Dr. Thomas F. Kirk, Ph.D.
President, American Orthotic & Prosthetic Association

and

Mr. Thomas F. Fise, J.D.
Executive Director, American Orthotic & Prosthetic Association
330 John Carlyle Street
Alexandria, VA 22314

Dear Sirs:

Thank you for your letter to the Office of Inspector General (OIG), dated January 8, 2013, outlining the American Orthotic & Prosthetic Association’s (AOPA) concerns about our December 2012 report entitled *Medicare Supplier Acquisition Costs for L0631 Back Orthoses*, OEI-03-11-00600. We address your concerns related to our report and have organized our comments by topic area.

**Rationale**
The rationale for conducting this study was not based solely on the doubling of allowed amounts for L0631 orthoses between 2008 and 2011. As we state in the report, Medicare paid more in 2011 for L0631 than for the other 12 lower-back orthoses codes combined. Medicare allowed $96 million for L0631 alone—58 percent of the $166 million paid for all lower-back orthoses. OIG acknowledges that the number of Medicare enrollees increased during the 2008–2011 time period; however, the rate of increase of enrollees was significantly smaller than the rate of increase for allowed amounts for L0631.

**Appropriateness of Device**
The purpose of our report was to collect information regarding the cost of the device and any services provided to the beneficiary related to the device. We did not conduct a medical review to assess whether the device was medically appropriate. There are no requirements regarding the type of supplier that may provide an L0631; beneficiaries can obtain one from any enrolled Medicare supplier provided that they have a written order from a physician. Therefore, OIG cannot, as you suggest, draw any “correlations to the appropriateness of the device and the type of supplier providing the device.”
Fitting and Adjustment Services and Followup Visits
The data regarding fitting and adjustment services were self-reported by suppliers. The report’s “one-third estimate”—i.e., its estimate that for one-third of claims, suppliers did not provide fitting and adjustment services—is based on suppliers’ answers to our survey question as to whether they provided these services. We requested documentation regarding fitting and adjustment services. However, documentation for these services (or the lack thereof) was not considered when reporting the estimate. Therefore, the one-third estimate reflects what suppliers reported to be their practices and not what suppliers were able to document; we have no reason to believe that suppliers underreported their fitting and adjustment practices.

As part of our data collection efforts, OIG asked suppliers whether they provided any additional services to beneficiaries who received an L0631. This question gave suppliers the opportunity to indicate whether they provided any followup care. Suppliers self-reported that for 93 percent of claims, no additional services were provided to beneficiaries.

Reimbursement Rates/Competitive Bidding
OIG’s recommendation to the Centers for Medicare & Medicaid Services (CMS) was to use the information provided in our report to lower the reimbursement amount for L0631. We do not state in our report, nor do we believe, that supplier acquisition costs should be the sole basis for setting reimbursement rates. However, OIG does believe that the collection of accurate data on acquisition costs is a necessary and integral step in setting appropriate reimbursement rates for supplies. Our report provides CMS with a comprehensive set of data regarding acquisition costs and services that could assist it in lowering the reimbursement amount for L0631. Including the L0631 code in the competitive acquisition program will not preclude beneficiaries from obtaining necessary fitting and adjustment services from suppliers.

Your letter references the definition of an “off-the-shelf” orthosis. An orthotic is designated as off-the-shelf if it does not require an expert in trimming, bending, molding, assembling, or customizing the fit to the individual. In our report, we found that a certified orthotist (an expert) provided the fitting and adjustment services for only 9 percent of claims. Therefore, the vast majority of beneficiaries are being fitted by individuals who are not experts. This conclusion would still have held true if OIG had also included certified fitters as experts. This fact is also highlighted by AOPA’s own analysis of the types of suppliers who provide L0631. Because our analysis indicates that L0631 is not an orthotic for which experts are providing fitting and adjustment services, OIG believes L0631 is an applicable code for possible inclusion in the Competitive Bidding Program.

Devices on Pricing, Data Analysis, and Coding Contractor’s Classification List
Appendix B of the report states that some devices were not included in the L0631 Product Classification List displayed on the Pricing, Data Analysis, and Coding (PDAC) Contractor’s Website. We did not exclude from our analysis models that were not on the L0631 Product Classification List because these models were provided to beneficiaries and billed to Medicare as L0631. However, OIG did submit a list of these models to CMS for its review.
OIG thanks AOPA for its comments and appreciates its efforts to improve the care provided to Medicare beneficiaries. If you have any questions, please contact me, or your staff may contact Erin Bliss, Director of External Affairs, at (202) 205-9523 or Erin.Bliss@oig.hhs.gov.

Sincerely,

Stuart Wright
Deputy Inspector General
for Evaluation and Inspections