

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**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**

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Inspector General

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Office of Inspector General

<http://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.

CMS awarded contracts to 63 suppliers that did not meet licensure requirements in at least one competition for which they received a contract under Round 2 of the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Bidding Program primarily because of incomplete and inaccurate licensure data.

INTRODUCTION

WHY WE DID THIS REVIEW

To address market changes and increasing Medicare Part B expenditures for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) items, Congress required the Centers for Medicare & Medicaid Services (CMS) to implement a Medicare competitive bidding program (the competitive bidding program). Under the competitive bidding program, prices for selected DMEPOS items sold in specified areas would generally be lower than historical prices for those items.

The Medicare Improvements for Patients and Providers Act of 2008 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 CMS to conduct the competitive bidding and subsequent pricing determinations that are the basis for the single payment amounts under Rounds 1 and 2 of the competitive bidding program. In addition, we have received congressional requests to look into complaints that some suppliers that were offered contracts for Round 2 of the competitive bidding program (contract suppliers¹) may not have met licensure requirements under the awarded contracts.² We conducted this audit in response to these congressional requests.

OBJECTIVE

Our objective was to determine whether suppliers that received contracts in Round 2 of the DMEPOS competitive bidding program and about whom CMS received complaints met licensure requirements.

BACKGROUND

Medicare Part B covers DMEPOS items, including wheelchairs, hospital beds, diabetic test strips, walkers, and oxygen. Traditionally, Medicare has paid for DMEPOS using a fee schedule. Congress mandated 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

¹ For purposes of this report, the term “contract suppliers” refers to those suppliers that were offered a contract. These suppliers did not necessarily have to accept a contract and, in some cases, may have originally accepted a contract and subsequently had their contract voided or terminated.

² The term “licensure requirements” refers to a Medicare requirement for the competitive bidding program. To meet the Medicare “licensure requirements,” a supplier must hold the State-required licenses in all the States and product categories for which it was awarded a contract. The scope of our audit did not include determining whether suppliers actually met State requirements to obtain or maintain applicable licenses.

generally lower single payment amount determined through a competitive bidding process. Under this process, DMEPOS suppliers that submit qualifying bids and accept competitive bidding contracts are paid the competitively determined single payment amounts to provide certain DMEPOS items to Medicare beneficiaries.

CMS contracts with Palmetto GBA as its National Supplier Clearinghouse (NSC) enrollment contractor and as its Competitive Bidding Implementation Contractor (CBIC). The NSC is primarily responsible for ensuring that DMEPOS suppliers meet all Federal and State requirements, including licensing requirements, to participate in Medicare, and the CBIC is generally responsible for administering the competitive bidding program. CMS is responsible for oversight of both contracts.

There are 100 competitive bidding areas (CBAs) in Round 2 of the competitive bidding program, and some CBAs include multiple States.³ Therefore, a supplier that may have historically served only one State may now be part of a CBA that also includes neighboring States. Any contract supplier serving a multi-State CBA must meet licensing requirements in each of those States.

A supplier may meet all the licensure requirements in one competition⁴ within one State but not meet licensure requirements in another competition in the same State. Also, a supplier may meet all licensure requirements for a product category in one State but not meet licensure requirements for the same product category in another State.

Before a contract is offered to a supplier, the CBIC determines whether a supplier is properly licensed and accredited for each competition in which it bid. The NSC verifies that contract suppliers are licensed upon revalidation and investigates situations in which CMS is not certain that contract suppliers are properly licensed in accordance with its oversight of all fee-for-service suppliers.

To maintain proper oversight, the NSC contacts each State every 3 months in an attempt to maintain current, accurate information. However, maintaining a complete and accurate licensure database is a complicated task. First, States are not legally required to report licensing information to CMS's contractors, and as a result information regarding requirement changes may not be reported quickly enough or not reported at all. Second, requirements can change frequently and be interpreted differently between States and stakeholders—and even among State officials. Finally, some States implement requirements without considering the time it takes suppliers to meet the requirements or the time it takes the agencies to process the license applications.

³ CMS, *Durable Medical Equipment, Prosthetics, Orthotics, and Supplies: DMEPOS Competitive Bidding Program—About the Program*, <http://www.dmecompetitivebid.com/palmetto/cbicrd2.nsf/DocsCat/Home>. Accessed on March 1, 2016. For future competitive bidding rounds, CMS defined the CBAs so that there are no multi-State CBAs.

⁴ A competition refers to a combination of a product category and competitive bid area that suppliers may bid to service.

Whether under the competitive bidding 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 number, suppliers are required to maintain proper licensure for the products and States in which they furnish items and services. After suppliers are enrolled in Medicare, they are responsible for informing the NSC of any changes in status, such as any expansion of business into other States or product categories.⁵ The NSC verifies that suppliers have the required licenses in the applicable States and 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 the licenses for the duration of the 3-year contracts that started on the July 1, 2013, contract implementation date.⁶

HOW WE CONDUCTED THIS REVIEW

After CMS announced the names of the contract suppliers, CMS received complaints stating that certain contract suppliers were not licensed in a State for a product category or categories. Of a potential 233 unlicensed suppliers identified in complaints, our review focused solely on 146 unique contract suppliers that may not have been licensed in some States included in Round 2 of CMS's competitive bidding program. Specifically, we reviewed documentation demonstrating licensure for contract suppliers in Round 2 of the competitive bidding program in 50 CBAs in the following 11 States: Tennessee, Ohio, Maryland, Louisiana, Virginia, New York, California, Florida, Georgia, Michigan, and Mississippi. We interviewed and obtained documentation from CMS, NSC, and CBIC officials regarding the processes used to ensure that contract suppliers met licensure requirements. We did not independently verify whether suppliers met individual requirements to obtain or maintain a license. Rather, we reviewed licensure documentation to verify whether the suppliers held the licenses for the product category or categories for which they were offered a contract.

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.

FINDINGS

Some contract suppliers about which CMS received complaints had not met all of the competitive bidding licensure requirements. Specifically, of the 146 suppliers covered in our audit, we determined that:

⁵ 42 CFR § 424.57(c)(2).

⁶ 42 CFR § 414.422(a) and individual supplier contracts.

- 69 had met State licensure requirements,
- 63 had not met State licensure requirements⁷ for some of the competitions for which they received a contract,⁸ and
- 14 need to be further researched by CMS and its contractors to determine whether the suppliers met State licensure requirements.⁹

The licensure database that CMS and its contractors used when awarding contracts to suppliers was incomplete and inaccurate. These licensure database deficiencies occurred as a result of variations in State licensure requirements and challenges in coordinating with States to ensure that the database was kept current. As explained earlier, each State establishes its own licensure requirements. These requirements frequently change, and some changes may occur after CMS's designated licensure deadline or contract implementation date. CMS cannot require States to report changes in the requirements, and according to CMS officials, changes are generally not reported in a timely fashion despite CMS actively requesting current licensure information on a quarterly basis.

In addition, each State can have multiple boards that oversee various DMEPOS items, and licensure requirements can vary depending on whether the supplier is in-State or out-of-State. Further, in some States, having a license that was granted by one board can exempt a supplier from needing another license under a different board. For example, certain States that require a license to supply oxygen do not require that license if the supplier is already a licensed pharmacy. This added complexity makes it more challenging for CMS to verify State licensure requirements for DMEPOS suppliers and particularly when CBAs cross State lines. CMS stated that when it became aware of licensure issues, it took immediate action.

The 63 suppliers we determined not to be properly licensed to provide DMEPOS items affected 90 of the 800 competitions in Round 2 of the DMEPOS competitive bidding program. For the first 6 months of Round 2 of competitive bidding, CMS paid just over \$1 million to these 63 suppliers for product categories they were not licensed to provide. This represented only 0.58 percent of the \$184 million paid in the 16 affected CBAs for the applicable product categories.

Appendix B includes the number of unlicensed suppliers by State.

⁷ Suppliers did not meet State licensure requirements either by the May 1, 2012, bid evaluation deadline or by the July 1, 2013, contract implementation date. Of the 63 unlicensed suppliers, 12 suppliers in Louisiana were licensed as of the May 1, 2012, bid evaluation deadline but not the July 1, 2013, contract implementation deadline.

⁸ Of the 63, CMS voided 27 supplier contracts in Tennessee before contract implementation and terminated 2 supplier contracts in Maryland and 1 supplier contract in Virginia after contract implementation.

⁹ CMS and its contractors were not able to provide licensure information for us to verify that these suppliers had the required licenses.

RECOMMENDATIONS

To address the challenges associated with maintaining an accurate and complete licensure database, we recommend that CMS:

- complete the research required to determine whether 14 suppliers had a proper license and make a licensure determination regarding those suppliers;
- identify all applicable State licensure requirements to prevent suppliers that do not have all currently required licenses from receiving contracts in future rounds of the competitive bidding program; and
- work with State licensing boards to better coordinate, identify, and maintain an accurate and complete licensure database of currently required State licenses.

CMS COMMENTS

In written comments on our draft report, CMS concurred and discussed steps it has and will take regarding our first two recommendations. CMS also stated that it has taken additional steps in the competitive bidding process to address State licensing issues. However, CMS did not concur with our third recommendation. Specifically, CMS stated that it takes several steps to maintain a complete database of State licensure requirements and will consider ways to improve the accuracy of the licensure database, encourage States to provide timely and accurate information, and enforce their licensing requirements.

OFFICE OF INSPECTOR GENERAL COMMENTS

Based on CMS's comments, we revised our third recommendation to give CMS flexibility in the manner it works with State licensing boards to better coordinate, identify, and maintain an accurate and complete licensure database of currently required State licenses. While we revised our recommendation, we continue to believe entering into written agreements with State licensing boards could be an effective way to encourage them to provide timely and accurate information and help CMS to identify all applicable State licensure requirements. This would be beneficial not only to CMS's competitive bidding program but also to its entire DMEPOS program.

CMS's comments are included in their entirety as Appendix C.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Of a potential 233 unlicensed suppliers identified in complaints from the supplier community (i.e., trade association and individual suppliers) and congressional inquiries, our review focused solely on 146 unique contract suppliers that may not have been licensed in some States under Round 2 of CMS's competitive bidding program. Specifically, we reviewed documentation demonstrating licensure for contract suppliers in Round 2 of the competitive bidding program in 50 CBAs in the following 11 States: Tennessee, Ohio, Maryland, Louisiana, Virginia, New York, California, Florida, Georgia, Michigan, and Mississippi. We interviewed and obtained documentation from CMS, NSC, and CBIC officials regarding the processes used to ensure that contract suppliers met licensure requirements.

We did not review all licensure requirements for all contract suppliers in all competitions for which the contract suppliers won contracts. We interviewed CMS, NSC, and CBIC officials and reviewed documentation related to licensure in the competitions relevant to complaints received by CMS.

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

We performed our fieldwork from September 2013 through November 2014.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal and State laws, regulations, and guidance related to State licensure requirements identified in complaints under Round 2 of the competitive bidding program;
- obtained an understanding of the process for selecting suppliers for the competitive bidding program;
- interviewed CMS, NSC, and CBIC officials to obtain information as to whether suppliers met licensure requirements;
- reviewed documentation related to CMS's efforts to determine whether suppliers identified in complaints met licensure requirements, including CMS's correspondences with State licensing boards;
- identified 233 potentially unlicensed contract suppliers from the complaints received from CMS;

- identified and reviewed 146 unique contract suppliers from the 233 potentially unlicensed contract suppliers identified in complaints;
- reviewed NSC and CBIC actions to improve the licensure review process; and
- discussed the results of our review with CMS officials.

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: TABLE OF SUPPLIERS THAT DID NOT MEET LICENSURE REQUIREMENTS

State	Alleged Suppliers That Did Not Meet Licensure Requirements	Suppliers That Did Not Meet Licensure Requirements
Tennessee	48	27
Ohio	35	15
Maryland	44	14
Louisiana	20	12
Virginia	16	11
New York	55	0
California	7	0
Florida	0 ^a	0
Georgia	0 ^a	0
Michigan	8	0
Mississippi	0 ^a	0
TOTAL	233^b	79^c

^a Complaints were general and did not identify any specific contract suppliers.

^b Total numbers contain suppliers that have been counted more than once because some suppliers received a contract in multiple competitions in different States.

^c While 63 unique contract suppliers did not meet all licensure requirements, some of these suppliers also did not meet licensure requirements in more than one State. The 79 suppliers contain 16 duplicate suppliers for purposes of identifying unlicensed suppliers by State.

APPENDIX C: CMS RESPONSE



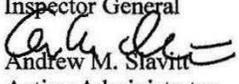
DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

200 Independence Avenue SW
Washington, DC 20201

DATE: FEB -4 2016

TO: Daniel R. Levinson
Inspector General

FROM: 
Andrew M. Slavitt
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "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)

The Centers for Medicare and Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report. CMS is committed to the continued success of the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program (CBP).

The CBP uses market forces to help Medicare pay claims appropriately and lower beneficiary out-of-pocket expenses for certain items of DMEPOS, while ensuring beneficiary access to quality items and services. In 2011, CMS successfully implemented the Round 1 Rebid of the CBP in nine metropolitan areas after making a number of improvements, including adopting new requirements from Congress. In July 2013, Round 2 of the CBP expanded to 91 additional areas, and we implemented a national mail-order program for diabetes testing supplies.

The program saved more than \$580 million in the nine markets at the end of the Round 1 Rebid's 3-year contract period due to lower payments and decreased unnecessary utilization. Additional savings are being achieved as part of the Affordable Care Act's expansion of the CBP—at the end of the first year of Round 2 and the national mail-order program, Medicare has saved approximately \$2 billion. Furthermore, CMS has received few complaints about the program and data indicate no changes to beneficiary health outcomes.

Before a CBP contract is offered to a supplier, CMS determines whether a supplier is properly licensed and accredited for each competition (competitive bidding area (CBA)/product category combination) in which it bids and meets specific CBP financial standards. Medicare's accreditation and financial standards 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.

As noted in the report, the complexity and ambiguity of state licensure requirements make it challenging for CMS to verify state licensure requirements for suppliers, particularly when CBAs cross State lines. CMS reaches out to each state every quarter to obtain updates to their

licensure requirements. CMS cannot compel states to enforce their own licensing requirements, however, CMS has made a considerable effort to educate suppliers on the need for compliance.

When CMS is made aware of additional or updated state licensure requirements, these requirements are included as competitive bidding requirements as long as they are effective prior to the opening of the bid window. CMS does not apply additional bidding requirements during or after bidding. However, CMS incorporates new and updated requirements into the Medicare program's supplier standards that all DMEPOS suppliers must comply with. Suppliers are notified and offered a grace period, if necessary, to demonstrate compliance with updated requirements.

CMS revokes the Medicare billing number for each supplier location that does not demonstrate compliance. Should a revoked billing number result in a contract supplier not having at least one qualified and active location for each of its competitions on the contract, CMS will pursue a contract termination. To avoid any disruption in patient care, CMS generally attempts to work with suppliers to bring them into compliance.

When CMS is made aware of issues of suppliers not meeting the CBP rules such as state licensure, CMS has investigated the situation and taken appropriate action according to the regulations. In addition, CMS has taken steps in the subsequent Rounds of the CBP to address these state licensing issues. For Round 2 Recompete and Round 1 2017, CMS changed the CBAs so that there are no CBAs in more than one State. Also, CMS implemented a preliminary bid evaluation process that checks all supplier enrollment data, as specified in the Request for Bids including state licensure, before the bid evaluation process starts. A bidder will be notified if the requirements are not met and would have a limited time to potentially remedy the issue prior to the start of the bid evaluation or the bid(s) would be disqualified.

OIG's recommendations and CMS' responses are below.

OIG Recommendation

Complete the research required to determine whether 14 suppliers had a proper license and make a licensure determination regarding those suppliers

CMS Response

CMS concurs with OIG's recommendation. CMS will examine the data provided by OIG to determine whether it needs to take action on these suppliers. It is important to note that OIG identified only a small number of suppliers with potential compliance concerns, resulting in a minimal impact to beneficiaries and Medicare reimbursements.

Additionally, CMS conducted research on the 63 suppliers the OIG identified in the report. Of these suppliers, only one supplier did not meet the licensure requirements CMS was aware of for a state by the May 1, 2012, Round 2 competitive bidding licensure deadline. CMS has worked to address these few licensure deficiencies. CMS is also establishing a process to enforce licensure compliance for all contract suppliers in future rounds.

OIG Recommendation

Identify all applicable State licensure requirements to prevent suppliers that do not have all currently required licenses from receiving contracts in future rounds of the competitive bidding programs

CMS Response

CMS concurs with OIG's recommendation. To maintain proper oversight, CMS reaches out to each state every three months to learn about updates to their licensure requirements. In addition, CMS works with state officials to clarify ambiguity or request more information about licensing requirements. As noted in the report, CMS does not have the authority to require states to report changes in licensing requirements.

In addition, as noted above, CMS has made improvements in the future CBP rounds to ensure that bidders meet state licensing requirements such as using a preliminary bid evaluation process to ensure that the requirements are met before a bid is accepted. CMS also changed the CBAs in the future CBP rounds so that there are no CBAs in more than one state which was one of the challenges noted in ensuring suppliers met all state licensure requirements.

OIG Recommendation

Consider entering into written agreements with State licensing boards to better coordinate, identify, and maintain an accurate and complete licensure database of currently required State licenses

CMS Response

CMS does not concur with OIG's recommendation. CMS takes several steps to maintain a complete database of state licensure requirements, including reaching out to each state every three months to learn about updates to their licensure requirements. As we work to improve our processes, CMS will consider ways to improve the accuracy of the licensure database, encourage states to provide timely and accurate information, and enforce their licensing requirements.

CMS thanks OIG for their efforts on this issue and looks forward to working with OIG on this and other issues in the future.