 2013.

[45] CMS pays 5 percent of the base SPA amount for claims with the MS modifier (42 CFR § 414.408(h)(6)). All of the lines of service for MS in the 6 months of claims data were for HCPCS Code B9002: Enteral infusion pump w/ala.

APPENDIX E: SAMPLE RESULTS AND ESTIMATES

Table 1: Sample Details and Results

Frame Size	Value of Frame	Sample Size	Value of Sample	Number of Inaccurately Calculated SPAs[46] in the Sample
20,200	$553,719,716	240	$3,583,659	99

Table 2: Estimated Impact of the Inaccurately Calculated SPAs
(Limits Calculated for a 90-Percent Confidence Interval)

Point estimate	-$181,980[47]
Lower limit	-843,675
Upper limit	479,715

[46] Of the 99 incorrectly computed SPAs, 70 had monetary impact on actual claims paid to suppliers.

[47] This represents projected underpayments on the $553,719,716 in the sampling frame.

APPENDIX F: SUMMARY OF DIFFERENCES BETWEEN CMS- VERSUS OIG-CALCULATED SINGLE PAYMENT AMOUNTS

Table 3: OIG Review Determinations for the 99 Affected Single Payment Amounts

Legend

Error Type	Description
1	Amounts within the financial statements did not total properly.
2	Amounts for the same account on related financial statements did not match.
3	Supplier(s) did not have a required license at the May 1, 2012, licensure deadline.

Sample No.	Single Payment Amount Computation: Over (Under)[48]	Percentage Change From CMS Calculation	Error Type
1	($0.63)	(4.38%)	2,3
2	$0.10	2.86%	3
3	$0.07	0.64%	3
4	$0.01	2.86%	3
11	($2.12)	(3.66%)	3
31	($0.48)	(7.36%)	2
32	($25.63)	(0.85%)	2
73	($1.88)	(1.23%)	1
99	($89.96)	(5.51%)	1
100	($2.82)	(3.01%)	1
101	($0.56)	(2.88%)	1
103	$0.85	5.78%	1
104	($4.71)	(3.68%)	1
105	($21.85)	(5.46%)	1
108	($25.83)	(4.92%)	1
109	($0.50)	(1.11%)	1
111	($15.00)	(3.33%)	1
112	($16.39)	(4.52%)	1
113	($7.50)	(5.17%)	1
114	($1.31)	(11.31%)	1
115	($1.00)	(1.89%)	1
116	($250.00)	(11.90%)	1
117	($300.00)	(5.36%)	1
118	$1.65	3.50%	1

[48] This column shows only the amount for the error in the SPA and not the total effect created by multiplying the error times the number of instances. Therefore, the total will not add up to -$14,558.

Sample No.	Single-Payment Amount Computation: Over (Under)	Percentage Change From CMS Calculation	Error Type
119	$0.20	0.50%	1
120	$0.83	4.21%	1
121	$1.91	12.73%	1
122	($3.37)	(3.68%)	1
123	($0.94)	(7.67%)	1
125	$0.03	2.86%	1
127	($0.94)	(3.42%)	1
128	$1.48	0.09%	1
129	($300.00)	(4.00%)	1
130	($0.18)	(0.99%)	1
131	$2.04	3.53%	1
132	($0.75)	(1.02%)	1
133	$0.38	2.03%	1
134	($13.50)	(8.44%)	1
135	($0.50)	(1.43%)	1
136	($1.00)	(1.05%)	1
138	($0.85)	(0.72%)	1
139	($1.49)	(0.45%)	1
140	($0.98)	(1.74%)	1
141	($0.01)	(0.02%)	1
142	($1.44)	(0.60%)	1
143	($20.94)	(7.14%)	1
144	($31.08)	(6.42%)	1
145	($3.80)	(0.43%)	1
146	($0.98)	(1.03%)	1
147	$10.40	0.59%	1
148	($5.00)	(0.28%)	1
149	($230.00)	(18.44%)	1
182	$0.20	1.80%	2
183	$0.33	2.47%	2
186	$0.34	0.63%	1
193	$0.35	0.84%	1
194	($2.17)	(2.08%)	1
195	$0.30	1.94%	1
196	($5.45)	(2.16%)	1
197	($1.05)	(1.18%)	1
198	$0.08	0.54%	1
199	$0.99	1.90%	1
200	($0.07)	(0.18%)	1

Sample No.	Single-Payment Amount Computation: Over (Under)	Percentage Change From CMS Calculation	Error Type
201	($0.60)	(1.80%)	1
202	($3.19)	(1.19%)	1
203	$50.84	7.25%	1
204	($0.07)	(0.09%)	1
205	($26.42)	(1.79%)	1
206	($100.00)	(5.88%)	1
210	$1.00	1.89%	1
211	($1.39)	(8.52%)	2,3
212	($47.50)	(6.83%)	3
213	($1.59)	(2.55%)	3
214	($15.00)	(2.65%)	1
215	$34.65	4.54%	1
216	$2.50	1.96%	1
217	$14.07	10.35%	1
218	$0.50	0.22%	1
219	($0.01)	(0.05%)	3
220	($0.68)	(1.11%)	3
221	$0.03	0.04%	1
222	$0.22	1.66%	1
223	$1.10	1.44%	1
224	($2.55)	(3.70%)	1
225	($1.78)	(1.31%)	1
226	($5.83)	(1.44%)	1
227	($0.50)	(0.07%)	1
228	($0.20)	(0.54%)	1
229	($1.68)	(4.71%)	1
230	$2.54	2.90%	1
231	$3.78	3.01%	1
232	$1.97	3.40%	1
233	($4.57)	(1.55%)	1
234	($3.00)	(0.77%)	1
236	($7.75)	(0.39%)	1
237	($87.75)	(1.90%)	1
238	$0.64	0.25%	1
239	$0.14	0.19%	1
240	$0.51	2.62%	1

APPENDIX G: MEDICARE PAYMENT EFFECT OF DIFFERENCES

Table 4: OIG Review Determinations for the 70 Affected Single Payment Amounts That Had Associated Claims

Sample No.	Dollar Impact
1	($406.35)
2	$402.70
4	$1,117.40
31	($177.60)
32	($304.36)
73	($8.08)
100	($5.64)
101	($2,211.44)
103	$2.55
104	($32.97)
105	($144.18)
108	($103.32)
109	($1.00)
113	($90.00)
114	($18.34)
115	($2.00)
119	$0.80
121	$4,402.55
123	($0.94)
125	$65.22
129	($4,485.00)
130	($10.26)
131	$314.16
132	($3.75)
133	$22.67
135	($5.00)
138	($22.10)
140	($1.95)
141	($0.24)
144	($132.09)
145	($3.98)
146	($41.67)
148	($7.50)
149	($1,023.50)
182	$16.19

Sample No.	Dollar Impact
183	$106.59
186	$31.45
193	$688.45
194	($4.34)
195	$106.38
196	($37.06)
198	$1.60
199	$5.94
201	($247.02)
203	$345.71
206	($111.00)
210	$1,615.70
211	($147.34)
212	($1,819.25)
213	($69.48)
214	($7.13)
215	$1,161.64
216	$7.75
217	$168.84
218	$4.28
219	($3.07)
220	($868.36)
221	$0.18
222	$42.04
223	$35.20
224	($51.51)
225	($101.46)
226	($48.97)
228	($3.40)
229	($23.52)
232	$47.28
233	($77.69)
236	($13.49)
239	$0.42
240	$1.53

APPENDIX H: CMS COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

200 Independence Avenue SW
Washington, DC 20201

DATE: AUG 29 2017

TO: Daniel R. Levinson
Inspector General

FROM: Seema Verma
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: CMS Generally Met Requirements in Round 2 of the DMEPOS Competitive Bidding Program (A-05-14-00049)

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 is committed to ensuring the success of the durable medical equipment, prosthetics, orthotics, and supplies competitive bidding program for patients, suppliers, and providers.

The Medicare durable medical equipment, prosthetics, orthotics, and supplies 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 and the Patient Protection and Affordable Care Act of 2010.

Under the program, suppliers of durable medical equipment, prosthetics, orthotics, and supplies compete to become Medicare contract suppliers by submitting bids to furnish certain items in competitive bidding areas. Before a contract is offered to a supplier, CMS determines whether a supplier is properly licensed and accredited for each competition in which it bids and meets specific competitive bidding program financial standards. Medicare's accreditation and financial standards are intended to ensure that contract suppliers provide high quality items and services and are viable entities that can meet beneficiaries' needs for the duration of the contract period. When CMS is made aware of issues of suppliers not meeting competitive bidding program rules, including state licensure requirements, CMS investigates the situation and takes action in accordance with regulations.

CMS continues to evaluate ways to improve the competitive bidding process. For example, CMS has implemented a preliminary bid evaluation process that checks supplier enrollment data before the bid evaluation starts. Bidders are notified if the requirements are not met and have a limited time to remedy the issue prior to the start of the bid evaluation or the bid(s) is disqualified. Additionally, because CMS does not have the authority to require states to report changes in licensing requirements, the Medicare contractor responsible for enrolling suppliers of durable medical equipment, prosthetics, orthotics, and supplies, reaches out to each state every three months to identify any changes in their state licensure requirements. The contractor notifies the impacted suppliers of the changes in an effort to promote compliance. Suppliers who fail to come into

compliance within a specified timeframe may face administrative action in accordance with CMS regulations.

The OIG's recommendations and CMS' responses are below.

OIG Recommendation
The OIG recommends that CMS follow its established program procedures and applicable Federal requirements consistently in evaluating the financial documents of all suppliers.

CMS Response
CMS concurs with this recommendation. CMS works to consistently apply all program procedures and applicable federal requirements during all phases of bid evaluation. CMS ensures that all reviewers involved in the financial review phase of the bid evaluation process are accountants. Additionally, CMS reconciles the financial statements provided so that companies were not incorrectly qualified or disqualified, using all information presented, while at the same time, applying the request for bids requirements uniformly.

CMS has not yet received the data on the suppliers OIG identified as not meeting financial standards, therefore, we are unable to determine if OIG has accurately identified these suppliers as not being reviewed in accordance with the policies and procedures.

OIG Recommendation
The OIG recommends that CMS ensure that suppliers have applicable licenses for the specific competitions in which they are submitting a bid by continuing to work with State licensing boards, as recommended in our previous report.

CMS Response
CMS concurs with this recommendation. CMS recognizes the importance of running a program that impacts millions of patients who depend on essential medical equipment, prosthetics, orthotics, and supplies. CMS will continue to take steps to ensure that suppliers have applicable licenses for furnishing durable medical equipment, prosthetics, orthotics, and supplies. The Medicare contractor validates supplier licenses at the time of bidding for the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Bidding Program.

However, CMS has not yet received the data on the suppliers that the OIG identified as not having applicable licenses, therefore, we are unable to determine if OIG has accurately identified certain suppliers as not being licensed.

OIG Recommendation
The OIG recommends that CMS monitor licensure requirements by implementing a system to identify and address potential unlicensed suppliers.

CMS Response
CMS concurs with this recommendation. CMS recognizes the importance of running a program that impacts millions of beneficiaries that allow patients to live independently and maintain quality of life. The Medicare contractor is required to validate supplier licenses at initial enrollment and revalidation. CMS is also working to establish a system that would help continuously monitor suppliers of durable medical equipment, prosthetics, orthotics, and supplies to ensure that they maintain an active license throughout the duration of their Medicare enrollment.