AOPA Policy on Used Devices or Components

Re: Purchasing Used Custom Prosthetic and Orthotic Devices or Components ("O&P devices or components")

Prosthetic and orthotic components are intended for use by certified and/or licensed prosthetists and orthotists to build custom medical devices. AOPA is concerned about a growing number of instances in which used prosthetic (artificial limbs) and orthotic (orthopedic braces) devices are being resold, *e.g.*, through third-party services such as eBay. We believe this practice is unfortunate, poses significant risk and potential danger to the patient, and in most cases, likely illegal.

If you are deciding whether to purchase a used O&P device or component, please be aware of the following:

* In the U.S. health care system, most O&P devices can only be provided to patient pursuant a prescription from a licensed physician.

*Almost all prosthetic and orthotic devices require fitting and adjustment and are only prescribed for certain medical conditions specific to an individual patient. There could be potential liability should someone buy an artificial leg or orthopedic brace that has not been custom fabricated or fitted to their patient's specific anatomy and needs and that patient later experiences medical problems as a result of incorrect fit or inappropriate use.

*The acquisition of used O&P devices makes it difficult, if not impossible, to determine whether required maintenance of the used device or component was complete and timely, or the circumstances under which it was used. This lack of information may pose a significant safety risk to patients.

*Both manufacturer/suppliers and patient care facilities have substantial concerns about how a medically unsupervised user of a used device impacts device warranties, malpractice coverage, FDA Good Manufacturing Practices, and records and reports requirements. Most of these devices are regulated by the Food and Drug Administration ("FDA"), including some that are subject to FDA's 510(k) premarket notification process. FDA expects that all of these devices should be limited to single patient use unless otherwise specifically cleared or approved by the agency.

*The emerging market for used O&P devices and components negatively affects device tracking for purposes of potential FDA or manufacturer recalls, compliance with physician prescription requirements by bodies that accredit O&P facilities, and the patient care facilities' ability to assure the quality and appropriate fit of the device.

*Generally, manufacturers warrant their products only to the original patient, so any further required service for the used component will likely not be covered under the terms of the manufacturers' warranty.

*Typically, liability insurance policies apply to the work of an orthotist or prosthetist on new component parts with an established chain of custody, and may well be void for work performed on used components. Practitioners could find themselves at greater risk of an insurer refusing to cover a claim to the extent that work is performed with components that were previously used and fall outside of a manufacturer's official reprocessing/refurbishing program.

*Most insurers only pay for the purchase of new -- not used -- custom devices and components . Providing such items to patients but billing them as new devices may be considered a fraudulent claim or billing by payors.

AOPA does not support the resale of any prosthetic or orthotic components that would be used by a certified and/or licensed prosthetist or orthotist to build a custom device. We urge you to consider very carefully the multiple issues outlined above, and avoid purchasing/using used orthotic and prosthetic devices or components, except for internal assessment purposes in the course of evaluating the progress of a patient's treatment program.