

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**CMS HAS NOT PROMULGATED
REGULATIONS TO ESTABLISH
PAYMENT REQUIREMENTS FOR
PROSTHETICS AND
CUSTOM-FABRICATED
ORTHOTICS**



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EXECUTIVE SUMMARY: CMS HAS NOT PROMULGATED REGULATIONS TO ESTABLISH PAYMENT REQUIREMENTS FOR PROSTHETICS AND CUSTOM-FABRICATED ORTHOTICS

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WHY WE DID THIS STUDY

Section 427(a) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) prohibits Medicare payments for prosthetics and custom-fabricated orthotics unless the items are (1) furnished by a qualified practitioner and (2) fabricated by either a qualified practitioner or a qualified supplier. Section 427(b) of the BIPA required the Secretary to promulgate regulations to implement the requirements at section 427(a) of the BIPA. As required by 42 CFR § 424.57(c)(12), Medicare suppliers must also maintain documentation supporting that prosthetics and custom-fabricated orthotics were delivered to beneficiaries. In 2010, the Centers for Medicare & Medicaid Services (CMS) allowed \$276 million in Medicare payments for 257,797 prosthetic and custom-fabricated orthotic claims (excluding accessories, additions, and other supplemental prosthetic and orthotic items).

HOW WE DID THIS STUDY

We selected a sample of 1,135 Medicare-allowed claims for prosthetics and custom-fabricated orthotics in 2010 to determine whether the claimed items were (1) furnished by qualified practitioners, (2) fabricated by either qualified practitioners or qualified suppliers, and (3) met delivery documentation requirements. We interviewed CMS staff regarding the implementation status of the BIPA payment requirements.

WHAT WE FOUND

To date, CMS has not promulgated regulations related to BIPA payment requirements for practitioner and supplier qualifications for prosthetics and custom-fabricated orthotics. CMS used other legal authorities that limit who can be paid for prosthetics and custom-fabricated orthotics; notwithstanding, in 2010, Medicare allowed nearly 1,000 claims inappropriately. Despite the lack of regulations, most claims were allowed for prosthetics and custom-fabricated orthotics furnished and/or fabricated by practitioners and/or suppliers that were licensed, certified, or accredited. Finally, Medicare inappropriately allowed 12 percent of claims for prosthetics and custom-fabricated orthotics that did not meet Federal requirements for delivery documentation.

WHAT WE RECOMMEND

We recommend that CMS (1) promulgate regulations to implement the BIPA payment requirements, (2) ensure that suppliers maintain delivery documentation that meets Federal requirements, and (3) take appropriate action to address inappropriately allowed claims identified in the population related to payment edits and in our sample related to delivery documentation. CMS concurred with all three recommendations.

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OBJECTIVES

To determine the extent to which:

1. the Centers for Medicare & Medicaid Services (CMS) has implemented the payment requirements found at Section 427(a) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA);
2. Medicare allowed claims for prosthetics and custom-fabricated orthotics furnished and/or fabricated by unqualified practitioners and/or suppliers; and
3. Medicare allowed claims for prosthetics and custom-fabricated orthotics that lacked delivery documentation that met Federal requirements.

BACKGROUND

Prosthetics and orthotics are covered under the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Medicare benefit.¹ In 2010, CMS allowed \$276 million in Medicare payments for 257,797 prosthetic and custom-fabricated orthotic claims (excluding accessories, additions, and other supplemental prosthetic and orthotic items).² Industry representatives have asserted that unqualified practitioners and suppliers are furnishing and/or fabricating Medicare-paid prosthetics and custom-fabricated orthotics. These representatives are concerned that unqualified practitioners and suppliers, who lack necessary training and education, are providing substandard custom-fabricated items to Medicare beneficiaries.³ Additionally, a 2000 Office of Inspector General (OIG) report concluded that qualifications of orthotic suppliers varied, with noncertified suppliers being the ones most likely to provide inappropriate items and services.⁴ OIG has not specifically reviewed the qualifications of practitioners and suppliers of prosthetics and custom-fabricated orthotics previously.

¹ To be payable by Medicare, prosthetics and orthotics must be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member. Social Security Act (SSA) § 1862(a)(1)(A); 42 U.S.C. 1395y(a)(1)(A).

² Custom-fabricated items are individually fabricated over a positive model of the patient.

³ We conducted preinspection interviews with several industry representatives, who expressed their opinions that enforcement of Medicare qualifications is lax, and that many unqualified practitioners are fitting and fabricating prosthetics and custom-fabricated orthotics.

⁴ OIG, *Medicare Payments for Orthotics: Inappropriate Payments*, OEI-02-99-00120, March 2000.

Federal Statutory Payment Requirements

Section 427(a) of the BIPA, enacted on December 21, 2000, added special payment requirements for prosthetics and certain custom-fabricated orthotics at section 1834(h)(1)(F) of the SSA (the BIPA payment requirements).⁵ This section prohibits Medicare payments for prosthetics and custom-fabricated orthotics unless the items are (1) furnished by a qualified practitioner and (2) fabricated by a qualified practitioner or a qualified supplier at a facility that meets such criteria as the Secretary determines appropriate.⁶ Generally, Medicare qualifications are intended to protect beneficiaries, promote high-quality care, and safeguard Medicare funds by ensuring that only qualified individuals and health care organizations furnish Medicare items and services.⁷ Section 427(b) of the BIPA required the Secretary to promulgate regulations to implement Section 427(a) of the BIPA no later than December 21, 2001 (i.e., 1 year after the date of enactment), using a negotiated rulemaking process.⁸

Qualified practitioners. The BIPA payment requirements define a qualified practitioner as a physician or other individual who is:

- a qualified physical or occupational therapist;⁹
- licensed in prosthetics or orthotics by the State in which the item is supplied;¹⁰ or
- providing prosthetics or orthotics in a State that does not license practitioners of prosthetics and orthotics and is specifically trained and

⁵ BIPA, H.R. 5601, 106th Cong. § 427(a) (2000), adding SSA § 1834(h)(1)(F), 42 U.S.C. 1395m(h)(1)(F). For purposes of this payment prohibition, “certain custom-fabricated orthotics” is defined to mean only those custom-fabricated orthotics that require education, training, and experience to custom fabricate and that are included in a list established by the Secretary of the Department of Health and Human Services (the Secretary) in consultation with appropriate experts in orthotics, including national organizations representing manufacturers of orthotics. SSA § 1834(h)(1)(F)(ii); 42 U.S.C. 1395m(h)(1)(F)(ii). We refer to certain custom-fabricated orthotics simply as custom-fabricated orthotics.

⁶ SSA § 1834(h)(1)(F)(i); 42 U.S.C. 1395m(h)(1)(F)(i).

⁷ 71 Fed. Reg. 20754 (Apr. 21, 2006).

⁸ CMS is the agency that would promulgate regulations to implement the BIPA payment requirements on the Secretary’s behalf.

⁹ Per 72 Fed. Reg. 66222, 66328 (Nov. 27, 2007), personnel qualifications in 42 CFR § 484.4 are applicable to all outpatient physical and occupational therapy services. See also, CMS, *Medicare Benefit Policy Manual*, Pub. No. 100-02, ch. 15, §§ 230.1(B) and 230.2(B) (defining qualified physical therapist and qualified occupational therapist, respectively).

¹⁰ If a practitioner (other than a physician, qualified physical therapist, or qualified occupational therapist) supplies the item in a State that provides for licensing of orthotics and prosthetics and the practitioner is not licensed by that State, under the BIPA payment requirement, the practitioner would not be a “qualified practitioner” and, therefore, would not be entitled to Medicare payment for the item.

educated to provide or manage the provision of prosthetics and/or custom-fabricated orthotics, and is certified by the American Board for Certification in Orthotics, Prosthetics & Pedorthics (ABC) or the Board of Certification/Accreditation, International (BOC), or is credentialed and approved by a program that the Secretary determines (in consultation with appropriate experts in prosthetics and orthotics) has training and education standards that are necessary to provide such prosthetics and orthotics.¹¹

See Appendix A for an overview of States that license prosthetists and orthotists.

Qualified suppliers. The BIPA payment requirements define a qualified supplier as any entity that is:

- accredited by ABC or BOC, or
- accredited and approved by a program that the Secretary determines has accreditation and approval standards that are essentially equivalent to those of ABC or BOC.¹²

CMS Actions That Limit Medicare Payment for Prosthetics and Custom-Fabricated Orthotics

CMS has established payment edits and implemented Medicare supplier enrollment requirements that limit who can be paid for prosthetics and custom-fabricated orthotics.¹³ For example, CMS issued Transmittal 656 to establish a payment edit based on an existing supplier standard.¹⁴ This transmittal explains that, in States that license prosthetists or orthotists, Medicare payments for prosthetics and custom-fabricated orthotics are prohibited unless the furnisher is licensed by the State.¹⁵ More specifically, in States that license prosthetists and orthotists, Transmittal

¹¹ SSA § 1834(h)(1)(F)(iii)(III). The Secretary has not issued guidance specifying which programs, if any, meet the latter requirement found at SSA § 1834(h)(1)(F)(iii)(III).

¹² In December 2006, CMS issued a document entitled *Medicare New Deemed Accreditation Organizations For Suppliers of Durable Medical Equipment, Prosthetics, Orthotics And Supplies (DMEPOS)* that lists the accrediting organizations for durable medical equipment (DME) suppliers based on the quality standards. However, the Secretary has not issued guidance specifying which programs, if any, are essentially equivalent to those of ABC or BOC for the purposes of the BIPA payment requirements. See footnote 19.

¹³ Payment edits are safeguards built into claims processing computer systems designed to prevent payment for noncovered and/or not medically necessary services.

¹⁴ CMS, *Medicare Claims Processing Manual*, Pub. No. 100-04, Transmittal 656, Change Request 3959 (revising CMS, *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 20, § 130.1). Accessed online at <http://www.cms.gov> on September 3, 2010.

¹⁵ Transmittal 656 is based on a CMS DMEPOS supplier standard, which requires that suppliers furnish all Medicare-covered items in compliance with all applicable Federal and State licensure and regulatory requirements. 42 CFR § 424.57(c)(1). See also SSA § 1834(j)(1)(B)(ii)(I).

656 directs suppliers to send a copy of their State licenses to the National Supplier Clearinghouse (NSC) to ensure that the correct specialty code is on file. The transmittal also directs that claims for prosthetics and custom-fabricated orthotics submitted by a supplier in one of those States be denied unless the claims contain one of the specialty codes listed in the transmittal.¹⁶ See Appendix B for the specialty codes listed in Transmittal 656. Transmittal 656 also contains an attachment listing the Healthcare Common Procedure Coding System (HCPCS) codes for prosthetics and custom-fabricated orthotics affected by this payment edit.

CMS also implemented Medicare quality standards that require DMEPOS suppliers to be accredited to furnish certain items and services, including prosthetics and orthotics.¹⁷ Quality standards are applied by independent accreditation organizations designated by the Secretary.¹⁸ CMS has deemed 10 organizations to be accrediting organizations, 9 of which (including ABC and BOC) are approved to accredit suppliers of prosthetics and custom-fabricated orthotics.¹⁹ Some suppliers, such as physicians, physical therapists, occupational therapists, prosthetists, and orthotists, are exempt from accreditation requirements.²⁰

¹⁶ Specialty codes indicate the specialty of the practitioner or supplier furnishing the item. For States that have licensure requirements, Transmittal 656 limits payment for prosthetics and custom-fabricated orthotics to items furnished by physicians, physical therapists, occupational therapists, prosthetic personnel, orthotics personnel, pedorthists, or medical supply companies with orthotics and/or prosthetics personnel as indicated by their specialty codes; these codes are listed in Transmittal 656.

¹⁷ SSA § 1834(a)(20)(A) (paragraph 1834(a)(20) was added by Section 302(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. 108-173). SSA § 1834(a)(20)(F)(i) (subparagraph 1834(a)(20)(F), directing suppliers to submit evidence of accreditation by October 1, 2009, was added by Section 154(b) of the Medicare Improvements for Patients and Providers Act of 2008, P.L. 110-275).

¹⁸ SSA § 1834(a)(20)(A) and (B).

¹⁹ Because the legal basis for these accreditation requirements is the DMEPOS quality standards, the accreditation requirements apply to a wide range of DMEPOS items, not just prosthetics and custom-fabricated orthotics. Notwithstanding, the accreditation requirements included in the DMEPOS quality standards overlap with the BIPA payment requirements regarding qualified suppliers. See SSA § 1834(a)(20)(F)(i) regarding the Medicare quality standards accreditation requirement. See also SSA § 1834(h)(1)(F)(iv) on the subject of the BIPA payment requirement regarding qualified suppliers.

²⁰ SSA § 1834(a)(20)(F)(ii). CMS, One-Time Notification, Pub. No. 100-20, Transmittal 710, Change Request 6566, dated May 21, 2010. See also Attachment A of Transmittal 710 for a full list of exempt suppliers.

All suppliers are responsible for the delivery of Medicare-covered items to beneficiaries and are required to maintain proof of delivery for 7 years.^{21, 22} CMS guidance outlines documentation requirements for different methods of delivery. Examples of delivery documentation include a delivery slip signed by the beneficiary or beneficiary's designee or, if the supplier uses a shipping service, the service's tracking slip and the supplier's shipping invoice.²³

Previous OIG Work

A 2000 OIG study found that miscoded orthotics resulted in \$33 million in excessive Medicare payments in 1998.²⁴ That study concluded that qualifications of orthotic suppliers varied, with noncertified suppliers being most likely to provide inappropriate devices and services. The study also found that Medicare payments occurred even when the orthotics did not meet the specifications billed, the orthotics were not custom fabricated, or the parts billed were included in the base code for a larger orthotic.

A 2011 OIG study examining questionable billings found that, in 2009, Medicare inappropriately paid \$43 million for lower limb prostheses that did not meet local coverage determination requirements and that payments for these items could have been prevented by using claims-processing edits.²⁵ Further, Medicare paid an additional \$61 million for lower limb prostheses for beneficiaries who had not received an office visit or any other services from their referring physicians in the last 5 years. The study also found that 267 suppliers providing lower limb prostheses had engaged in questionable billing practices. The study concluded that Medicare contractors' efforts to safeguard payments for lower limb prostheses varied.

²¹ See 42 CFR § 424.57(a), stating that a DMEPOS supplier is an entity or individual, including a physician or a Part A provider, which sells or rents Part B-covered items to Medicare beneficiaries and meets the supplier standards outlined in 42 CFR § 424.57(c). The individual practitioners who received payments for the claims in our sample were also enrolled DMEPOS suppliers. Therefore, they must meet the supplier standards. Because the individual practitioners were also enrolled DMEPOS suppliers, we use the term "suppliers" only when discussing our findings regarding delivery documentation.

²² CMS, *Medicare Program Integrity Manual*, Pub. No. 100-08, ch. 4, § 4.26. See also, 42 CFR § 424.57(c)(12).

²³ *Ibid.*, ch. 4, § 4.26.1.

²⁴ OIG, *Medicare Payments for Orthotics: Inappropriate Payments*, OEI-02-99-00120, March 2000.

²⁵ OIG, *Questionable Billing by Suppliers of Lower Limb Prostheses*, OEI-02-10-00170, August 2011.

METHODOLOGY

We evaluated Medicare-allowed claims for prosthetics and custom-fabricated orthotics in 2010 to determine whether the claimed items were (1) furnished by qualified practitioners and (2) fabricated by either qualified practitioners or qualified suppliers. We conducted structured interviews with CMS staff regarding the status of the implementation of the BIPA payment requirements. For a sample of 1,135 claims, we collected and reviewed documentation relating to (1) the qualifications of the practitioners and suppliers that furnished and/or fabricated the claimed items and (2) the delivery of the items. All estimates in this report are projected to the specified population or subpopulation of allowed claims excluding accessories, additions, and other supplemental prosthetic and orthotic items (e.g., straps and joints added to a prosthetic limb).

Scope

We determined whether practitioners and suppliers were qualified to furnish and fabricate prosthetics and custom-fabricated orthotics using the definitions in Section 427(a) of the BIPA, together with the requirements in Transmittal 656 and the applicable quality standards. We analyzed documentation submitted by the practitioners and suppliers that were paid for the sampled claims. We did not determine the medical necessity of the claimed items.

Population

Our population included 257,797 Medicare-allowed claims in 2010, amounting to \$276 million, for prosthetics and custom-fabricated orthotics. The population excluded accessories, additions, and other supplemental prosthetic and orthotic items. We obtained data from the 2010 DME Standard Analytical File from the National Claims History File. From the Standard Analytical File, we constructed a population of all allowed claims for prosthetics and custom-fabricated orthotics. CMS provided a list of HCPCS codes for prosthetics and custom-fabricated orthotics.

Sample Selection

We selected a stratified random sample totaling 1,135 claims. The sample had 12 strata based on specialty code and allowed dollar amounts. See Table 1 for a summarized sampling design; Appendix C provides a table showing all 12 strata and details regarding the sample and population. We designed the sample to produce estimates based on practitioner or supplier specialty codes and allowed dollar amounts. As our data analysis progressed, it became clear that the number of unqualified practitioners and suppliers was too small for us to make reliable estimates based on

specialty codes and allowed dollar amounts as we had planned. Instead, we produced overall estimates of the number and amount of payments to unqualified practitioners and suppliers as defined in the BIPA payment requirements.

Table 1: Population and Sample Data for Medicare-Allowed Claims for Prosthetics and Custom-Fabricated Orthotics by Practitioner and Supplier Specialty, 2010

Specialty	Allowed Dollars	Allowed Claims	Sample Size
Prosthetics: Medical Supply Companies	\$45,607,574	28,465	165
Prosthetics: Individual Practitioners	\$118,473,931	69,997	335
Prosthetics: All Other Practitioners and Suppliers*	\$11,309,824	10,023	115
Total Prosthetics:	\$175,391,329	108,485	615
Orthotics: Medical Supply Companies	\$24,950,710	29,663	145
Orthotics: Individual Practitioners	\$46,099,212	57,572	220
Orthotics: All Other Practitioners and Suppliers*	\$30,031,273	62,077	155
Total Orthotics:	\$101,081,195	149,312	520
Overall Total:	\$276,472,524	257,797	1,135

Source: OIG analysis of Medicare-allowed claims for prosthetics and custom-fabricated orthotics, 2010.

*Transmittal 656 sets up these general groups of specialty codes, listing medical supply companies, prosthetic and orthotic personnel, physical and occupational therapists, and all other providers with specialty codes listed in Chapter 26 of the *Medicare Claims Processing Manual*. The "All Other Practitioners and Suppliers" category includes physical and occupational therapists and all other providers with specialty codes listed in Chapter 26 of the *Medicare Claims Processing Manual*. See Appendix D for a description of specialty codes for all "other" practitioners and suppliers.

We did not send requests for documentation to the practitioners and suppliers for eight sampled claims because they were associated with ongoing OIG investigations. As a result, we sent requests for 1,127 claims to practitioners and suppliers.

Data Collection

For each sampled claim, we sent a letter requesting documentation to support the certification, licensure, or accreditation of the practitioner that furnished and the practitioner or supplier that fabricated the prosthetic or custom-fabricated orthotic item. We also requested documentation to support delivery of the item. We sent a second letter to practitioners or suppliers that did not respond to our initial documentation request. We attempted to contact practitioners or suppliers that did not respond to our second request by telephone to verify that they were in business and that we had the correct mailing address. In a last attempt to contact the nonresponsive practitioners or suppliers, we sent a final certified letter through the U.S. Postal Service.

We received responses for 1,116 of the 1,127 claims for which we requested documentation, a response rate of 98 percent.²⁶ Of the 11 sampled claims for which we did not receive documentation, 8 were from practitioners or suppliers that received but did not respond to our request for documentation, 2 were from suppliers that did not respond to our request and whose operational status could not be confirmed, and 1 was from a supplier that was no longer in business.²⁷

Data Analysis

We determined whether the claimed prosthetic and custom-fabricated orthotic items were (1) furnished by qualified practitioners and (2) fabricated by either qualified practitioners or qualified suppliers. Although CMS may make different determinations when promulgating regulations to implement the BIPA payment requirements, for the purposes of this evaluation, we made certain broad assumptions regarding parts of the BIPA that are not yet defined. We assumed that the nine organizations currently approved to accredit suppliers of prosthetics and custom-fabricated orthotics will be approved once the BIPA payment requirements are implemented. We did not make any assumptions about the criteria the Secretary will determine to be appropriate for facilities at which prosthetics and custom-fabricated orthotics are fabricated.

Determination of Whether Practitioners and Suppliers Were Qualified. In the 38 States that do not license prosthetists and orthotists, we considered items to have been furnished or fabricated by unqualified practitioners or suppliers if:

- the furnisher (1) was not a physical or occupational therapist or a physician, or (2) did not have ABC or BOC certification on the date of the claim;²⁸ or
- the fabricator was not (1) a physical or occupational therapist or a physician, or (2) a practitioner that had ABC or BOC certification on

²⁶ We selected a sample of 1,135 claims but sent requests for documentation for only 1,127 of those claims, as explained above. To calculate the response rate, we divided the 1,116 responses received by the total sample size of 1,135.

²⁷ We referred these 11 nonresponding practitioners and suppliers to CMS for appropriate action.

²⁸ BIPA, H.R. 5601, 106th Cong. § 427(a) (2000), adding SSA § 1834(h)(1)(F), 42 U.S.C. 1395m(h)(1)(F). Under the BIPA payment requirements, a qualified practitioner would also include an individual credentialed and approved by another program designated by the Secretary. Therefore, if this provision is implemented, there may be other programs that can credential and approve individuals to become qualified practitioners.

the date of the claim, or (3) a supplier that had accreditation from one of the nine accrediting agencies on the date of the claim.²⁹

For claims from the 13 States that license prosthetists and orthotists, we considered items to have been furnished or fabricated by unqualified practitioners or suppliers if:

- the furnisher (1) was not a prosthetist, orthotist, physical or occupational therapist, or physician; or (2) did not have licensure in the appropriate State on the date of the claim; or
- the fabricator was not (1) a prosthetist, orthotist, physical or occupational therapist, or physician who had licensure in the appropriate State on the date of the claim; or (2) a supplier that had accreditation from one of the nine accrediting agencies on the date of the claim.

In some cases, practitioners or suppliers indicated that a furnisher or fabricator was qualified but did not supply supporting documentation (e.g., a practitioner indicated that he or she was licensed but did not provide licensure documentation). In these instances, we contacted the practitioner or supplier and requested the missing documentation a second time. If the practitioner or supplier still did not provide the missing documentation, we attempted to verify the practitioner's or supplier's qualifications by independently researching publicly available State licensure and/or certification and accreditation information online. States and some certification and accreditation organizations maintain databases of their licensees and members online. For example, if a practitioner claimed to be licensed by the State of Texas, we checked the Texas Department of State Health Services Web site to attempt to verify his or her licensure. If a supplier claimed to be accredited by ABC, we checked the ABC Web site to verify that supplier's accreditation. If we neither received documentation from the practitioner or supplier nor were able to independently verify the information, we considered the furnisher or fabricator unqualified.

Determination of Delivery Documentation Errors. In all States, we considered a claim to be allowed inappropriately if the documentation submitted did not meet Federal requirements for documentation of delivery to the beneficiary. We determined claims to have been allowed inappropriately if we did not receive any delivery documentation or if the

²⁹ For purposes of the BIPA payment requirements, CMS has not issued guidance specifying which programs, if any, have accreditation and approval standards that are equivalent to ABC or BOC. However, for this evaluation, we consider accreditation from any of the nine CMS-approved accrediting organizations to be sufficient.

documentation that was provided lacked a beneficiary or designee signature.³⁰

Communication With CMS Staff

Throughout our data collection and analysis, we conducted structured interviews and corresponded via email with CMS staff regarding: (1) the status of implementation of the BIPA payment requirements, and (2) the application of the requirements of Transmittal 656 and the Medicare quality standards to the practitioners and suppliers in our sample of claims.

Limitations

Our analysis was limited to the information available in the claims data and the documentation that we requested from the practitioners and suppliers of the sampled claims. Therefore, we were unable to determine whether the furnishers and fabricators identified in the documentation that we received did indeed furnish and/or fabricate the prosthetic or custom-fabricated orthotic. For example, if a claim in our sample was billed by a licensed prosthetist, we requested documentation to support the qualifications of the prosthetist listed on the claim. Some items claimed in our sample were furnished by a registered assistant practicing under the supervision of a licensed prosthetist or orthotist. We confirmed with CMS staff that a registered assistant met the definition of a qualified practitioner. It is possible that other items claimed in our sample were furnished by a registered assistant not practicing under the supervision of a licensed prosthetist or orthotist. However, if the licensed prosthetist or orthotist did not inform us that the claimed item was furnished by the registered assistant and simply provided documentation to support his own qualifications, we had no way of determining that the registered assistant furnished the item.

While we did not set out to review the payment edits based on specialty codes in Transmittal 656, we noted that some claims in our sample were from practitioners and suppliers with specialty codes not listed in Transmittal 656. Our evaluation did not include determining why the payment edits failed; therefore, we cannot determine why claims were paid to practitioner and suppliers with specialty codes not listed in Transmittal 656.

Standards

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

³⁰ In cases in which the delivery documentation provided was a shipping receipt, the claim was not determined to be inappropriately allowed despite the lack of a beneficiary or designee signature.

FINDINGS

CMS has not promulgated regulations related to payment requirements for practitioner and supplier qualifications for prosthetics and custom-fabricated orthotics

Section 427(a) of the BIPA, enacted December 21, 2000, prohibits Medicare payment for prosthetics and custom-fabricated orthotics unless they are furnished by a qualified practitioner and fabricated by a qualified practitioner or a qualified supplier at a facility that meets criteria determined by the Secretary. Section 427(b) requires the Secretary to promulgate regulations to implement section 427(a) of BIPA not later than December 21, 2001, using a negotiated rulemaking process. To date, CMS has not promulgated regulations to implement this requirement.

Beginning in 2002, CMS established a negotiated rulemaking committee and held several meetings to attempt to reach consensus on the substance of a proposed rule.³¹ CMS set a deadline of 6 months, beginning with the date of the first meeting (October 1, 2002), for the committee to complete work on the proposed rule.³² The final meeting of the negotiated rulemaking committee was scheduled for July 2003 (i.e., more than 8 months after the first meeting), and the committee failed to reach consensus.³³

In 2002, CMS stated that if the negotiated rulemaking committee was unable to reach consensus, CMS would develop a proposed rule.³⁴ However, in October 2005, CMS indicated that it had terminated the rulemaking process in June 2005, almost 2 years after the final meeting of the negotiated rulemaking committee.³⁵ Thus, despite the BIPA mandate to promulgate regulations to implement the BIPA payment requirements

³¹ See, e.g., 67 Fed. Reg. 48839 (July 26, 2002) (announcing the establishment of the Negotiated Rulemaking Committee on Special Payment Provisions and Requirements for Prosthetics and Certain Custom-Fabricated Orthotics and the dates of the first two meetings) and 68 Fed. Reg. 38269 (June 27, 2003) (announcing the date of the final meeting).

³² 67 Fed. Reg. 13297 (March 22, 2002).

³³ 68 Fed. Reg. 38269 (June 27, 2003).

³⁴ 67 Fed. Reg. 13297 (March 22, 2002).

³⁵ A proposed rule implementing Section 427(a) was listed in the semiannual regulatory agenda, but CMS withdrew the item from its agenda in June 2005. See, e.g., 69 Fed. Reg. 73119, 73168 (Dec. 13, 2004); and 70 Fed. Reg. 26817, 26871 (May 16, 2005) (providing a timetable for issuance of a proposed rule implementing Section 427 of the BIPA). See 70 Fed. Reg. 64533, 64623 (Oct. 31, 2005) (indicating that action on the proposed rule was completed because it was withdrawn).

no later than December 21, 2001, to date, no regulations have been promulgated.

CMS has used other legal authorities that limit who can be paid for prosthetics and custom-fabricated orthotics; notwithstanding, in 2010, Medicare allowed nearly 1,000 claims inappropriately

In lieu of implementing the BIPA payment requirements, CMS has used other legal authorities that limit who can be paid for prosthetics and custom-fabricated orthotics.³⁶ For example, based on the supplier standards, CMS issued Transmittal 656, instructing its contractors to implement payment edits based on specialty codes in the 13 States that license prosthetists and orthotists. Notwithstanding, in 2010, Medicare allowed 966 claims, totaling \$776,154, for prosthetics and custom-fabricated orthotics from practitioners and suppliers in the 13 States that license prosthetists and orthotists that did not have a specialty code listed in Transmittal 656. Transmittal 656 states that claims from practitioners and suppliers with specialty codes not listed in that document should be denied payment. Therefore, these payments were inappropriate.

Another approach CMS used, based on the quality standards, mandates that all nonexempt DMEPOS suppliers attain accreditation. See Appendix E for an overview of actions taken that limit who can be paid for prosthetics and custom-fabricated orthotics.

Despite the lack of regulations, most claims were allowed for prosthetics and custom-fabricated orthotics furnished and/or fabricated by practitioners and/or suppliers that were licensed, certified, or accredited

Approximately 97 percent of Medicare-allowed claims (246,081 claims) for prosthetics and custom-fabricated orthotics were for items furnished by practitioners and/or fabricated by practitioners or suppliers that were licensed, certified, or accredited per the BIPA definition of qualified practitioners or qualified suppliers. The payments for these claims amounted to \$260 million in 2010. See Appendix F for 95-percent confidence intervals and sample sizes for all estimates presented in this report.

³⁶ The limits established based on the other legal authorities do not fulfill the mandate to promulgate regulations to implement the BIPA payment requirements.

Medicare inappropriately allowed 12 percent of claims for prosthetics and custom-fabricated orthotics that did not meet Federal requirements for delivery documentation

For 12 percent of claims, amounting to \$13.6 million, suppliers failed to provide documentation meeting Federal requirements to show that prosthetics and custom-fabricated orthotics were delivered to beneficiaries. These claims were either missing all documentation of delivery, or lacked a beneficiary signature on the provided documentation. As Table 2 indicates, claims for custom-fabricated orthotics were more likely to lack delivery documentation.³⁷ Tables F-2 and F-3 in Appendix F show the statistical tests supporting this analysis.

Table 2: Inappropriately Allowed Claims and Payments Because of Lack of Delivery Documentation

Type of Claim	Percentage of Claims Inappropriately Allowed	Inappropriate Payments
Overall	11.6*	\$13,588,310
Prosthetics	4.0	\$4,771,226
Custom-Fabricated Orthotics	17.2	\$8,817,084

*The weighted average of the inappropriately allowed rates for prosthetics and custom-fabricated orthotics using the estimated proportion of population claims for each type of claim as weights.

Source: OIG analysis of Medicare-allowed claims for prosthetics and custom-fabricated orthotics, 2011.

Eight percent of claims had documentation of delivery that was insufficient because it lacked a beneficiary's or designee's signature. A beneficiary's or designee's signature acknowledges that the beneficiary or designee received the item. For 3 percent of claims, we received a response from the supplier, but the response did not include any documentation to support the delivery of the item. Table 3 provides estimates of the claims lacking beneficiary or designee signatures on delivery documents or lacking delivery documents altogether.

³⁷ The percentage of custom-fabricated orthotics claims lacking delivery documentation was statistically higher than the percentage of prosthetics claims lacking delivery documentation based on a Wald chi-square test of independence at the 95-percent confidence interval.

Table 3: Inappropriately Allowed Claims and Payments Because of Lack of Delivery Documentation by Type of Missing Documentation

Type of Missing Documentation	Percentage of Inappropriately Allowed Claims	Inappropriate Payments
Overall	11.6	\$13,588,310
Lacked Beneficiary's or Designee's Signature	8.3	\$9,354,658
Lacked Any Documentation To Support Delivery	3.3	\$4,233,652

Source: OIG analysis of Medicare-allowed claims for prosthetics and custom-fabricated orthotics, 2011.

“Other” practitioners and suppliers of custom-fabricated orthotics, such as physicians, physical and occupational therapists, and podiatrists, were most likely to lack delivery documentation

“Other” practitioners and suppliers (i.e., physicians, physical and occupational therapists, podiatrists, and orthopedic surgeons) of custom-fabricated orthotics were most likely to lack delivery documentation.³⁸ See Appendix D for a description of the specialty codes for all “other” practitioners and suppliers.

As Table 4 shows, 40 percent of the “other” practitioners and suppliers of custom-fabricated orthotics lacked delivery documentation, whereas less than 4 percent of the medical supply companies and individual practitioners lacked delivery documentation.³⁹ Tables F-2 and F-4 in Appendix F show the statistical tests supporting this analysis.

³⁸ Ten percent of “other” practitioners and suppliers who submitted claims for prosthetics lacked delivery documentation, whereas 1 percent of medical supply companies and 4 percent of individual prosthetists lacked delivery documents. However, these differences are not statistically significant and, therefore, “other” practitioners and suppliers of prosthetics were not more likely to lack delivery documentation than the medical supply companies or individual practitioners who submitted claims for prosthetics. See Table F-2 in Appendix F for these point estimates and their confidence intervals.

³⁹ The percentage of “other” practitioners and suppliers of custom-fabricated orthotics lacking delivery documentation was statistically higher than both the percentages of medical supply companies and individual practitioners of custom-fabricated orthotics lacking delivery documentation at the 95-percent confidence interval.

Table 4: Percentage of Practitioners and Suppliers of Custom-Fabricated Orthotics Lacking Delivery Documentation by Specialty

Specialty	Percentage of Providers Lacking Delivery Documentation	Claims in Sample
Overall	17.2*	507
Medical Supply Companies	3.2	139
Individual Orthotists	0.2	219
“Other” Practitioners and Suppliers	40.1	149

*The weighted average of the percentages for each specialty using the estimated proportion of population claims for each specialty as weights.

Source: OIG analysis of delivery documentation for custom-fabricated orthotics, 2011.

CONCLUSION AND RECOMMENDATIONS

Section 427(a) of the BIPA, enacted December 21, 2000, prohibits Medicare payment for prosthetics and custom-fabricated orthotics unless they are furnished by a qualified practitioner and fabricated by a qualified practitioner or a qualified supplier at a facility that meets criteria determined by the Secretary. Section 427(b) requires the Secretary to promulgate regulations to implement section 427(a) of BIPA not later than December 21, 2001, using a negotiated rulemaking process. To date, CMS has not promulgated regulations to implement this requirement. In lieu of implementing the BIPA payment requirements, CMS has used other legal authorities that limit who can be paid for prosthetics and custom-fabricated orthotics. For example, based on the supplier standards, CMS issued Transmittal 656, instructing its contractors to implement payment edits based on specialty codes in the 13 States that license prosthetists and orthotists. Notwithstanding, in 2010, Medicare allowed 966 claims, totaling \$776,154, for prosthetics and custom-fabricated orthotics from practitioners and suppliers in the 13 States that did not have a specialty code listed in Transmittal 656. Another method, based on the quality standards, mandates that all nonexempt DMEPOS suppliers attain accreditation.

Despite the lack of regulations, approximately 97 percent of Medicare-allowed claims for prosthetics and custom-fabricated orthotics were for items furnished by practitioners and/or fabricated by practitioners or suppliers that were licensed, certified, or accredited per the BIPA definition of qualified practitioners or qualified suppliers. Medicare inappropriately allowed an additional \$13.6 million for prosthetics and custom-fabricated orthotics that did not meet Federal requirements for delivery documentation. “Other” practitioners and suppliers of custom-fabricated orthotics, such as physicians, physical and occupational therapists, and podiatrists, were most likely to lack delivery documentation.

To ensure appropriate Medicare payments and beneficiary quality of care, we recommend that CMS:

Promulgate Regulations To Implement the BIPA Payment Requirements

Section 427(b) of the BIPA required regulations to implement the payment requirements found in Section 427(a) to be promulgated no later than December 21, 2001; however, CMS failed to do so. To comply with Federal law and clarify who may be paid for prosthetics and custom-

fabricated orthotics, CMS should promulgate regulations to implement the BIPA payment requirements.

Ensure That Suppliers Maintain Delivery Documentation That Meets Federal Requirements

CMS should ensure that suppliers are aware of their responsibility to maintain delivery documentation. CMS should consider aiming its education efforts at suppliers of custom-fabricated orthotics other than medical supply companies and individual practitioners because these “other” practitioners and suppliers (e.g., physicians, physical and occupational therapists, podiatrists, and orthopedic surgeons) are most likely to lack required delivery documentation. CMS could accomplish this by educating suppliers that they must meet certain standards, including maintaining delivery documentation.

Take Action To Address Inappropriately Allowed Claims Identified in the Population Related to Payment Edits and in Our Sample Related to Delivery Documentation

We will provide information regarding the claims inappropriately allowed in the population related to payment edits and in our sample related to delivery documentation to CMS in a separate memorandum.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In its comments, CMS concurred with all three recommendations. In response to the first recommendation, CMS stated that it is developing proposed regulations to implement the BIPA payment requirements. In response to the second recommendation, CMS stated that it will direct the NSC to disseminate educational material about maintaining delivery documentation on its Web site and through other media as appropriate. In response to the final recommendation, CMS indicated that it will investigate our finding of inappropriate payments for claims paid to suppliers that did not meet the specialty requirements, and it will determine the need to strengthen the existing claims processing edit, or establish a new edit, to ensure proper payment of claims. See Appendix G for the full text of CMS’s comments.

We did not make any changes to the report based on the CMS’s comments.

APPENDIX A

Table A-1: States That License Prosthetists and Orthotists

Does State License Prosthetists and Orthotists?	States	Number of States
Yes	Alabama, Arkansas, Florida, Georgia, Illinois, Mississippi, New Jersey, Ohio, Oklahoma, Rhode Island, Tennessee, Texas, Washington	13
No	Alaska, Arizona, California, Colorado, Connecticut, Delaware, District of Columbia, Hawaii, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Pennsylvania, South Carolina, South Dakota, Utah, Vermont, Virginia, West Virginia, Wisconsin, Wyoming	38
Total:		51

Source: Office of Inspector General analysis of States' licensing of prosthetists and orthotists, 2011.

APPENDIX B

Specialty Codes Listed in Transmittal 656

Transmittal 656 updated the *Medicare Claims Processing Manual* to require that, in those States that license prosthetists and orthotists, only claims for prosthetics and custom-fabricated orthotics from suppliers with the following specialty codes be paid:⁴⁰

- Medical supply company with orthotics personnel—specialty code 51;
- Medical supply company with prosthetics personnel—specialty code 52;
- Medical supply company with prosthetics and orthotics personnel—specialty code 53;
- Orthotics personnel—specialty code 55;
- Prosthetics personnel—specialty code 56;
- Prosthetics personnel, orthotics personnel, and pedorthists (i.e., practitioners who design and fabricate therapeutic shoes)—specialty code 57;
- Physical therapist—specialty code 65;
- Occupational therapist—specialty code 67; and
- Any Medicare physician specialty code, as listed in § 10.8.2 of chapter 26 of the *Medicare Claims Processing Manual*.⁴¹

⁴⁰ Centers for Medicare & Medicaid Services, *Medicare Claims Processing Manual* (Internet-only manual), Pub. No. 100-04, ch. 20, § 130.1.

⁴¹ In addition, Transmittal 656 contains a list of Healthcare Common Procedure Coding System codes for prosthetics and custom-fabricated orthotics that are subject to the payment edits defined in the transmittal.

APPENDIX C

Table C-1: Detailed Sampling Design and Response Rates

Stratum	Provider Type	Dollar Amount	Total Claims in Population	Average Payment per Population Claim	Claims in Sample	Number of Nonresponding Sample Claims*	Response Rate (Percentage)
1	Medical Supply Companies	\$1–\$960	21,299	\$570	80	4 (4)	95.0
2	Medical Supply Companies	Over \$960	8,364	\$1,530	65	2 (0)	96.9
3	Individual Practitioners	\$1–\$930	42,829	\$557	110	0 (0)	100.0
4	Individual Practitioners	Over \$930	14,743	\$1,510	110	1 (1)	99.1
5	Other Practitioners	\$1–\$740	52,321	\$338	95	3 (1)	96.8
6	Other Practitioners	Over \$740	9,756	\$1,265	60	3 (1)	95.0
Total orthotics			149,312	\$677	520	13 (7)	97.5
7	Medical Supply Companies	\$1–\$1,400	14,866	\$454	45	3 (1)	93.3
8	Medical Supply Companies	Over \$1,400	13,599	\$2,857	120	0 (0)	100.0
9	Individual Practitioners	\$1–\$1,360	34,592	\$445	50	0 (0)	100.0
10	Individual Practitioners	\$1,361–\$4,250	33,120	\$2,681	235	2 (0)	99.1
11	Individual Practitioners	Over \$4,250	2,285	\$6,257	50	0 (0)	100.0
12	Other Practitioners	All	10,023	\$1,128	115	1 (0)	99.1
Total prosthetics			108,485	\$1,617	615	6 (1)	99.3
Total overall			257,797	\$1,072	1,135	19 (8)	98.3

* The first value is the number of claims for which practitioners and suppliers did not respond. The number in parentheses indicates how many of the nonresponding claims were from practitioners and suppliers that did not receive requests because they were associated with ongoing Office of Inspector General (OIG) investigations.

Source: OIG analysis of Medicare-allowed claims for prosthetics and custom-fabricated orthotics, 2011.

APPENDIX D

Specialty Codes for All “Other” Practitioners and Suppliers

We selected a stratified random sample totaling 1,135 claims. The sample had 12 strata based on specialty code and allowed dollar amounts. We defined the following groups of specialty codes for use in stratification: medical supply companies (specialty codes 51–53), individual practitioners of prosthetics and orthotics (specialty codes 55–57), and all “other” practitioners and suppliers. The specialty codes of the “other” practitioners and suppliers that were in our sample appear below.

01—General practitioner

02—General surgery

08—Family practice

20—Orthopedic surgery

35—Chiropractic

40—Hand surgery

41—Optometry

48—Podiatry

54—Medical supply company not included in specialty codes 51–53

65—Physical therapist

67—Occupational therapist

70—Single or multispecialty clinic or group practice

77—Vascular surgery

87—All other suppliers (e.g., drugstores)

99—Unknown physician specialty

A0—Hospital

A5—Pharmacy

A6—Medical supply company with respiratory therapist

B2—Podiatric personnel

APPENDIX E

Table E-1: Actions Taken That Limit Who Can Be Paid for Prosthetics and Custom-Fabricated Orthotics

Date	Legal Basis			Additional Information
	Statutory Payment Prohibition SSA* § 1834(h)(1)(F)	Supplier Standard 42 CFR § 424.57(c)(1)	Quality Standards SSA § 1834(a)(20)	
December 21, 2000	<p>Medicare, Medicaid, and SCHIP** Benefits Improvement and Protection Act of 2000 (BIPA) enacted:</p> <p>(1) adding payment prohibition at 1834(h)(1)(F), and</p> <p>(2) mandating issuance of regulations within 1 year using negotiated rulemaking process</p>			<p>(1) Section 427(a) of BIPA added subsection (F) to SSA § 1834(h)(1), the payment prohibition for prosthetics and certain custom-fabricated orthotics.</p> <p>(2) Section 427(b) of BIPA provided that “[n]ot later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall promulgate revised regulations to carry out the amendment made by subsection (a) using a negotiated rulemaking process under subchapter III of chapter 5 of title 5, United States Code.” However, to date, the Centers for Medicare & Medicaid Services (CMS) has not promulgated regulations to implement this provision.</p>
October 1, 2002	<p>First scheduled negotiated rulemaking committee meeting</p>			<p>CMS established the Negotiated Rulemaking Committee on Special Payment Provisions and Requirements for Prosthetics and Certain Custom-Fabricated Orthotics. 67 Fed. Reg. 48839 (July 26, 2002). According to that notice, the first meeting for the negotiated rulemaking committee was scheduled for October 1–3, 2002.</p> <p>In an earlier notice of intent to establish the negotiated rulemaking committee at 67 Fed. Reg. 13297, 13300 (Mar. 22, 2002), CMS stated that “[i]f the committee is unable to reach consensus, we will proceed to develop a proposed rule.”</p>
July 14, 2003	<p>Final scheduled negotiated rulemaking committee meeting</p>			<p>In 68 Fed. Reg. 38269 (June 27, 2003), CMS scheduled the final negotiated rulemaking committee meeting for July 14, 2003, and stated that the “Committee does not anticipate the need for additional meetings.”</p>

*Social Security Act.

**State Children’s Health Insurance Program.

Table E-1: Actions Taken That Limit Who Can Be Paid for Prosthetics and Custom-Fabricated Orthotics (continued)

Date	Legal Basis			Additional Information
	Statutory Payment Prohibition SSA § 1834(h)(1)(F)	Supplier Standard 42 CFR § 424.57(c)(1)	Quality Standards SSA § 1834(a)(20)	
December 8, 2003			Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) enacted, adding supplier quality standards at SSA § 1834(a)(20).	Section 302(a) of MMA added SSA § 1834(a)(20), requiring the Secretary of Health and Human Services (the Secretary) to establish and implement quality standards for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) suppliers to be applied by independent accreditation organizations. It also requires suppliers to comply with the quality standards to furnish items set forth in 1834(a)(20)(D), including prosthetic devices, orthotics, and prosthetics, and to receive or retain their provider or supplier numbers. SSA § 1834(a)(20)(E) permits the Secretary to establish the quality standards "by program instruction or otherwise" and requires the standards to be "published on the Internet website of the Centers for Medicare & Medicaid Services."
October 22, 2004	CMS issued Transmittal 329, Change Request 3373, entitled "DMERC* Only - Payment to Providers/Suppliers Qualified to Bill Medicare for Prosthetics and Certain Custom-Fabricated Orthotics." The effective date was July 1, 2005, but the transmittal was rescinded before that date.			
November 23, 2004	CMS rescinded Transmittal 329, Change Request 3373.			
December 13, 2004	In its semiannual regulatory agenda, CMS stated that it was considering issuance of a proposed rule implementing the payment prohibition at § 427 of BIPA by July 2005.			CMS included a Notice of Proposed Rule Making to implement 427 of BIPA in its semiannual regulatory agenda at 69 Fed. Reg. 73119, 74268 (Dec. 13, 2004), with a timetable date of July 2005. That date was postponed in other Federal Register documents (see e.g., 70 Fed. Reg. 26817, 26871 (May 16, 2005) (postponing date to November 2005)).

*Durable Medical Equipment Regional Carrier (DMERC).

Table E-1: Actions Taken That Limit Who Can Be Paid for Prosthetics and Custom-Fabricated Orthotics (continued)

Date	Legal Basis			Additional Information
	Statutory Payment Prohibition SSA § 1834(h)(1)(F)	Supplier Standard 42 CFR § 424.57(c)(1)	Quality Standards SSA § 1834(a)(20)	
August 19, 2005		CMS issued Transmittal 656, Change Request 3959, entitled "Full Replacement of Change Request 3607, Payment Edits in Applicable States for DMEPOS Suppliers of Prosthetics and Certain Custom-Fabricated Orthotics, Change Request 3607 is rescinded (DMERC only)."		Acknowledging the "absence of national Medicare payment policy regarding who may bill and be paid for prosthetics and certain custom-fabricated orthotics," Transmittal 656 directed Durable Medical Equipment Medicare Administrative Contractors (DMEMACs) to implement payment edits in States that license/certify orthotists or prosthetists, effective October 1, 2005. This transmittal was based on the supplier standard at 42 CFR 424.57(c)(1), requiring suppliers to comply with all applicable Federal and State licensure and regulatory requirements. Transmittal 656 also revised Chapter 20, section 130.1 of the <i>Medicare Claims Processing Manual</i> , Pub. No. 100-04, to address this payment edit.
October 31, 2005	In its semiannual regulatory agenda, CMS indicated that the proposed rule that would have implemented section 427 of BIPA was "[w]ithdrawn" on June 28, 2005.			See 70 Fed. Reg. 64553, 64623 (Oct. 31, 2005).
May 25, 2007			CMS announced that it had deemed 10 national accreditation organizations for DMEPOS.	See 72 Fed. Reg. 29326 (May 25, 2007).
February 1, 2008			CMS issued Transmittal 236, Change Request 5892, entitled "Update to Chapter 10."	Transmittal 236 added a new § 21.1 (entitled "DMEPOS Supplier Accreditation") to Chapter 10 of the <i>Medicare Program Integrity Manual</i> , Pub. No. 100-08, providing that: (1) on or after March 1, 2008, new DMEPOS suppliers must be accredited before submitting an application to the National Supplier Clearinghouse (NSC); (2) DMEPOS suppliers that enrolled for the first time with NSC between January 1 and February 28, 2008, must obtain and submit evidence of accreditation to NSC by January 1, 2009; (3) DMEPOS suppliers that enrolled in Medicare prior to January 1, 2008, must provide evidence of accreditation to NSC by September 30, 2009; and (4) NSC shall revoke a supplier's billing privileges if the supplier fails to obtain and submit required evidence of accreditation.

Table E-1: Actions Taken That Limit Who Can Be Paid for Prosthetics and Custom-Fabricated Orthotics (continued)

Date	Legal Basis			Additional Information
	Statutory Payment Prohibition SSA § 1834(h)(1)(F)	Supplier Standard 42 CFR § 424.57(c)(1)	Quality Standards SSA § 1834(a)(20)	
July 15, 2008			<p>Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) enacted, adding SSA § 1834(a)(20)(F), requiring suppliers to provide evidence of accreditation by October 1, 2009.</p>	<p>Section 154(b) of MIPPA added subparagraph (F) to SSA 1834(a)(20):</p> <p>(1) requiring suppliers furnishing items and services on or after October 1, 2009, directly or as a subcontractor for another entity, to have submitted evidence of accreditation;</p> <p>(2) stating that eligible professionals (as defined at SSA 1848(k)(3)(B)) and other persons specified by the Secretary are exempt from the accreditation deadline, unless the Secretary determines that the quality standards are specifically designed to apply to such professionals and persons; and</p> <p>(3) allowing the Secretary to exempt such professionals and other persons specified by the Secretary from the accreditation deadline if the Secretary determines that licensing, accreditation, or other mandatory quality requirements apply to such professionals and persons.</p>
October 2008			<p>CMS issued final guidance entitled "Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Quality Standards"</p>	<p>This final guidance (the "DMEPOS Quality Standards") is at http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Downloads/DMEPOSAccreditationStandardsCMB.pdf</p> <p>Appendix C of the DMEPOS Quality Standards is entitled "Custom Fabricated and Custom Fitted Orthoses, Prosthetic Devices, External Breast Prostheses, Therapeutic Shoes and Inserts, and their Accessories and Supplies; Custom-Made Somatic, Ocular and Facial Prostheses."</p>
May 4, 2010			<p>CMS issued a document entitled "Medicare New Deemed Accreditation Organizations For Suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)."</p>	<p>This document lists the 10 accreditation organizations and refers to the DMEPOS Quality Standards document.</p> <p>This document is at: http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Downloads/DeemedAccreditationOrganizationsCMB.pdf</p>

Table E-1: Actions Taken That Limit Who Can Be Paid for Prosthetics and Custom-Fabricated Orthotics (continued)

Date	Legal Basis			Additional Information
	Statutory Payment Prohibition SSA § 1834(h)(1)(F)	Supplier Standard 42 CFR § 424.57(c)(1)	Quality Standards SSA § 1834(a)(20)	
May 21, 2010			CMS issued Transmittal 710, Change Request 6566, entitled "Guidance on Implementing System Edits for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)"	<p>Transmittal 710 identified the following as being exempt from the September 30, 2009, accreditation deadline:</p> <p>(1) eligible professionals (as defined at SSA 1848(k)(3)(B)), including, but not limited to, physicians, physical therapists, and occupational therapists; and</p> <p>(2) specified "other persons," including, but not limited to, orthotists and prosthetists. (See Attachment A of Transmittal 710.)</p> <p>If a supplier is not exempt from accreditation, Transmittal 710 directs DMEMACs to deny a supplier's claim for Healthcare Common Procedures Coding System (HCPCS) codes in Attachment C if the supplier has not been identified by NSC as being accredited to supply the specific product/service. This requirement applies to claims with dates of service on or after July 6, 2010.</p> <p>Transmittal 710 states that edits for accreditation will begin by "phasing in a limited number of product categories and HCPCS codes, as listed in Attachment C...." Attachment C does not include orthotics or prosthetics.</p>

Source: Office of Inspector General analysis of actions taken that limit who can be paid for prosthetics and custom-fabricated orthotics, 2012.

APPENDIX F

Table F-1: Point Estimates, Sample Sizes, and Confidence Intervals

Estimate Description	Sample Size	Point Estimate	95-Percent Confidence Interval
Estimates Related to Practitioner and Supplier Qualifications			
Percentage of claims that were furnished and fabricated by qualified providers as defined in the Medicare, Medicaid, and SCHIP* Benefits Improvement and Protection Act of 2000 (BIPA) in 2010	1,116	97.3	96.2–98.1
Total claims for items furnished by practitioners and/or fabricated by practitioners or suppliers that were licensed, certified, or accredited per the BIPA definition of qualified practitioners or qualified suppliers in 2010	1,116	246,081	242,668.5–249,494.2
Payments for claims for items furnished by practitioners and/or fabricated by practitioners or suppliers that were licensed, certified, or accredited per the BIPA definition of qualified practitioners or qualified suppliers in 2010	1,116	\$259,998,432.51	\$253,578,219.90–\$266,418,645.12
Estimates Related to Delivery Documentation			
Payments for claims that did not meet Federal requirements for delivery documentation	1,116	\$13,588,310	\$10,162,404–\$17,014,217
Percentage of claims that did not meet Federal requirements for delivery documentation	1,116	11.6	9.5–14.2
Percentage of prosthetics claims that did not meet Federal requirements for delivery documentation	609	4.0	2.2–7.1
Payments for prosthetics claims that did not meet Federal requirements for delivery documentation	609	\$4,771,226	\$2,388,422–\$7,154,030
Percentage of custom-fabricated orthotics claims that did not meet Federal requirements for delivery documentation	507	17.2	13.9–21.2
Payments for custom-fabricated orthotics claims that did not meet Federal requirements for delivery documentation	507	\$8,817,084	\$6,355,564–\$11,278,605
Percentage of claims that lacked beneficiary signatures on delivery documentation	1,116	8.3	6.4–10.8
Percentage of claims that lacked any documentation to support delivery	1,116	3.3	2.1–5.1
Payments for claims that lacked beneficiary signatures on delivery documentation	1,116	\$9,354,658	\$6,487,930–12,221,386
Payments for claims that lacked any documentation to support delivery	1,116	\$4,233,652	\$2,190,121–\$6,277,183

Source: Office of Inspector General (OIG) analysis of Medicare-allowed claims for prosthetics and custom-fabricated orthotics, 2011.

*State Children's Health Insurance Program, now referred to as CHIP.

Table F-2: Point Estimates and Confidence Intervals Related to Delivery Documentation by Supplier Specialty

Estimate Description	Sample Size	Point Estimate	95-Percent Confidence Interval
Percentage of claims from “other” practitioners and suppliers of custom-fabricated orthotics lacking delivery documentation	149	40.1	31.8–49.1
Percentage of claims from medical supply companies providing custom-fabricated orthotics lacking delivery documentation	139	3.2	1.3–8.0
Percentage of claims from individual practitioners providing custom-fabricated orthotics lacking delivery documentation	219	0.2	0.03–1.6
Percentage of claims from “other” practitioners and suppliers of prosthetics lacking delivery documentation	114	10.5	6.1–17.6
Percentage of claims from medical supply companies providing prosthetics lacking delivery documentation	162	1.2	0.4–3.7
Percentage of claims from individual practitioners providing prosthetics lacking delivery documentation	333	4.1	1.8–9.3

Source: OIG analysis of Medicare-allowed claims for prosthetics and custom-fabricated orthotics, 2012.

Table F-3: Chi Square Analysis on Delivery Documentation and Claim Type

Claim Type Compared (Group A vs. Group B)	Group A Rate	Group B Rate	Wald Chi-Square Test Statistic	F-Test Degrees of Freedom	P-Value
Prosthetics vs. Custom-Fabricated Orthotics	4.0	17.2	36.1	numerator = 1 denominator = 1104	<0.0001

Source: OIG analysis of Medicare claims data and supplier documentation, 2012.

Table F-4: Chi Square Analysis on Delivery Documentation and Practitioner and Supplier Specialty

Practitioner and Supplier Specialties Compared (Group A vs. Group B)	Group A Rate	Group B Rate	Wald Chi-Square Test Statistic	F-Test Degrees of Freedom	Bonferroni Threshold*	Unadjusted P-Value
Medical Supply Companies vs. “Other” Practitioners and Suppliers	3.2	40.1	61.1	numerator = 1 denominator = 284	0.01667	<0.0001
Individual Practitioners vs. “Other” Practitioners and Suppliers	0.2	40.1	79.6	Numerator = 1 Denominator = 364	0.01667	<0.0001

*We did not plan on statistically testing whether “other” practitioners and suppliers were more likely to lack required delivery documentation than medical supply companies and individual practitioners, but we saw this through exploratory data analysis. Consequently, we included a Bonferroni correction to account for this in the two comparisons above to keep our confidence level for these comparison tests at 95 percent. For the percentages for the groups compared to be considered statistically different at the 95-percent confidence level, the unadjusted p-values need to be less than the Bonferroni Threshold of $0.05/3 = 0.01667$.

Source: OIG analysis of Medicare claims data and supplier documentation, 2012.

APPENDIX G

Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: AUG 27 2012

TO: Daniel R. Levinson
Inspector General

FROM: Marilyn Tavenner
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "CMS Has Not Promulgated Regulations to Establish Payment Requirements for Prosthetics and Custom-Fabricated Orthotics" (OEI-07-10-00410)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the OIG draft report entitled, "CMS Has Not Promulgated Regulations to Establish Payment Requirements for Prosthetics and Custom-Fabricated Orthotics." Section 427(a) of the Medicare, Medicaid, and State Children Health Insurance Program Benefits Improvement and Protection Act of 2000 (BIPA) prohibits Medicare payments for prosthetics and custom-fabricated orthotics unless the items are (1) furnished by a qualified practitioner, and (2) fabricated by either a qualified practitioner or a qualified supplier at a facility that meets such criteria as the Secretary determines appropriate. These qualifications are intended to protect beneficiaries, promote high quality care, and safeguard Medicare funds by ensuring that only qualified individuals and health care organizations furnish Medicare items and services.

The CMS takes seriously its responsibility to protect the Medicare Trust Funds and ensure that payments made to providers and suppliers for covered health care services are appropriate and consistent with Medicare policy. CMS is in the process of developing proposed regulations to implement the BIPA provisions.

As detailed in OIG's report, CMS has taken action by issuing Transmittal 656 (Change Request 3959, issued on August 19, 2005). Transmittal 656 directs the Medicare contractors to establish a claims processing edit to ensure that proper editing of that Medicare claim will occur in those states where prosthetics or orthotics must be provided by a licensed or certified orthotist or prosthetist. Even without regulations in place, the report found that 97 percent of Medicare-allowed claims for prosthetics and custom-fabricated orthotics were for items furnished by licensed, certified, or accredited providers and suppliers.

We appreciate OIG's efforts in working with CMS to help ensure that prosthetics and custom-fabricated orthotics do not continue to be vulnerable to abuse. Our responses to the OIG recommendations follow.

Agency Comments (continued)

Page 2 – Daniel R. Levinson

OIG Recommendation

The CMS should promulgate regulations to implement the BIPA payment requirements.

CMS Response

The CMS concurs with this recommendation and proposed regulations are under development to implement the BIPA provisions.

OIG Recommendation

The CMS should ensure that suppliers maintain delivery documentation that meets federal requirements.

CMS Response

The CMS concurs with this recommendation. The National Supplier Clearinghouse (NSC) processes all enrollment related action for suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) that are enrolled in Medicare. The NSC is charged with the responsibility of performing site inspections of durable medical equipment suppliers and ensuring suppliers comply with the supplier standards found at 42 CFR 424.57. As part of the site visit process and as stipulated in its statement of work, the NSC reviews a small, random sample of beneficiary records to ensure suppliers maintain adequate delivery documentation in accordance with 42 CFR 424.57(c)(12). Furthermore, DMEPOS suppliers must also comply with provisions found at 42 CFR 424.516(f) that require them to maintain documentation related to the ordering of DMEPOS products/services for a period of 7 years from the date of service. Failure to adhere to both reporting requirements may result in the revocation of the DMEPOS supplier billing number.

To ensure all DMEPOS suppliers are once again reminded of these documentation and reporting requirements, CMS will direct the NSC to disseminate educational material on this topic on its website and through other messaging media as deemed appropriate.

OIG Recommendation

The CMS should take appropriate action to address inappropriately allowed claims identified in the population related to payment edits and in the sample related to delivery documentation.

CMS Response

The CMS concurs with this recommendation. CMS will investigate OIG's finding of inappropriate payments for claims paid to suppliers in 2010 that did not meet the specialty requirements to furnish these items, and will determine the need to strengthen the existing claims processing edit, or establish a new edit, to ensure proper payment for these claims.

The CMS takes seriously its responsibility to protect the Medicare Trust Funds and ensure that payments made to providers and suppliers for covered health care services are appropriate and

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consistent with Medicare policy. Upon receipt, CMS will review the detailed information supplied by OIG to focus on any necessary processes that would ensure that payment for these services is appropriate and determine the appropriate actions to take.

Again, we appreciate the opportunity to comment on this draft report and look forward to working with OIG on this and other issues.

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