THE ORTHOTIC AND
PROSTHETIC ALLIANCE

1501 M Street, NW, 7th Floor
Washington, DC 20005
Phone: 202-466-6550
Fax: 202-785-1756
Email: opalliance@gmail.com

September 6, 2011

Daniel R. Levinson, Inspector General
U.S. Department of Health & Human Services
Office of Inspector General
Cohen Building
330 Independence Ave., S.W.
Washington, D.C. 20201

RE: **Office of Inspector General Report "Questionable Billing by Suppliers of Lower Limb Prostheses" (OEI-02-10-00170)**

Dear Mr. Levinson:

On behalf of the Orthotic & Prosthetic Alliance (the Alliance), a coalition of the four major national orthotic and prosthetic organizations representing over 10,000 O&P professionals and 3,000 accredited O&P facilities, we are writing to express our concerns over the findings contained in the OIG's recently published report "Questionable Billing by Suppliers of Lower Limb Prostheses."

We would like to preface our comments by clarifying that the O&P Alliance and its member organizations support and applaud recent legislative and regulatory efforts that seek to reduce fraud, waste and abuse, particularly those that restrict the right to bill the Medicare program for orthotic and prosthetic (O&P) services to only those practitioners and suppliers who are qualified to provide them.

The Benefits Improvement and Protection Act of 2000, Section 427 ("BIPA 427"), establishes guidelines that restrict Medicare reimbursement for certain orthotic and prosthetic (O&P) services to specific healthcare professionals. Of overriding significance in BIPA 427 is the requirement that a "qualified practitioner" must provide the designated O&P services in order for them to be considered for reimbursement by Medicare.

BIPA 427 recognizes more than one category of individuals who are considered "qualified" to provide O&P services, including:

- Physicians
- Qualified Physical Therapists
- Qualified Occupational Therapists
- Individuals licensed by their State to provide O&P services

- Individuals credentialed by one of the two major O&P accrediting bodies[1], ABC or BOC, and who are specifically trained and educated to provide customized O&P services.

Section 302 of the Medicare Modernization Act of 2003 (MMA) added a new paragraph 1834(a)(20) to the Social Security Act; this paragraph requires the establishment and implementation of quality standards for suppliers of durable medical equipment, prosthetics, orthotics and supplies ("DMEPOS"). Under MMA Section 302, all suppliers that furnish DME; medical supplies; home dialysis supplies and equipment; therapeutic shoes; parenteral and enteral nutrition and equipment; transfusion medications; and prosthetic and orthotic devices must comply with quality standards in order to bill and receive Medicare Part B payments. There are general quality standards that apply to the broad range of DMEPOS suppliers, as well as additional standards that apply to specific supplier types. Orthotic and prosthetic suppliers are among those to whom additional supplier-specific quality standards apply, contained in Appendix C of the DMEPOS quality standards.

Section 154(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) added a new subparagraph (F) to Section 1834(a)(20) of the Social Security Act that requires suppliers to become accredited by a designated accreditation organization no later than September 30, 2009, unless an exemption applies. Further, this legislation allowed for the Secretary of the Department of Health and Human Services (DHHS) to extend an exemption to additional supplier types that were not specifically named. Based on the decision of the Secretary, the following suppliers, when providing services that fall within their scope of practice, are exempt from DMEPOS accreditation:

- Orthotists
- Prosthetists
- Opticians
- Audiologists

Finally, on August 19, 2005, CMS issued Transmittal 656 (CR 3959). This Transmittal was reissued in early 2010 when CMS released Change Request 6566 (CR6566) that established claim level edits that will automatically deny claims for certain DMEPOS codes unless:

1. The supplier has been identified as accredited for the timeframe that covers the date of service on the claim; or
2. The supplier is currently exempt from meeting accreditation requirements.

Finally, CMS codified these change requests in regulation on August 27, 2010, effective one month later, by requiring DMEPOS suppliers subject to state licensure requirements to be licensed to provide the item or service at issue. 75 Fed. Reg. 52,629, [pin cite] (August 27, 2010). To date, we believe that CMS has failed to fully implement these change requests and regulations through Medicare claim edits applied to the HCPCS codes used to describe O&P services.

In spite of the legislation and regulations outlined above, it is our understanding that efforts to enforce the qualified practitioner, quality standards, and accreditation rules have thus far been limited to screening for licensure and certification at the time of enrollment for Medicare billing privileges, and during periodic revalidations of the information and documentation the supplier provided at initial

[1] American Board for Certification in Orthotics, Prosthetics, and Pedorthics; Board for Certification/Accreditation, International.

enrollment. Additionally, each deemed accreditation organization provides regular reports to CMS showing the supplier locations it accredits, and for which product and service categories.

However, at the claims processing level, there appear to be few, if any, edits in place to ensure that the supplier billing for O&P services does, in fact, meet the qualifications to provide them. It appears that the claims processing system does not edit to ensure that the supplier billing for an O&P service is appropriately licensed (if licensure exists in the supplier's State), certified, accredited or otherwise qualified to provide the service. While O&P suppliers must meet all of the supplier and enrollment requirements to enroll in the Medicare program properly, there is apparently no screening mechanism in place in the payment processing of O&P claims to ensure that the supplier is considered qualified to bill the codes that describe the items provided to the beneficiary.

It appears that O&P claims are allowed to pass through the Medicare billing system, regardless of the type of supplier submitting the claim, and be paid. For example, once enrolled as a DMEPOS supplier, an oxygen supplier could arguably bill for a lower limb prostheses, even though it lacks the licensed/certified and qualified staff to provide prosthetic services, and does not hold the proper accreditation to provide prosthetic services. As a result of this lack of claim edits, once a supplier has been granted Medicare DMEPOS billing privileges, it is largely free to submit claims for any type of DMEPOS service, including many of those for which it is not licensed or certified, or does not meet the definition of "qualified."

We believe that a failure to segregate claims by the qualifications of the supplier has contributed to the OIG's negative findings in its report, and caused the OIG to unfairly characterize the billing practices of legitimate and qualified providers of O&P services as "questionable." We would further suggest that this study highlights the flaws in the current system in that the supplier enrollment process does not ensure that claims are being submitted by qualified suppliers. This could be easily accomplished by simply enforcing existing law and having CMS create a claim edit based on the appropriateness of the qualifications of the supplier to the type of service billed.

Had claim edits already been in place to deny O&P claims from suppliers who did not meet the requirements of BIPA 427, the MMA or MIPAA, we could reasonably have assumed that the claim sample utilized in the study was representative of the universe of claims from legitimate, qualified providers of O&P services. In the absence of these claim edits, we believe the sample could be effectively tainted and not representative of claims submitted solely by qualified O&P suppliers. We would further argue that many of the claims the OIG reviewed that were determined to be "questionable" were likely submitted by unqualified suppliers who are not adequately familiar with O&P coding, functional level assessments, or local coverage determination requirements**.**

Before using the results of a study where the data studied is potentially flawed in order to "crack down" on the billing practices of legitimate O&P professionals, we encourage OIG to revisit the claims sampling in order to ascertain precisely from whom the "questionable" claims were received, and to what extent these questionable claims were submitted by unqualified suppliers.

We were also troubled by the attention that OIG paid to the issue of claims for bilateral lower limb prostheses provided on the same date of service being submitted on separate claims. By definition, a bilateral amputee may receive two separate prosthetic devices and each is, in fact, a separate service. It is well within regulation and appropriate claims submission policy to submit two separate claims on the same date of service for bilateral amputees. If claims were edited for appropriate modifier usage,

claims that did not contain the appropriate side modifiers (e.g., "LT" for the left side of the body, and "RT" for the right side) should be rejected and should not have been included in the sample.

In addition, if these modifiers were missing from the claim, any services that appeared to be duplicates should have been rejected at the DME MAC contractor level. However, two separate claims appropriately labeled RT and LT are absolutely permissible for the same date of service under Medicare coverage and payment policy. Further, claims for prosthetic devices contain multiple codes and line items that describe the various componentry used for lower limb prostheses. Occasionally, the exact same set of procedures and components are medically appropriate for both limbs of a bilateral amputee and each device's base and addition codes are treated as separate claims with the appropriate RT and/or LT modifier.

The issue of claims for bilateral lower limb prostheses provided on the same date of service being submitted on separate claims may have been misunderstood as an attempt at "claim splitting." The CMS Medicare Claims Processing Manual, Chapter 1, Section 70.8.1, provides instructions to Medicare administrative contractors on instances where it is appropriate to split claims. In this regard, the dividing of bilateral prostheses provided on the same day and billed on two claims does not appear to be a prohibited practice. In the delivery of prosthetic care, a claim describes a complete device designated by a base code as the first line item and addition codes on subsequent line items to fully describe the service. It is not uncommon for claims that exceed a given number of lines to be continued on a second or third claim form, or electronic claim record.

The fact that bilateral lower limb prostheses are billed on separate claims—or on more than one claim form—does not, by itself, point to questionable or fraudulent billing practices.

The OIG's report includes a recommendation "…to implement requirements for a face-to-face [physician] encounter to establish the beneficiary's need for prostheses" and adds that CMS has concurred with that recommendation. CMS' contractors, the DME MACs have already published a "Dear Physician" letter stipulating the importance of physician records—and factors that those records need to include—in order to support the physician's prescription of a prosthesis. In fact, an August 2011 letter from Noridian Administrative Services, LLC, to Medicare physicians states: "It is the treating physician's records, not the prosthetist's, which are used to justify payment."

The O&P Alliance believes that justifying payment to the prosthetist based on the quality and content of the prescribing physician's medical records alone is not reasonable. The qualified prosthetist, working with the physician and the patient, is the health care professional with the greatest specialized education, training, and experience to recommend appropriate prosthetic prescription. CMS/OIG will do the prosthetic patient a grave disservice if it simply denies coverage and payment of prosthetic care needed to restore mobility based on inadequate physician documentation alone.

The OIG concludes that the lack of a physician office visit to accompany a beneficiary's physician order for a prosthesis is indicative of potential abuse of the Medicare program. However, this is an oversimplification of the process of appropriate prosthetic care. For example, if the referring physician were the surgeon who performed the amputation, follow-up care from that physician may be the exception, not the rule. We believe this issue is complex enough to require further study, fact-finding, and consultation with patients, physicians and prosthetists before the validity of any conclusion can be evaluated.

We hope to have the occasion to meet with key representatives from CMS, OIG and other stakeholders for a fuller explanation of the appropriate course of prosthetic patient care and the role of the physician and prosthetist in that course of treatment.

Finally, the O&P Alliance views the implementation of payment edits at the claim level to deny unqualified suppliers the right to bill Medicare as the single, most important step the federal government could take to reduce fraud and abuse in the prosthetic and orthotic benefit category. The Alliance, and its individual member organizations, has presented this same argument since the year 2000 to all levels at CMS and the Department of HHS, including key officials with responsibility over the program in the current Administration. Within the last 18 months, we have presented data and facts regarding the danger inherent in the apparent lack of claim edits to deny unqualified suppliers payment for prosthetic services. Throughout this time our message has been clear:

i. ***Implement and enforce Section 427 of the Beneficiary Improvements and Protection Act of 2000 (BIPA);***

ii. ***Comply with state O&P licensure laws and only pay providers and suppliers who are appropriately licensed in the 13 states that have such laws, consistent with CMS Transmittal 656, CR6566, and 75 Fed. Reg. 52,629 [pin cite] (August 27, 2010;***

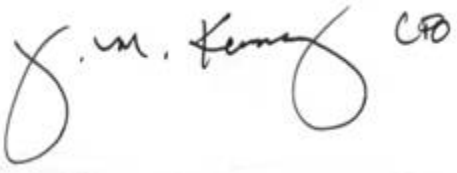
iii. ***Link the right to receive payment from Medicare with the qualifications of the provider and the complexity of the O&P care being provided; and,***

iv. ***Embrace H.R. 1958, the Medicare Orthotics and Prosthetics Improvement Act of 2011, introduced by Congresswoman Berkley, as a mechanism for expeditiously implementing all of these recommendations and protecting against fraud and abuse in the prosthetic and orthotic benefit category.***

We appreciate your time and the opportunity to make comments on this important report. If you have any questions or would like to discuss our concerns and observations, please contact our Washington counsel, Peter Thomas, as 202-466-6550.

Sincerely,

Paul E. Prusakowski, CPO, FAAOP
President
National Association for the
Advancement of Orthotics and Prosthetics



John M. Kenney, CPO, FAAOP
President
American Board for Certification in
Orthotics, Prosthetics and Pedorthics, Inc.

Mark Muller, MS, CPO, FAAOP
President
American Academy of Orthotists and Prosthetists

Tom DiBello, CO, FAAOP
President
American Orthotic & Prosthetic Association

Cc: DHHS Secretary Kathleen Sebelius
Jonathan Blum, Deputy Administrator and Director, Center for Medicare at CMS
Laurence Wilson, Director, Chronic Care Policy Group, CMS
Peter Budetti, Deputy Administrator/Director, CMS Center for Program Integrity
John Spiegel, Director of the Medicare Program Integrity Group at CMS