Department of Health and Human Services
OFFICE OF INSPECTOR GENERAL

CMS Generally Met Requirements for the DMEPOS Competitive Bidding Program Round 1 Recompete

Inquiries about this report may be addressed to the Office of Public Affairs at Public.Affairs@oig.hhs.gov.

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.
Why OIG Did This Audit
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 the Round 1 Recompete in accordance with its established Program procedures and applicable Federal requirements.

How OIG Did This Audit
We verified the calculation for a sample of 30 SPAs and audited CMS’s supplier selection process for 225 suppliers.

To determine the effect of errors on Medicare payments, we reviewed covered paid claims data for DMEPOS items from January 1 through June 30, 2014. Specifically, we reviewed 11,443 lines of service, totaling $1.1 million, paid during the first 6-month period of the Program.

CMS Generally Met Requirements for the DMEPOS Competitive Bidding Program Round 1 Recompete

What OIG Found
CMS consistently followed its established Program procedures and applicable Federal requirements for 219 of the 225 winning suppliers associated with the sampled SPAs reviewed.

Although the overall effect on Medicare payments to suppliers was relatively small, CMS did not consistently follow its established procedures and applicable Federal requirements for selecting suppliers during the bid process for 6 of the 225 winning suppliers. This inconsistency affected 3 of the 30 sampled SPAs. Specifically, CMS awarded contracts to five suppliers that did not meet financial statement requirements and one supplier that did not have the applicable State license in one competition. Additionally, CMS did not monitor suppliers in accordance with established procedures and Federal requirements for another seven suppliers that did not maintain the applicable license, as required by their contracts, for the first 6 months of 2014.

On the basis of our sample, we estimated that CMS paid suppliers $24,054 more than they would have received without any errors, or less than 0.03 percent of the $73 million paid under the Round 1 Recompete during the first 6 months of 2014.

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. CMS stated that it works to consistently apply all Program procedures and applicable Federal requirements in all phases of bid evaluation and that it will continue to take steps to ensure that suppliers have applicable licenses for furnishing DMEPOS. CMS said that it is working to establish a system that would help continuously monitor DMEPOS suppliers to ensure that they maintain an active license throughout the duration of their Medicare enrollment.

The full report can be found at https://oig.hhs.gov/oas/reports/region5/51600051.asp.
# TABLE OF CONTENTS

INTRODUCTION .......................................................................................................................... 1

Why We Did This Audit ............................................................................................................... 1

Objective .................................................................................................................................. 1

Background ................................................................................................................................. 1
  How Medicare Determines Payment Amounts for Some Durable Medical Equipment .......... 2
  The Competitive Bidding Process ........................................................................................... 2
  CMS Contractors in Competitive Bidding ............................................................................... 3

How We Conducted This Audit ................................................................................................ 3

FINDINGS .................................................................................................................................... 4

CMS Did Not Select Some Suppliers From Our Sample in Accordance With Established Procedures and Federal Requirements ......................................................................................... 4
  Five Winning Suppliers From Our Sample Did Not Meet Financial Statement Requirements ........................................................................................................................................... 4
  One Winning Supplier From Our Sample Did Not Have the Applicable License in One Competition ................................................................................................................................. 6
  CMS Miscalculated Some Sampled Single-Payment Amounts, but the Financial Impact Was Immaterial................................................................................................................................. 6

CMS Did Not Monitor Suppliers To Ensure That They Maintained Applicable Licenses ......................................................................................................................................................... 7

RECOMMENDATIONS ............................................................................................................... 8

CMS COMMENTS ....................................................................................................................... 8

APPENDICES

A: Audit Scope and Methodology ............................................................................................... 9

B: History of Competitive Bidding for Durable Medical Equipment ........................................ 13

C: Statistical Sampling Methodology ......................................................................................... 18

D: Mathematical Calculation Plan ............................................................................................ 20

*CMS’s Round 1 Recompete of the Competitive Bidding Program (A-05-16-00051)*
E: Sample Results and Estimates ................................................................. 21

F: Summary of Differences Between CMS- and OIG-Calculated Single-Payment Amounts .................................................................................................................. 22

G: The Effect of the Differences on Medicare Payments ........................................ 23

H: CMS Comments .............................................................................................. 24
INTRODUCTION

WHY WE DID THIS AUDIT

Federal law contains a broad mandate (1) requiring the Office of Inspector General (OIG) to assess, “through 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 first two rounds of the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (the Program) and (2) permitting OIG to continue to verify such calculations for subsequent rounds.1,2 On October 31, 2013, CMS announced the contract suppliers for the Round 1 Recompete of the Program.

We have issued previous reports under the mandate related to the first two rounds of the Program (i.e., the Round 1 Rebid and Round 2).3 After Round 2 was implemented, Congress received complaints alleging that certain suppliers that did not have applicable licenses were awarded contracts. In response to these complaints and a request by Congress, we conducted a review of supplier licensure and issued a report in May 2016.4

OBJECTIVE

Our objective for this review was to determine whether CMS selected DMEPOS suppliers, calculated the SPAs, and monitored the suppliers for the Round 1 Recompete in accordance with its established Program procedures and applicable Federal requirements.

BACKGROUND

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

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1 An 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 the Round 1 Recompete (42 CFR § 414.416(b)). The “Round 1 Recompete” is how CMS refers to this DMEPOS Competitive Bidding Round.


3 CMS Generally Met Requirements in the Durable Medical Equipment Competitive Bidding Round 1 Rebid Program (A-05-12-00067) and CMS Generally Met Requirements in Round 2 of the DMEPOS Competitive Bidding Program (A-05-14-00049).

Before 2011, CMS paid for DMEPOS items based on a fee schedule. To address flaws in the fee schedule and the increased Medicare Part B expenditures for DMEPOS, Congress enacted legislation. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) phased 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.

Appendix B contains a more detailed history of the Program.

**How Medicare Determines Payment Amounts for Some Durable Medical Equipment**

Congress mandated the Program through the MMA and made certain revisions to the Program through the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). The Program requires that Medicare set payment rates for selected DMEPOS items using a competitive bidding process.

The intent of the Program is to reduce beneficiary out-of-pocket expenses and save Medicare money 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.

**The Competitive Bidding Process**

Suppliers that wanted to provide DMEPOS to Medicare beneficiaries under the Round 1 Recompete 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, a supplier’s eligibility, which included checking the supplier’s license status, its financial stability, the bid price, and the total of all winning suppliers’ capacity to meet beneficiary demand in a competitive bidding area (CBA).

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

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

6 42 CFR §§ 414.414(a), (b), (c), (d), and (e).

7 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)).

8 42 CFR §§ 414.416(b)(1) and (2).

9 42 CFR § 414.408(a); the Act § 1847(b)(5)(B); 42 U.S.C. § 1395w-3(b)(5)(B).
CMS Contractors in Competitive Bidding

CMS contracts with Palmetto GBA (Palmetto) to be the Competitive Bidding Implementation Contractor (CBIC), as well as the National Supplier Clearinghouse Medicare Administrative Contractor (NSC MAC). The CBIC, in coordination with CMS, performs certain functions, including evaluating bids, selecting qualified suppliers, setting SPAs for all CBAs, and supporting 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 various functions, including verifying and validating licensure and accreditation status of bidding suppliers.

The NSC MAC uses the Provider Enrollment, Chain, and Ownership System (PECOS) to access and store supplier licensure information, which it uses to verify that contract suppliers are properly licensed. The NSC MAC revalidates supplier licenses every 3 years and investigates situations in which CMS is not certain that contract suppliers are properly licensed.

HOW WE CONDUCTED THIS AUDIT

We audited the Round 1 Recompete phase of the Program in nine CBAs and covered six product categories. Bidding began on October 15, 2012, and ended on December 14, 2012. In October 2013, CMS announced SPAs and the winning contract suppliers. On January 1, 2014, CMS implemented the contracts and prices for the Round 1 Recompete Program.10 We reviewed CMS’s process for selecting DMEPOS suppliers and its computation of SPAs for the Round 1 Recompete phase of the Program. We used a cluster sample with 30 randomly selected SPAs.11

Specifically, we examined the supplier selection process for the 225 winning suppliers and 10 nonwinning suppliers associated with the sample and each related payment calculation by reviewing financial documentation, bid amounts, and applicable licenses and by whether winning suppliers maintained the applicable licenses for our audit period.

Our audit covered all lines of service12 on Medicare claims for all competitively bid DMEPOS items with dates of service from January 1 through June 30, 2014. During this period, Medicare paid $73,242,414 for 1,241,631 lines of service. We reviewed 11,443 lines of service, totaling


11 In this audit, a “cluster sample” refers to all payments made by Medicare based on the randomly sampled SPAs.

12 A Medicare DMEPOS claim can contain up to 13 lines of service. An example of a line of service in this review would be 1 month rental of an oxygen concentrator. Another line of service on the same claim could include accessories for the oxygen concentrator.
$1,137,771, related to the 30 SPAs that we sampled. These lines of service were paid during the first 6 months of the Round 1 Recompete phase of the 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 A 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 and OIG’s calculation of a sampled SPA, and Appendix G contains the three SPAs affected by those differences on Medicare payments.

**FINDINGS**

CMS usually selected DMEPOS suppliers, calculated the sampled DMEPOS SPAs, and monitored suppliers in accordance with its established Program procedures and applicable Federal requirements. However, of the 225 winning DMEPOS suppliers associated with the 30 SPAs in our sample, CMS selected 6 suppliers that did not meet requirements in accordance with its established procedures and applicable Federal requirements. Of those six suppliers, CMS awarded contracts to five suppliers that did not meet financial statement requirements and to one supplier that did not have the applicable license in one competition.

Because CMS did not follow established procedures and Federal requirements in selecting 6 of the 225 winning DMEPOS suppliers associated with our sample of 30 SPAs, it miscalculated 3 of the sampled SPAs. On the basis of our sample results, we estimated that CMS paid suppliers $24,054 more than they would have received if CMS had not awarded contracts to suppliers that did not meet requirements. That amount is less than 0.03 percent of the more than $73 million paid in the Round 1 Recompete during the first 6 months of 2014.

After selecting the winning suppliers, CMS did not monitor all suppliers to ensure that they maintained applicable licenses. We identified seven suppliers that did not maintain applicable licenses, as required by their contracts, for the first 6 months of 2014. (Because the SPAs had already been calculated, these seven suppliers’ failure to maintain the applicable licenses had no effect on the SPA computations.)

**CMS DID NOT SELECT SOME SUPPLIERS FROM OUR SAMPLE IN ACCORDANCE WITH ESTABLISHED PROCEDURES AND FEDERAL REQUIREMENTS**

**Five Winning Suppliers From Our Sample 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 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.

Round 1 Recompete bid instructions list several requirements for financial documentation, which include, but are not limited to, the following:

- the financial statements should be prepared in accordance with Generally Accepted Accounting Principles,
- each financial statement must correspond with related financial statements, and
- data within the financial statements must accurately total.

To determine whether CMS properly evaluated suppliers, we obtained documentation from CMS explaining its reasons for not selecting the 10 suppliers that were not offered contracts. We identified that CMS did not offer contracts to some of these suppliers because they did not comply with the financial documentation requirements detailed above.

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

- one winning supplier submitted financial statements with data that did not accurately total,
- two winning suppliers submitted financial statements that did not correspond with related financial statements,

- one winning supplier submitted a statement of cash flows that did not have the required beginning and ending cash balances, and

- one winning supplier submitted a tax extract from a different legal entity than the bidding supplier for which the financial statements were submitted.

CMS did not detect that the financial statements did not meet the requirements. CMS stated that while it does not perform a full audit, it does review all financial statements for misstatements.

**One Winning Supplier From Our Sample Did Not Have the Applicable License in One Competition**

To be awarded a contract, a supplier must meet all the applicable State licensure requirements. Bidding suppliers must have ensured that copies of all applicable State licenses were received by the NSC MAC on or before December 14, 2012, when the 60-day bid window closed.

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 MAC’s PECOS, which is used to keep track of supplier licensure.

We found that of the 225 winning suppliers in our sample, 1 did not have the applicable license for the competition for which it had submitted a bid by December 14, 2012, when the 60-day bid window closed. Thus, this supplier should not have been awarded a contract for that competition.

**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 6 of the 225 winning DMEPOS suppliers associated with our sample of 30 SPAs, it miscalculated 3 of the sampled SPAs. On the basis of our sample results, we estimated that in the first 6 months of 2014 CMS paid suppliers $24,054 more than they would have received if CMS had not

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18 Licensure requirements refer to licenses, permits, or certificates that suppliers must obtain through their respective State licensing boards to furnish supplies to beneficiaries.

19 A competition is a combination of a product category and a CBA.
awarded contracts to suppliers that did not meet requirements. That amount was less than 0.03 percent of the more than $73 million paid in the Round 1 Recompete during the first 6 months of 2014.

Because a supplier must bid on every item in a competition, any error in determining eligibility can potentially affect the 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 resulting small estimated effect on aggregate payments to winning suppliers in this report.

**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 (DME) they provide to Medicare beneficiaries. To remain in good standing with Medicare and to maintain their supplier billing number, suppliers are required to maintain applicable licenses for the products and States in which they furnish items and services.\(^20\)

After suppliers are enrolled in Medicare, they are responsible for informing the NSC MAC of any changes in information supplied on their applications.\(^21\) The NSC MAC is responsible for verifying that suppliers have the required licenses in the applicable States and for the product categories and 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 January 1, 2014, contract implementation date.\(^22\)

Of the 225 winning suppliers associated with our sampled SPAs, we determined that 7 did not maintain their required license for the entire audit period. These seven suppliers did not affect the SPAs because they were properly licensed by December 14, 2012, which was the close of the 60-day bid window. However, we determined that these suppliers did not maintain the proper licensure from the January 1, 2014, contract implementation date to the end of our audit period, June 30, 2014.

\(^{20}\) 42 CFR § 424.57(c)(1)(ii)(A).

\(^{21}\) 42 CFR § 424.57(c)(2).

\(^{22}\) 42 CFR § 414.422(a) and individual supplier contracts.
In accordance with the Round 1 Recompete guidelines, CMS verified licensure requirements as of December 14, 2012, when the 60-day bid window closed. However, CMS did not verify licensure requirements again before the January 1, 2014, contract implementation date or during the term of the contract unless a supplier was scheduled for a revalidation.\(^2\) CMS did not have a system in place to identify these seven unlicensed suppliers during our audit period. Even though these unlicensed suppliers did not affect the SPA computations, unlicensed suppliers should not have remained as contract suppliers serving Medicare beneficiaries. CMS has told us that it is working to establish a system that would help continually monitor suppliers of DMEPOS to ensure that they maintain an active license throughout the duration of their enrollment in Medicare.

**RECOMMENDATIONS**

We recommend that the Centers for Medicare & Medicaid Services:

- 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
- ensure that it has a system to monitor supplier licensure requirements and identify potentially unlicensed suppliers.

**CMS COMMENTS**

In written comments on our draft report, CMS concurred with our recommendations. CMS stated that it works to consistently apply all Program procedures and applicable Federal requirements in all phases of bid evaluation. CMS stated that it will continue to take steps to ensure that suppliers have applicable licenses for furnishing DMEPOS. CMS noted that the Medicare contractor is required to validate supplier licenses at initial enrollment and revalidation. CMS also noted that it does not have the authority to require States to report changes in licensing requirements and that the Medicare contractor responsible for enrolling suppliers of DMEPOS reaches out to each State every 3 months to identify any changes in their State licensure requirements. CMS said that it is working to establish a system that would help continuously monitor DMEPOS suppliers to ensure that they maintain an active license throughout the duration of their Medicare enrollment. Finally, CMS provided technical comments on our draft report, which we addressed in this final report, as appropriate.

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

\(^2\) DMEPOS suppliers typically go through revalidation every 3 years.
APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed the Round 1 Recompete phase of the Program in nine CBAs and covered six product categories. Bidding began on October 15, 2012, and ended on December 14, 2012. In October 2013, CMS announced SPAs and the winning contract suppliers. On January 1, 2014, CMS implemented the contracts and prices for the Round 1 Recompete Program.24

We did not review the overall internal control structure of the Round 1 Recompete phase of the Program. Rather, we reviewed only those controls related to meeting our objective.

We performed our fieldwork at the CBIC, Palmetto, in Columbia, South Carolina.

METHODOLOGY

To accomplish our objective, we:

• reviewed applicable Federal statutes, regulations, and other guidance related to the Round 1 Recompete;

• reviewed the Bid Evaluation Manual, an internal CMS manual, to obtain an understanding of CMS’s and Palmetto’s processes for selecting suppliers and computing SPAs;

• interviewed CMS and Palmetto officials about Palmetto’s process for ensuring that supplier applications met basic supplier eligibility requirements and that suppliers had:
  o an active NSC MAC status,
  o a CMS-approved accreditation for the product categories for which the suppliers submitted a bid,
  o applicable State licenses,
  o a bona fide bid,25 and


25 A bona fide bid is one that, when considered by itself, passes scrutiny as a rational and feasible price for furnishing the item (42 CFR § 414.414(b)(4) and page 7 of the Request for Bids Instructions). Available online at https://www.dmecompetitivebid.com/Palmetto/Cbic.nsf/files/R1RC_RFB.pdf/$File/R1RC_RFB.pdf. Accessed on August 8, 2019.
CMS’s Round 1 Recompete of the Competitive Bidding Program (A-05-16-00051)

- 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 from CMS’s Pricing Data Analysis Contractor with dates of service from January 1 through June 30, 2014;

- selected a cluster sample with 30 randomly selected SPAs as our sample unit (Appendix C);

- identified the 22 competitions related to the DMEPOS items listed in our 30 SPAs;

- identified the 225 winning suppliers, of which 211 were awarded contracts within the 22 competitions;

- verified that the 225 winning suppliers in our sample met these basic eligibility requirements:
  - had the necessary network documentation if the winning supplier was part of a network,
  - had the proper financial documentation showing that the documentation had met financial standards,
  - had a bid that met the “small supplier” classification if submitting a bid as a small supplier, and
  - the applicable license for the product category for 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 first 6 months of 2014;

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26 We reviewed suppliers’ financial documentation to determine whether it met requirements.

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

28 A “small supplier” is one that generates $3.5 million or less in gross revenue, which includes both Medicare and non-Medicare revenue (42 CFR § 414.402).
• calculated the weighted bid\(^{29}\) for each winning supplier’s DMEPOS item in each competition;

• calculated the composite bid\(^{30}\) by adding all the weighted bids for a winning supplier in each competition;

• verified the pivotal bid\(^{31}\) calculations by:
  o arraying all of the winning supplier composite bids from smallest to largest,
  o identifying the demand CMS established and used for each competition in our sample, and
  o computing the pivotal bid for each sampled competition by determining the total supplier capacity of the arrayed eligible suppliers that met the demand;\(^{32}\)

• compared our calculated pivotal bids to those calculated by CMS to identify any discrepancies;

• verified that the 30 randomly selected SPAs were calculated correctly by:
  o arraying the winning suppliers by their bid amounts for each item in the product category and
  o computing the sampled SPA by calculating the median bid amount for all the winning bids in the competition;

• compared our calculated SPAs to the amounts CMS calculated;

• verified that nonwinning suppliers that were not offered contracts for reasons other than price were properly disqualified by:

\(^{29}\) A “weighted bid” is a specific DME’s “item 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).

\(^{30}\) A “composite bid” is the sum of a supplier’s weighted bids for all items within a product category that allows a comparison across bidding suppliers (42 CFR § 414.402).

\(^{31}\) A “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).

\(^{32}\) 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)).
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: HISTORY OF COMPETITIVE BIDDING FOR DURABLE MEDICAL EQUIPMENT

Historically, Medicare has paid for most DMEPOS using fee schedules. 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 $6 billion to $7 billion.

Medicare has sometimes paid above-market prices for certain DMEPOS. These above-market payments may be due partly to the fee schedule, 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 flaws in the fee schedule and the increased Medicare Part B expenditures for DMEPOS, 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. 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, imposed additional requirements, and directed CMS to conduct a Round 1 rebid.

For each round of competitive bidding, CMS updates its competitive bidding process. CMS uses OIG’s audits to help develop improved competitive bidding procedures. In addition to assisting CMS in program improvements, OIG audits add credibility to CMS’s competitive bidding program as a whole.

ROUND 1 REBID

On January 1, 2011, CMS implemented the Round 1 Rebid in nine CBAs for nine product categories. CMS defines CBAs 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. Each product category comprised related

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

34 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)).

35 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)).

36 The 73 competitions comprised 8 product categories in 9 CBAs plus the support surfaces product category offered only in the Miami-Fort Lauderdale-Pompano Beach, Florida, CBA.
items, and each item was identified by a Healthcare Common Procedure Coding System (HCPCS) code or payment class.\textsuperscript{37} The contract period for mail-order diabetic supplies ended on December 31, 2012. The contract period for other Round 1 Rebid product categories ended on December 31, 2013. To respond to the Federal mandate that OIG review CMS’s competitive bidding process, we conducted a review of the Round 1 Rebid and issued a report in April 2014.\textsuperscript{38}

**ROUND 2**

In July 2013, CMS implemented Round 2 in 100 CBAs and 8 product categories. 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.\textsuperscript{39} MIPPA allows for the subdivision of MSAs with populations of more than 8 million into multiple CBAs.\textsuperscript{40} 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 CBAs. To respond to the Federal mandate that OIG review CMS’s competitive bidding process, we conducted a review of Round 2 and issued a report in November 2017.\textsuperscript{41}

After Round 2 was implemented, Congress received complaints that certain suppliers that did not have applicable licenses were awarded contracts. In response to these complaints and a request by Congress, we conducted a review of supplier licensure and issued a report in May 2016.\textsuperscript{42} The contract period for Round 2 product categories ended on June 30, 2016.

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.

\textsuperscript{37} HCPCS codes are used throughout the health care industry to standardize coding for medical procedures, services, products, and supplies.

\textsuperscript{38} *CMS Generally Met Requirements in the Durable Medical Equipment Competitive Bidding Round 1 Rebid Program (A-05-12-00067).*

\textsuperscript{39} 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)).

\textsuperscript{40} 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)).

\textsuperscript{41} *CMS Generally Met Requirements in Round 2 of the DMEPOS Competitive Bidding Program (A-05-14-00049).*

\textsuperscript{42} *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).*
ROUND 1 RECOMPETE

Federal law requires CMS to recompete contracts under each round of the Program at least once every 3 years.43 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.

ROUND 2 RECOMPETE

On July 15, 2014, CMS announced that it would recompete 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 geographical locations as the previous round; however, CMS expanded the number of CBAs from 100 to 117.

In addition to subdividing the three largest MSAs (i.e., Chicago, Los Angeles, and New York) into multiple CBAs during Round 2, CMS redefined CBAs in multi-State MSAs for the Round 2 Recompete so that there were no multi-State CBAs.44 This change simplified requirements for suppliers and helped to address licensing concerns raised in the previous OIG reports on Round 2 of competitive bidding.45 Contracts for the Round 2 Recompete and National Mail-Order Recompete became effective on July 1, 2016, and expired on December 31, 2018.46

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

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


45 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) and CMS Generally Met Requirements in Round 2 of the DMEPOS Competitive Bidding Program (A-05-14-00049).

there are no longer any multi-State CBAs.\textsuperscript{47} As a result, 13 CBAs were in Round 1 2017. The contract period for Round 1 2017 product categories ended on December 31, 2018.\textsuperscript{48}

**ROUND 2019 and Temporary Gap Period**

CMS is required to recompete contracts under the Program at least once every 3 years. Because the Round 1 2017, Round 2 Recompete, and the National Mail-Order Recompete contract periods for all product categories were to expire on December 31, 2018, CMS announced plans on January 31, 2017, to recompete the supplier contracts and consolidate all current rounds and areas included in the DMEPOS CBP into a single round of competition named “Round 2019.”

However, CMS temporarily delayed moving forward with the next steps of Round 2019. Then, all information pertaining to Round 2019 was removed from both the CMS and the CBIC websites, and Round 2019 was canceled. In October 2018, CMS issued guidance stating that there would be a temporary gap in the Program beginning January 1, 2019.\textsuperscript{49}

**FINAL RULE**

On November 14, 2018, CMS issued a final rule\textsuperscript{50} modifying particular aspects of the DMEPOS CBP. Specifically, CMS:

- revised the DMEPOS CBP, including lead item pricing based on maximum winning bid amounts;
- adjusted the fee schedule for DMEPOS items and services furnished on or after January 1, 2019, in areas that are currently CBAs and currently not CBAs;


• added new, separate payment classes for portable gaseous oxygen equipment, portable liquid oxygen equipment, and high-flow portable liquid oxygen contents;

• added payment rules for certain ventilators that are classified under section 1834(a)(3) of the Act but also perform the functions of other items of DME that are subject to payment rules other than those in that section of the Act; and

• made changes to 42 CFR § 414.210(g)(7) indicating that, beginning on or after the date that contracts take effect for a national mail-order diabetic test strip phase of the program that includes the Northern Mariana Islands, the fee schedule adjustment methodology under this paragraph will no longer apply.

Round 2021

On March 7, 2019, CMS announced plans to consolidate the CBAs included in the Round 2 Recompete and Round 1 2017 phases of the Program into a single round of competition named “Round 2021.” Round 2021 contracts are scheduled to become effective on January 1, 2021, and extend through December 31, 2023.\(^{51}\)

CMS is incorporating some changes from previous DMEPOS competitive bidding rounds in the DMEPOS CBP for Round 2021. These changes include several initiatives that are part of CMS’s ongoing process improvements for the program, many of which are outlined in the revised Federal regulations at 42 CFR §§ 414.414 and 414.416.\(^{52}\)

There will be 130 CBAs\(^ {53}\) and 15 product categories\(^ {54}\) in Round 2021. Suppliers will bid for a lead item within a product category. This means that bidders will submit one bid for the lead item and that bid will be used to determine the SPAs for the other items in the product category.\(^ {55}\)


\(^{52}\) Available online at [https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&sid=c34da1854ec5c47e58e26b9ec18ad391&rgn=div6&view=text&node=42:3.0.1.1.1.6&idno=42#se42.3.414_1414](https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&sid=c34da1854ec5c47e58e26b9ec18ad391&rgn=div6&view=text&node=42:3.0.1.1.1.6&idno=42#se42.3.414_1414). Accessed on August 8, 2019.


APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

POPULATION

The population consisted of SPAs within each CBA for the Round 1 Recompete Program from January 1 through June 30, 2014.

SAMPLING FRAME

The sampling frame contained the nine CBAs included in the Round 1 Recompete Program. Each of the 9 CBAs contained SPAs for 309 HCPCS codes for a total of 2,781 SPAs. Medicare paid $73,242,414 for 1,241,631 lines of service from January 1 through June 30, 2014, for HCPCS codes associated with the 2,781 SPAs in the Round 1 Recompete Program.

SAMPLE UNIT

The primary sample unit was a SPA for HCPCS codes in CBAs and all of the SPA’s corresponding lines of service.

SAMPLE DESIGN

We used a cluster sample from the 2,781 SPAs for HCPCS codes, including modifiers for the HCPCS codes, in the Round 1 Recompete phase of the Program. For each SPA selected, we reviewed all the lines of service containing those HCPCS codes and any modifiers for the period January 1 through June 30, 2014.

SAMPLE SIZE

We selected a random sample of 30 SPAs from the sampling frame of 2,781 SPAs.

SOURCE OF RANDOM NUMBERS

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

METHOD FOR SELECTING SAMPLE ITEMS

We sequentially numbered the sampling frame from 1 to 2,781. After generating the random numbers, we selected the corresponding frame items.

ESTIMATION METHODOLOGY

We used paid claims data from the Round 1 Recompete phase of the Program 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 and rental items for Medicare’s DMFEP0S Round 1 Recompete Program from January 1 through June 30, 2014.

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 1 Recompete phase of the 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. The two modifier codes used for lines of service for the three sampled SPAs incorrectly calculated were new and rental:

• For lines of service having an HCPCS modifier code of NU (new items), there was no need to determine a modifier difference amount. Instead, we multiplied the identified SPA difference by the number of “Units Service Allowed” for that line of service and then summed those products to determine the total amount that Medicare paid incorrectly for the new items for that specific SPA.

• For lines of service having an HCPCS modifier code of RR (rental items), we multiplied the difference by the “Units Service Allowed” and summed those products for all the lines of service.56

Step 3—We summed the amounts that Medicare paid incorrectly from Step 2 to determine the total incorrect Medicare payment for January 1 through June 30, 2014.

56 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 as required by law (42 CFR §414.408(i)(1)).
APPENDIX E: SAMPLE RESULTS AND ESTIMATES

Table 1: Sample Details and Results

<table>
<thead>
<tr>
<th>Frame Size</th>
<th>Value of Frame</th>
<th>Sample Size</th>
<th>Value of Sample</th>
<th>Number of Inaccurately Calculated SPAs$^{57}$ in the Sample</th>
<th>Value of Net Overpayments in the Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>2,781</td>
<td>$73,242,414</td>
<td>30</td>
<td>$1,137,771</td>
<td>3</td>
<td>$259</td>
</tr>
</tbody>
</table>

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

Point estimate $24,054^{58}$
Lower limit 715
Upper limit 47,393

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$^{57}$ All three of the inaccurately calculated SPAs had monetary impact on actual claims paid to suppliers.

$^{58}$ This represents projected overpayments on the $73,242,414 in the sampling frame.
APPENDIX F: SUMMARY OF DIFFERENCES BETWEEN CMS- AND OIG-CALCULATED SINGLE-PAYMENT AMOUNTS

Table 3: OIG Audit Determinations for the Three Affected Single-Payment Amounts

Legend

<table>
<thead>
<tr>
<th>Error Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Amounts within the financial statements did not total properly.</td>
</tr>
<tr>
<td>2</td>
<td>Supplier(s) did not have a required license at the December 14, 2012, licensure deadline.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sample No.</th>
<th>Single-Payment Amount—CMS Computation</th>
<th>Single-Payment Amount—OIG Computation</th>
<th>Single-Payment Amount Overpayment</th>
<th>Percentage Change From CMS Calculation</th>
<th>Error Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>9</td>
<td>$17.07</td>
<td>$16.91</td>
<td>$0.16</td>
<td>0.94%</td>
<td>2</td>
</tr>
<tr>
<td>18</td>
<td>$74.50</td>
<td>$73.01</td>
<td>$1.49</td>
<td>2.00%</td>
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<tr>
<td>19</td>
<td>$414.47</td>
<td>$410.14</td>
<td>$4.33</td>
<td>1.04%</td>
<td>1</td>
</tr>
</tbody>
</table>

59 This column shows only the amount for the error in the SPA and not the total effect created by multiplying the error amount by the number of instances Medicare made a payment based on this SPA.
APPENDIX G: THE EFFECT OF THE DIFFERENCES ON MEDICARE PAYMENTS

Table 4: OIG Audit Determinations for the Three Affected Single-Payment Amounts That Had Associated Claims

<table>
<thead>
<tr>
<th>Sample No.</th>
<th>Dollar Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>9</td>
<td>$84.32</td>
</tr>
<tr>
<td>18</td>
<td>$62.58</td>
</tr>
<tr>
<td>19</td>
<td>$112.58</td>
</tr>
</tbody>
</table>
APPENDIX H: CMS COMMENTS

DATE: June 8, 2020

TO: Christi Grimm
Principal Deputy Inspector General

FROM: Seema Verma
Administrator


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 (DMEPOS) Competitive Bidding Program for beneficiaries and suppliers.

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 and the Patient Protection and Affordable Care Act of 2010.

Under the program, suppliers of DMEPOS 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.

Contract suppliers are monitored to ensure they comply with the contract terms and 42 CFR §414.422 and conduct business in a manner that meets the Medicare Supplier Standards at 42 CFR §424.57(c) and the CMS Quality Standards to be accredited. CMS’s monitoring program includes routine analysis of supplier performance indicators, claims data monitoring, Medicare enrollment data, and a formal complaint monitoring system. In addition, extensive education is provided to ensure suppliers, beneficiaries, providers, and referral agents understand the rules that govern the DMEPOS Competitive Bidding Program. If 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.

OIG determined that CMS consistently followed its established program procedures and applicable Federal requirements in the review of winning suppliers associated with their sampled single-payment amounts. In addition, OIG estimated payment errors of less than 0.03 percent of total payments made under the Round 1 Recompete during the first six months of 2014. The design of
the single payment amount calculation that CMS has established for the DMEPOS Competitive Bidding Program creates stability in payments, even in the presence of minor procedural errors, as shown in the resulting small estimated effect on aggregate payments to winning suppliers in this report.

Despite the low estimated error rates, CMS continues to evaluate ways to further improve the competitive bidding process. For example, we have modified our financial evaluation process in Round 2021 to address unacceptable financial statements from bidders rather than automatically disqualifying them. CMS believes improvements such as these ultimately lead to a more robust and competitive program.

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

**OIG Recommendation**
The OIG recommends that the Centers for Medicare and Medicaid Services 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’s priority throughout its financial evaluation is to include bidders who meet our requirements as defined in the Request for Bids Instructions while, at the same time, including financially viable bidders that meet or exceed our minimum financial score threshold. CMS reconciles the financial statements provided so that bidders were not incorrectly qualified or disqualified, using all information presented, while at the same time, applying the statutory, regulatory, and other requirements uniformly. CMS recognizes that the review of financial statements is a manual process that is implemented through standard operating procedures and all attempts are made to ensure consistent treatment throughout this process. As such, all reviewers involved in the financial review phase of the bid evaluation process are accountants. CMS believes this process ultimately leads to a more robust and competitive program.

CMS’s experience with Round 1 Recompete and each subsequent round of bid evaluation has given us, and will continue to give us, additional insight on lessons learned and how the process could be improved. As mentioned above, we have modified our financial evaluation process in Round 2021 to address unacceptable financial statements from bidders rather than automatically disqualifying them.

**OIG Recommendation**
The OIG recommends that the Centers for Medicare and Medicaid Services 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 DMEPOS and will continue to take steps to ensure that contract suppliers have applicable licenses for furnishing DMEPOS. As such, the Medicare contractor validates supplier licenses at the close of the bid window for the DMEPOS Competitive Bidding Program.
Our experience with this round and each subsequent round of bid evaluation has given us, and will continue to give us, additional insight on lessons learned and how the process could be improved. 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 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 DMEPOS 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.

**OIG Recommendation**
The OIG recommends that the Centers for Medicare and Medicaid Services ensures that it has a system to monitor supplier licensure requirements and identify potentially 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 DMEPOS to ensure that they maintain an active license throughout the duration of their Medicare enrollment.