American Orthotic &
Prosthetic Association

April 19, 2013

Mr. Daniel Levinson
Inspector General
Office of the Inspector General
Department of Health & Human Services
330 Independence Ave., SW
Washington, DC 20201

Stuart Wright
Deputy Inspector General for Evaluation
Office of the Inspector General
Department of Health & Human Services
330 Independence Ave., SW
Washington, DC 20201

Dear Messrs. Levinson and Wright:

Your April 3, 2013 response to AOPA's January 8, 2013 letter to Inspector General Daniel R. Levinson is most appreciated and prompts our request for further clarification on several issues.

AOPA, guided by the opinions of its outside legal counsel, has a significantly differing view of the underlying law as well as the limits on CMS legitimate authority/responsibility as to competitive bidding and treatment of O&P accreditation in statute. The following topics are ones where we must underscore these differing viewpoints of CMS prerogatives, as well as how the facts and circumstances can be construed and interpreted.

(1) We cannot agree with the assertion that there are no requirements regarding the type of supplier that may provide an L0631;

Your response stated that "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." L0631 has never been considered to be an off-the-shelf device, and that is correct because it has never been considered to be a device that could be used by the patient "with minimal self-adjustment" [the specific language in the statutory definition of an off-the-shelf device, see 42 U.S.C. ss 1395w-3(a)(2)(C)]. Therefore, this device requires clinical care—adjustment and fitting—by a health professional with some measure of qualifications. AOPA remains concerned that the unregulated provision of custom fitted orthoses, like those described by L0631, by suppliers with limited or no knowledge of how to properly fit and adjust these types of orthoses will continue to result in poorly fit orthoses that ultimately provide a reduced clinical benefit to Medicare beneficiaries. Conversely, we believe that Medicare would fall short of its responsibility to these patients if it persists in not articulating the appropriate standards of training and qualifications to provide such custom-fitted orthoses.
(2) Your letter underscored a fact that eluded us from reading the OIG Report of December, 2012 on L0631, namely, in clarifying that the report's assertion that "one-third" did not provide fitting and adjustment was an estimate;

(3) Our letter to Mr. Levinson of January 8 had criticized what we had interpreted as the OIG's position that CMS should choose between paying for L0631 at the internet acquisition cost or

shift it to competitive bidding acquisition. Mr. Wright's letter pleasantly surprised us in stating the OIG's position that "acquisition costs should NOT be the sole basis for reimbursement" (emphasis added). This prompted us to look back, however, at the original report, and we have a hard time distinguishing this eschewing of internet acquisition costs as the sole basis for reimbursement from this sentence quoted directly from the report "(T)he program and its beneficiaries could have paid millions of dollars less if the Medicare reimbursement amount for L0631 back orthoses more closely resembled the cost to suppliers." While AOPA is encouraged by your acknowledgement that acquisition cost is only one part of the equation when establishing Medicare reimbursement rates, the statement in the original report appears to place a significant amount of weight on the supplier cost of an item when determining appropriate reimbursement rates. AOPA would like to reiterate that the reimbursement rate for all HCPCS codes, including those for L0631, include both the acquisition cost to the supplier as well as all fitting, training, and necessary follow up care required to ensure that the orthosis meets the clinical needs of the patient.

(4) We believe that Mr. Wright's statement that "the vast majority of beneficiaries are being fitted by individuals who are not experts" should have triggered recognition that OIG ought to be stating that delivering these devices to Medicare beneficiaries by unqualified providers violates the statute and undermines quality of beneficiary care;

We are quite concerned that the OIG's report on L0631, as well as Mr. Wright's letter, convey by their omission an apparent lack of familiarity with either the BIPA 427 requirements on accredited providers, and/or presumably with the report the OIG itself issued in October, 2012 chiding CMS for not enacting those regs. own report on this topic [CMS Has Not Promulgated Regulations to Establish Payment Requirements for Prosthetics and Custom-Fabricated Orthotics, OEI-07-10-00410].

(5) In light of the "one-third" asserted in #2 above being an estimate, we have trouble with the computation that prompted the OIG's conclusion that only 9 percent of patients (whether this is a real, or another estimate) received fitting from a certified orthotist;

Orthoses described by L0631 require appropriate knowledge, training, and expertise to ensure a proper fit and appropriate function of the orthosis. The OIG report's statement that a certified orthotist provided the fitting and adjustment services in only 9% of the claims for L0631 that were reviewed for purposes of the report. A closer look at utilization data gathered by AOPA, indicated that from 2008-2011, approximately 17% of claims for L0631 were submitted by suppliers who indicated that they had certified orthotic and prosthetic personnel on staff. If claims submitted by physicians and therapists are also considered, the percentage increases to 32%. While this represents more than the 9% reported in the original report, AOPA agrees that the majority of claims for L0631 are being billed by suppliers who claim to have no expertise in the proper fitting of orthoses. AOPA believes that this fact is of equal importance to the increased cost and utilization for L0631 that was the focus of the OIG report. AOPA believes that the inclusion of L0631 in future rounds of competitive bidding, in addition to violating the statute, would serve only to further reduce, by dramatic proportions, the percentage of claims that include proper fitting and training by qualified professionals resulting in lesser clinical outcomes for Medicare beneficiaries.

(6) Finally, we are troubled by what we believe is the flawed logic of asserting that the fact that as many as one-third of patients were reported not to have received clinical care with their L0631 back brace (and therefore, two-thirds of the patients **did** receive the appropriate clinical care which is incorporated into the cost of this device) is somehow an indicator that the code is appropriate for competitive bidding, largely ignoring that such determination can be legitimately made only with reference to the specifics in the statute.

While the OIG report indicated that 1/3 of suppliers who were surveyed did not report the provision of any fitting and training services when delivering an orthosis described by L0631, the report failed to acknowledge that 2/3 of those surveyed **did** report that fitting and training services were provided to Medicare beneficiaries in conjunction with the delivery of the orthosis. These services, which are required to ensure a proper fitting orthosis, require significant time and interaction with the patient and should be considered an integral part of the overall provision of the orthosis and any subsequent provider reimbursement for the orthosis.

AOPA believes that the OIG could better protect Medicare beneficiaries by addressing the failure of the minority of suppliers surveyed to provide required services for which they were reimbursed rather than arguing to reduce the overall reimbursement for the orthosis for all providers, including those who, in the majority of cases, actually provided appropriate fitting and training services. A comparable argument would be that because some percentage of citizens cheat on their tax returns, we should abolish the Internal Revenue Service.

We do not believe that the OIG, or any serious, informed health care commentator would opine--as to the sizeable collection of braces that are not capable of being used with "minimal self-adjustment"--that Medicare beneficiaries would do better NOT to have the clinical care component for fitting and adjusting their braces. Quite the contrary, Medicare beneficiaries will have better success, less pain, and fewer downstream health problems/expenses if they receive timely clinical care which assures the optimal effectiveness of their orthotic bracing. Stated differently, any delivery of 'non-off-the-shelf' orthotics through competitive bidding, as if the braces were commodities that can be provided without clinical care, is a change from the current statute which would be detrimental to the quality of care for Medicare beneficiaries.

AOPA looks forward to the continuation of this dialogue and supports the efforts of the OIG to eliminate fraud, waste, and abuse from the Medicare system. The provision of the highest quality care for Medicare beneficiaries at a reasonable cost to Medicare remains a common goal that we look forward to working toward.

Sincerely,

Thomas F. Kirk, Ph.D
President

Thomas F. Fise, JD
Executive Director