THE ORTHOTIC AND
PROSTHETIC ALLIANCE

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Direct-to-Consumer Provision of Custom Orthoses and Prostheses

The provision of limb prostheses and custom-fabricated and custom-fitted orthoses to individuals with limb loss or limb difference requires care from a trained clinician following a prescription from a treating medical provider. This clinician should be a certified and/or licensed orthotist or prosthetist who provides care as part of an overall treatment plan. This constitutes the optimal, time-tested system of orthotic and prosthetic care. In many instances, the certified or licensed orthotist or prosthetist also works in coordination with physical or occupational therapists to address the patient's therapeutic needs. While orthotic and prosthetic technology has improved dramatically over the past several decades, improvements in technology alone cannot and should not replace the patient-provider relationship.[1]

Advances in technology include additive manufacturing, 3D printing, new material applications, and new ways to take impressions and measurements of patients' anatomy. Orthotists and prosthetists routinely utilize these technological innovations; however, these developments have fueled a growing trend toward direct-to-consumer models in the provision of custom orthotic and prosthetic care. Some of these models omit the orthotist or prosthetist entirely and rely on the *patient or their caregiver* to perform critical tasks they are not trained to do. These include measuring, casting or scanning the affected limb, appropriately aligning the components, and assessing a correct fit of the prosthesis or orthosis. Even when there is some oversight from the manufacturer through some form of remote communication, this model cannot replace the need for an educated and trained prosthetic or orthotic clinician to assure that the prosthesis or orthosis is appropriate, safe, and effective.

The five national organizations that comprise the Orthotic and Prosthetic (O&P) Alliance stand in strong opposition to any direct-to-consumer delivery model for the provision of custom prostheses or orthoses as it circumvents the necessary, direct working relationship between the patient and an appropriately credentialed O&P clinician as part of an overall plan of care. In some instances, direct-to-consumer models may reduce initial costs to consumers, but the short-term cost savings are far outweighed by significant additional safety risks and the long-term costs associated with these models.

[1] Off-the-shelf orthotics that do not require clinical expertise or custom fitting or fabrication, the type typically available in a drug store or durable medical equipment supply store, are not addressed in this position statement. These orthoses are defined in the Medicare statute as requiring "minimal self-adjustment." 42 U.S.C. § 1395w-3(a)(2)(C).

Appropriately Credentialed Prosthetists and Orthotists in the Care Continuum

Certified and/or licensed prosthetists and orthotists are healthcare providers who undergo rigorous education in anatomy, biomechanics, materials science, and clinical assessment/reassessment directly related to the provision of orthoses and prostheses. They must also satisfy clinical rotations and residency requirements. Their education (currently at the master's level) aligns with standards developed by the Commission on Accreditation of Allied Health Education Programs (CAAHEP) and National Commission on Orthotic and Prosthetic Education (NCOPE). These professionals must pass national certification examinations and maintain certification through continuing education. They are also ethically bound to their credentialing body's Code of Professional Responsibility.[2] See the American Academy of Orthotists and Prosthetist's Position Statement on Minimum Education Standards and Credentialing for more details.

Prosthetists and orthotists are accountable for the clinical services they provide and are responsible for providing optimal care and achieving the best possible clinical outcomes given the unique characteristics of each patient. Patients need this point of contact to provide direct care to resolve routine problems and maintain the proper fit and function of the prosthesis or orthosis over time, and access to a care team to consult when medical or rehabilitation therapy needs arise**.**

Characteristics of Direct-to-Consumer Delivery Models

In contrast to optimal system of O&P care, direct-to-consumer models view prosthetic and orthotic care through the lens of the device alone and rely on technology to supplant essential clinical services. Models that employ multiple ways to obviate the direct, patient-provider relationship place the patient at risk and expose the health care system to inefficiency and waste. For instance, it is common for such patients to encounter problems with direct-to-consumer outcomes, leading to a need for patients to consult trained O&P clinicians after the fact. When direct-to-consumer models fail, patients must seek qualified practitioners to obtain proper clinical care and restart the care process, which is wasteful and time-consuming.
Technology alone cannot make nuanced assessments that factor-in myriad complications, circumstances, and real-life demands of patients with limb loss and limb difference. At the heart of high-quality, custom prosthetic and orthotic care is the O&P clinician working in conjunction with the individual's care team. Any model that fails to recognize this constitutes a disservice to patients, both short- or long-term.

Alarming Trends of Direct-To-Consumer Delivery Models

The O&P Alliance is aware of a growing trend of direct-to-consumer models that operate outside of the patient-centric medical approach to prosthetic and orthotic interventions. Frequently observed characteristics of direct-to-consumer models include:

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[2] The American Board for Certification in Orthotics, Prosthetics & Pedorthics' Code of Professional Responsibility and Rules & Procedures can be accessed here. The Board of Certification/Accreditation's Code of Ethics can be accessed here.

1. No Physician Involvement: In many instances, direct-to-consumer models do not include the requirement of a prescription from a physician to access the specific O&P technology or device in question. The omission of a physician alone places patients at risk and eliminates the medical care being provided from the health care system entirely. The device or technology available through these direct-to-consumer models become more like non-medical commodities than health care services. This raises serious concerns regarding Food and Drug Administration (FDA) classification, registration, and market approval of these devices, as well as other regulations designed to protect patients from ineffective or even harmful medical devices.

2. Omission of the Prosthetist/Orthotist: Subverting or entirely omitting the prosthetist or orthotist in the provision of O&P care removes the professional most qualified to provide O&P treatment from the care process. This is tantamount to eliminating the physical therapist from the provision of physical therapy. Having no O&P clinician to formulate and implement an O&P treatment plan runs counter to every system of care (e.g., the Veterans Administration's Amputee Systems of Care) and best practices designed to treat individuals with limb loss and limb difference. It is contrary to every accreditation system designed to address O&P rehabilitation, including accreditors such as the American Board for Certification in Orthotics, Prosthetics & Pedorthics (ABC), the Board of Certification/Accreditation (BOC), the Commission on Accreditation of Rehabilitation Facilities (CARF), and the Joint Commission. Direct-to-consumer models expressly violate state O&P licensure laws in effect in over 15 states, which require a licensed O&P practitioner to provide prostheses and custom orthoses to individuals with limb loss and limb difference.

3. Reliance on the Patient and/or Caregiver: In most direct-to-consumer O&P models, the patient or caregiver is heavily relied upon to be an active participant in the services provided, with or without coaching or other technical assistance from the manufacturer. While some patients, especially long-term users of orthoses or prostheses, may be capable of participating in certain aspects of the direct-to-consumer model, the vast majority of patients do not have the education, training, or experience to participate in the complexities of O&P assessment, evaluation, fitting, configuring, and other services necessary to effectuate a successful outcome. These models offload clinical responsibility from the manufacturer to the patient in a manner that creates the risk of patient harm and poor outcomes. They also tend to require up-front payment by the consumer. Because most direct-to-consumer models do not rely on physicians' prescriptions, third-party insurers and public programs are unlikely to cover these services, typically leaving the patient with the burden of paying for the device out-of-pocket.

4. Safety of the Patient and Quality of Care Are Paramount: The safety of the patient receiving any orthosis, prosthesis, or associated components must be the priority. Safety consists of structural safety, integrity of the materials and fabrication process, durability, and appropriate fit to prevent skin irritation and/or breakdown of the orthosis or prosthesis for long-term use during various activities, including normal activities of daily living and high-level activities such as recreation and sport. In addition, consistency

of material fabrication and design is critical to ensure the long-term safety and security of the patient as well as provide optimal functional outcomes.

Recommendations

For these reasons, the O&P Alliance:

- Supports the delivery model that preserves the meaningful person-to-person relationship between the patient and an appropriately credentialed O&P clinician to ensure that the custom orthosis or prosthesis is appropriate, safe, and effective.
- Rejects any direct-to-consumer delivery model for the provision of custom orthoses or prostheses that bypasses the critically important, direct relationship between the patient and an appropriately credentialed clinician.
- Supports the use of technology to enhance the ability of qualified healthcare providers to deliver high-quality, clinically appropriate care, but does not believe that technological advances should replace the clinical expertise of the orthotist and/or prosthetist.
- Recommends that third-party payers reject claims for orthotic and prosthetic care that do not meet current standards of clinical engagement in order to disincentivize the absence of safe and effective clinical care associated with direct-to-consumer models.
- Encourages the enforcement of state O&P licensure laws requiring a licensed O&P practitioner to provide orthotic and prosthetic care to individuals with limb loss and limb difference.