

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

November 18, 2013

VIA ELECTRONIC MAIL

Marilyn Tavenner, Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W.
Mail Stop 314G
Washington, D.C. 20201
Marilyn.Tavenner@cms.hhs.gov

Re: Physician-Owned Distributorships

Dear Administrator Tavenner:

We are writing on behalf of the Orthotic & Prosthetic (“O&P”) Alliance, a coalition of the five major national orthotic and prosthetic organizations representing over 10,000 O&P professionals and 3,000 accredited facilities. In response to a recent letter written to the OIG by the O&P Alliance that outlined a number of areas of concern to our profession, we were advised by Gregory Demske, Chief Counsel to the Inspector General, to bring certain of those concerns to the attention of CMS. For your reference, we have included a copy of our original letter to the OIG, where these concerns are discussed in-depth; below we’ve summarized our concerns that fall under the purview of CMS.

In-Office Ancillary Services Exception

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.

We 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.

American Academy of Orthotists and Prosthetists (AAOP)
American Board for Certification in Orthotics, Prosthetics, and Pedorthics, Inc. (ABC)
American Orthotic & Prosthetic Association (AOPA)
Board for Certification/Accreditation, International (BOC)
National Association for the Advancement of Orthotics and Prosthetics (NAAOP)

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. 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. 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 fabricated 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.

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.

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. CMS itself has maintained that the O&P Supplier's medical record cannot stand alone in justifying medical necessity, mainly due to the fact that O&P professional benefits financially from the interaction. We suggest that physician self-referral situations violate this CMS position.

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 billing of custom made or beyond basic custom fit prefabricated 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.

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We appreciate the opportunity to bring these issues to your attention, and would welcome additional dialogue with you surrounding these topics. If 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



Michelle J. Hall, CPO, FAAOP
President
American Academy of Orthotists
and Prosthetists



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



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



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