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

May 23, 2013

VIA EMAIL

Daniel R. Levinson, Inspector General
U.S. Department of Health & Human Services
Office of Inspector General
Cohen Building
330 Independence Avenue, S.W.
Washington, D.C. 20201
Dan.Levinson@oig.hhs.gov

Re: Appropriateness of Physician-Owned Distribution Entities Activities in Orthotics and Prosthetics, Particularly As IT Relates to: (1) Self-Referral Problems; and (2) Better Clarification on Indispensable Medicare Recognition of Separation of O&P from DME

Dear Inspector General Levinson:

We are writing to express concern over the recent increase in Medicare-enrolled physicians and physician groups who have made arrangements with other enrolled suppliers in order to bill for DMEPOS items, specifically custom orthotic and prosthetic (O&P) devices from their own physician owned laboratories.

We maintain that Medicare and its beneficiaries are best served by licensed and/or certified orthotic and prosthetic clinicians acting on a referral from a physician or other healthcare provider with no financial interest in the O&P practice. As we outline below, allowing for physician self-referral of O&P care, whether it is through the In-Office Ancillary Services Exception or allowing for joint ventures, does not serve to improve beneficiary access or quality of care. With the exception of certain prefabricated off-the-shelf orthoses or supply items, allowing the provision of other types of O&P care by referring physicians opens the door to overutilization, potentially suspect medical judgment, unfair competition and increased costs to the Medicare program and its beneficiaries.

We are aware that the potential profitability of self-referring to physician owned O&P laboratories is being presented at many medical business meetings, particularly in the specialty of Vascular Surgery. We also see entities marketing turnkey O&P laboratory services to physician groups, most notably again in the Vascular Surgery area, although not exclusively. In other words, there are entities marketing directly to physician groups the concept of physician owned O&P laboratories based on the profitability of those arrangements. This is being

presented to physicians who, on their own, had not expressed the desire or demonstrated the expertise to independently develop a P&O laboratory.

We note that these arrangements are not specifically prohibited in rule or regulation and while Custom O&P is a small subset of DMEPOS, these arrangements may dramatically and negatively affect the way care is provided to the beneficiary. We believe the OIG needs to analyze the effect of physician owned O&P laboratories; custom O&P services provided under the IOAS exception; and contractual joint ventures formed for the provision of custom O&P care

POD Special Fraud Alert—March 2013

On March 26, 2013, the OIG issued a Special Fraud Alert addressing physician-owned entities that derive revenue from selling, or arranging for the sale of, implantable medical devices ordered by their physician-owners for use in procedures the physician-owners perform on their own patients at hospitals or ambulatory surgical centers (ASCs.) Such entities are referred to as physician-owned distributorships, or "PODs." The focus of PODs tends to be in the surgical arena, with a particular emphasis on orthopedic implants (spine and joint prostheses) and cardiac implants (pacemakers and defibrillators.)[1] However, within a footnote to this Fraud Alert, the OIG notes that "…Although this Special Fraud Alert focuses on PODs that derive revenue from selling, or arranging for the sale of, implantable medical devices, the same principles would apply when evaluating arrangements involving other types of physician-owned entities."[2]

A prosthesis may be simply defined as "…a device, either external or implanted, that substitutes for or supplements a missing or defective part of the body."[3] Implantable medical devices, such as replacement joints or intraocular lenses (IOLs), as well as artificial limbs, all clearly meet this general definition of "prosthesis." We contend that many of the concerns that the OIG delineated in the POD Special Fraud Alert regarding implantable prostheses apply equally to external prostheses in the form of artificial limbs, and to custom orthopedic bracing (orthoses). We believe that fraud and abuse risks, as well as the more important patient safety concerns as they relate to PODs, are equally applicable to physician-owned orthotic and prosthetic (O&P) laboratories.

Through previously-published guidance, the OIG has made it clear that an opportunity for a referring physician to earn a profit, including through an investment in an entity for which the physician generates business (e.g., through referrals to the business) could constitute illegal remuneration under the anti-kickback statute. While it might not appear that there are significant

[1] *See* Deyon TA, Mirza SK, Martin BI; et al. *"Trends, major medical complications, and charges associated with surgery for lumbar spinal stenosis in older adults."* JAMA 2010; 303 (13); 1259-1265 (noting a marked fifteen fold increase in the number of spinal fusion surgeries from 2002-2007 and highlighting the significant financial incentive to both hospitals and surgeons to perform such complicated surgeries.)
[2] Office of the Inspector General, Special Fraud Alert: Physician-Owned Entities, March 2013 https://oig.hhs.gov/fraud/docs/alertsandbulletins/2013/POD_Special_Fraud_Alert.pdf
[3] Random House Kernerman Webster's College Dictionary, © 2010 K Dictionaries Ltd. Copyright 2005, 1997, 1991 by Random House, Inc. All rights reserved.

opportunities for fraud or abuse when a physician owns, or is in a joint venture in an O&P laboratory, that is not necessarily the case.

Further, the fact that physicians are exempt from the O&P accreditation requirement and quality standards creates a circumstance that could result in the physician opting to replace devices that otherwise would be repaired by an O&P facility that has the necessary equipment and laboratory to effect such repairs. This is because an accredited O&P practice is required to offer repairs, while an unaccredited practice is not[4]. In addition to fraud, abuse and overutilization, the OIG raises other concerns that may be associated with kickbacks: corruption of medical judgment, increased costs to Federal healthcare programs and unfair competition. Each of these concerns exists when discussing physician-owned O&P laboratories.

Due to the similarities that exist with PODs and physician-owned Orthotic and Prosthetic laboratories, we maintain that the suspicion with which the OIG views PODs should be applied equally to physician ownership of O&P laboratories. We further believe that insufficient attention has been paid to physician relationships with O&P laboratories, that are essentially the equivalent of PODs, and we encourage the OIG to apply the same principals when considering the legality of physician-owned O&P laboratories under the anti-kickback statutes.

In-Office Ancillary Services Exception

While we acknowledge that enforcement of the Physician Self-Referral ("Stark") Law[5] is within the jurisdiction of CMS, we wish to comment on several risk areas in this regard.

The In-Office Ancillary Services (IOAS) Exception delineated in Stark Law was implemented to provide patients the opportunity to receive certain medical tests or services (Designated Health Services, or "DHS") during the time of their physician office visit and was intended to accommodate certain legitimate physician business arrangements. Orthotic and prosthetic devices (O&P), as well as other items of DMEPOS, are included in this list of DHS. We believe that the IOAS exception and other loopholes in Medicare regulations related to O&P services are being exploited and foster physician business arrangements that do not conform to the IOAS exception's original intent.

Custom O&P services are rarely, if ever, completed at the time of an office visit and certainly do not meet the criteria for "ancillary to physician services." The provision of a custom orthotic or prosthetic device cannot be accomplished during a single office visit; rather, the patient assessment, casting, measurement, fabrication, fitting, adjustment and follow-up care may take several weeks—or even months—to complete.

We maintain that the loophole allowing physicians to refer services to O&P laboratories which they own or have a financial interest in should be eliminated. The current regulatory and legal

[4] http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Downloads/DMEPOSAccreditationStandardsCMB.pdf
[5] http://www.ssa.gov/OP_Home/ssact/title18/1877.htm

exceptions as they apply to all of DMEPOS, opens the door for prescribing physicians to over-order or upcode in the specific area of custom O&P devices.
We do acknowledge that it could in certain cases be in the interest of patient access or convenience of care to allow the provision of off-the-shelf orthotic (prefabricated) items, or very limited custom-fit (prefabricated) orthotic devices during a physician office visit. We will not argue that it can be a convenience for the patient to obtain simple prefabricated orthotic items, supplies, or items such as a cane or a sling during the course of a physician visit. In fact, we believe such scenarios were the original intent of the IOAS exception. However, to allow for the provision of custom made or beyond basic custom fit O&P devices under the IOAS exception simply serves as a mechanism to maximize physician profits, with no corresponding benefit to patients. During the design, manufacture, fitting, adjustment, and training regarding the use of a custom O&P device, the patient must return on multiple occasions. Unlike a one-time dispensing or pick-up of an off-the-shelf prefabricated product associated with a physician visit; it is not more convenient for a patient to have to return to a physician's medical office than to go to a specialized, accredited O&P facility. However, when a physician has a financial interest in the O&P business, that physician's patients surely will feel some obligation or possibly pressure to return to that physicians O&P laboratory - even if the services are not the most appropriate and may possibly be inferior.

Although lawmakers have progressively tightened the IOAS loopholes in recent years, even a narrow loophole affords ordering physicians incentives to self-refer. CMS acknowledged this in 2010, when it required physicians who self-refer under the IOAS exception to disclose when they were self-referring patients for advanced imaging services.[6] However, we feel that the only sure way to remove the influence of financial incentives on medical decision making is to remove the opportunity to financially benefit from that incentive. Simply put, allowing payment for custom O&P devices under the IOAS exception could lead to overutilization and self-referral abuses, and may restrict patient access to appropriate and quality custom O&P care.

Contractual Joint Ventures

Contractual Joint Ventures have long been of concern to the OIG, dating back as far as August 1989 when it released its Special Fraud Alert on Joint Venture Arrangements.[7] The OIG followed this Fraud Alert by a Special Advisory Bulletin addressing Contractual Joint Ventures during April 2003.[8]

The 1989 Fraud Alert addressed arrangements between those in a position to refer business (e.g., physicians) and those who provide items for which the Medicare and Medicaid programs

[6] MLN Matters® Number: SE1023 Revised August 12, 2012, Provisions in the Affordable Care Act of 2010 (ACA), http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1023.pdf
[7] Office of the Inspector General, Special Fraud Alert; Joint Venture Arrangements, August 1989 http://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html
[8] Office of the Inspector General, Special Advisory Bulletin, Contractual Joint Ventures, April 2003 https://oig.hhs.gov/fraud/docs/alertsandbulletins/042303SABJointVentures.pdf

make payment. The OIG contended that certain of those arrangements may violate the anti-kickback statutes. The April 2003 Advisory Bulletin focused more narrowly on those arrangements where a healthcare provider in one line of business (referred to by the OIG as the "Owner") expands into a related healthcare business by contracting with existing provider or supplier (referred to as the "Manager/Supplier") of the related item or service in order to provide the new item or service to the Owner's existing patient base. In these arrangements the Manager/Supplier would otherwise be a potential competitor in the provision of the Owner's new business line. The Manager/Supplier manages the new line of business on behalf of the Owner, and may go so far as to supply the Owner's new line of business with employees, inventory, space, and billing or other related services. The Owner receives the profits of the business as remuneration for his/her referrals.

We in the profession of O&P see an increasing number of such arrangements being proposed to providers of O&P services. Often, the potential Owner wishes to enter into a "turn-key" type arrangement, whereby the O&P provider's existing operation is absorbed by the Owner. We also see some O&P organizations marketing turnkey O&P laboratory arrangements to physician groups. As with POD arrangements and the IOAS exception, these Joint Venture arrangements can contribute to self-referral abuses and over-utilization. Some might attempt to make the argument that such arrangements improve patient access to service; however, these arrangements instead may limit access by removing the Manager/Supplier's ability to serve patients in its own right. We encourage the OIG to increase its enforcement activities as they relate to these often-abusive arrangements.

Documentation for Custom O&P Services

In recent years, orthotic and prosthetic clinicians engaged in providing services to Medicare beneficiaries have seen an increase in the amount and type of documentation required to support the medical necessity for the services they provide. In addition to a detailed physician prescription, certain circumstances require that the ordering physician's contemporaneous clinical documentation support the patient's diagnosis and the medical necessity for the O&P services ordered.

This issue brings several important questions to mind: When a medical doctor self-refers for O&P services under one of the above scenarios, he/she becomes the supplier of record when billing Medicare. When acting as the supplier, will the medical doctor's own clinical documentation be considered sufficient to support the medical necessity for O&P services? If a licensed and/or certified O&P clinician's documentation must be additionally supported by a third-party in the form of clinical notes, and in some instances letters of medical necessity, will the same standard be applied when a medical doctor acts as a supplier of O&P services?

These questions illustrate one of the inherent problems in allowing for the self-referral of O&P services. Under the typical model of O&P provision, the O&P clinician is financially independent of, but coordinates clinically with, the physicians from whom he/she receives referrals. The referring physicians act as "gatekeepers" of sorts, by providing the required prescriptions and documenting the need for any ordered O&P devices. Without this gatekeeper's prescription and clinical validation, the O&P clinician cannot be paid for the services provided to Medicare

patients. In a self-referral situation, no gatekeeper exists; no one independent of the supplier of record (the physician him or herself) has responsibility for supporting the medical necessity of the O&P devices provided. In these self-referral situations the checks and balances that are generally in place, no longer exist.

In order to ensure that both Medicare program and beneficiary interests continue to be served, that access to quality orthotic and prosthetic care is maintained, and to mitigate the potential for fraudulent and abusive activities we suggest the following:

- The suspicion with which the OIG views PODs should be applied equally to physician ownership of O&P laboratories. Insufficient attention has been paid to physician relationships with O&P practices, which are essentially the equivalent of PODs. We encourage the OIG to apply the same principals when considering the legality of physician-owned O&P laboratories under the anti-kickback statutes.

- The billing of custom made or beyond basic custom fit O&P devices under the IOAS exception should not be allowed. The IOAS exception when applied to custom prosthetics and orthotics does not serve any ancillary care advantage and simply serves as a mechanism to maximize physician profits. There are no corresponding benefits to patients. Allowing payment for custom O&P devices under the IOAS exception could lead to overutilization and self-referral abuses, and does not contribute to patient access to appropriate O&P care.

- The OIG's enforcement activities should be increased in relation to often-abusive contractual joint venture arrangements wherein a referring physician realizes the profits gained by referring his or her patients to an O&P laboratory in which he or she has ownership interest, with little or professional or clinical oversight.

- The requirement for all suppliers of O&P care, including physicians and physician practices, that a third-party referral source must prescribe and support the medical necessity for custom O&P devices provided to Medicare beneficiaries should be continued.

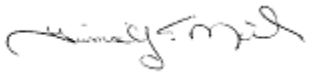
- Further analysis and observation of physician-owned O&P laboratories; custom O&P services provided under the IOAS exception; and contractual joint ventures formed for the provision of custom O&P care should be included within the OIG's FY 2014 Work Plan.

Conclusion

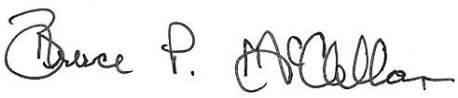
We appreciate your time and the opportunity to bring these concerns to your attention, and would be pleased to participate in any additional dialogue toward clarification or answering any questions. It you have any questions or would like to discuss our concerns and observations, please contact Thomas F. Fise, at either 571-431-0802 or 202-270-7630.

Sincerely,

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



Timothy E. Miller, CPO
President
American Board for Certification in
Orthotics, Prosthetics and Pedorthics, Inc.



Bruce "Mac" McClellan CPO, LPO, FAAOP
President
American Academy of Orthotists and
Prosthetists

Thomas F. Kirk, PhD
President
American Orthotic & Prosthetic Association

John P. Kenney, MURP, BOCO
BOC Chairman
Board of Certification/Accreditation, International