THE VIRGINIA BOARD OF HEALTH PROFESSIONS
THE VIRGINIA DEPARTMENT OF HEALTH PROFESSIONS

STUDY INTO THE NEED TO REGULATE ORTHOTISTS, PROSTHETISTS & PEDORTHISTS

Research and Recommendation of the Board of Health Professions

May 12, 2009

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EXECUTIVE SUMMARY

Background & Authority

By virtue of its statutory authority in §54.1-2510 of the *Code of Virginia* to advise the Governor, the General Assembly, and the Department Director on matters related to the regulation and level of regulation of health care occupations and professions, the Board is beginning an ongoing review of emerging health professions. The study will highlight individual professions selected by the Board for review. The Board selected *Orthotists, Prosthetists and Pedorthists* as emerging professions for review in 2008.

The study is governed by the methodology described in the Board's *Policies and Procedures for the Evaluation of the Need to Regulate Health Occupations and Professions, 1998*. The following seven criteria (the Criteria) collectively serve as the benchmark for its decisions.

(1) Unregulated practice of the profession poses a recognizable harm or risk for harm to the consumer resulting from practices inherent in the occupation, the characteristics of the clients served, the setting or supervisory arrangements for the delivery of services, or any combination of these factors.
(2) Practice requires specialized education and training, and the public needs to be assured of initial and continuing occupational competence.
(3) Autonomous practice occurs so that the functions and responsibilities of the practitioner require independent judgment.
(4) The scope of practice is distinguishable from other licensed, certified or registered occupations.
(5) The economic impact due to restriction on the supply of practitioners and the cost of board operations is justified.
(6) Alternatives to regulation have been explored and none are found which would adequately protect the public.
(7) The least restrictive regulation that is consistent with public protection must be recommended.

The Board reviewed the relevant literature related to orthotists, prosthetist, pedorthists and related occupations, federal and state laws and regulations, information on educational accreditation and credentialing programs, licensing and disciplinary information, salary and compensation and media coverage. They held a public hearing on August 14, 2008 and solicited and received written comment.

Findings

Orthotics, prosthetics and pedorthics (OP&P) is the practice of fabricating and fitting artificial limbs and orthopaedic braces for individual patients. All three disciplines are often considered together (OP&P), however orthotists and prosthetists are often considered as a separate category (O&P). Orthotists focus on orthopaedic braces (orthoses) of the spine and limbs, prosthetists on artificial limbs (prostheses), and

pedorthists on therapeutic footwear, inserts and foot braces. OP&P practitioners often work in independent shops and clinics, but do not provide services unless prescribed by a physician.

OP & P professionals work at four levels: practitioners, assistants, technicians and fitters. Practitioners provide direct patient care and manage the treatment plan. Assistants support practitioners, but do not practice independently. Technicians fabricate and repair orthoses and prostheses but do not provide direct patient care. Fitters apply and distribute prefabricated or "soft" orthoses and pedorthic devices.

OP&P is a well-defined and organized profession. OP&P professionals are represented by a research academy, two certification boards, educational accreditation commissions and several other trade, professional and philanthropic associations. Several professions share functions similar to OP&P professionals. The *Social Security Act* specifically identifies physical and occupational therapists for reimbursement of prosthetics and custom orthotics. Athletic Trainers and Orthopedic Technologists apply braces and orthoses. Orthoses, prostheses and pedorthic are often prefabricated and supplied with other durable medical equipment. Lastly, engineering, medical and sports medicine departments often collaborate with federal agencies to provide cutting edge research in prosthetic and orthotic care.

Two national certification boards provide certifications for O&P professionals. The American Board for Certification in Orthotics, Prosthetics & Pedorthics (ABC) provides certifications to O&P practitioners, pedorthists, technicians and fitters. The Board for Orthotist/Prosthetist Certification (BOC) provides certifications for O&P practitioners, pedorthists and fitters. Both ABC's and BOC's practitioner certifications are independently accredited, while only ABC's pedorthist and some of BOC's fitter certifications are independently accredited. Both organizations also offer accreditation to OP&P facilities, along with eight other groups recently granted deeming authority by the Centers for Medicare & Medicaid Services (CMS).

The National Commission on Orthotic and Prosthetic Education (NCOPE) in conjunction with the Commission on Accreditation of Allied Health Education Programs (CAAHEP) accredits O&P practitioner educational programs. NCOPE also accredits technician programs and post-graduate residencies. NCOPE currently accredits programs at the baccalaureate, masters and post-graduate certificate level. By 2012, NCOPE will only accredit master's level programs.

The Commission on Accreditation of Pedorthic Education (CAPE) accredits pedorthic educational programs. Programs must be 120 hours in length, including 54 hours of hands on education. CAPE is not independently recognized, but is sponsored by the ABC and the Pedorthic Footwear Association.

According to salary information provided by the Bureau of Labor Statistics (BLS) from May, 2007, employed O&P practitioners earn $64,280, on average, nationally and $66,550 in Virginia. Technicians earn $36,010 nationally and $51,370 in Virginia.

Technicians earn more, on average, in Virginia than in any other state. The BLS does not report independent statistics for pedorthists, however a survey of certified pedorthists by the Pedorthic Footwear Association estimated an average salary of $57,174. These salaries justify education and certification costs, but these costs may be difficult to meet by entry-level professionals.

Two major pieces of Federal legislation affect O&P professionals. The *Social Security Act* limits reimbursement for prosthetics or custom-made orthotics to qualified physical and occupational therapists or licensed or ABC/BOC certified orthotists and prosthetists provided by a qualified supplier at an approved facility. The *Medicare Improvements for Patients and Providers Act of 2008* requires that non-custom prosthetics and orthotics come from accredited facilities staffed by certified professionals, which could include fitters.

The Virginia Department of Medical Assistance Services (DMAS) limits Medicaid reimbursement for prosthetics to devices provided by an ABC (but not BOC) certified practitioner. Reimbursement for orthotics is limited to devices supplied as part of an approved Intensive Rehabilitation Program ordered by a physician, however there are no specific certification requirements.

The Virginia General Assembly is considering a bill (Senate Bill 931) that would require private health insurance companies to provide coverage for prosthetics equal to the coverage provided by Medicare. Though the bill does not refer to certification directly, Medicare requires certification of O&P practitioners for reimbursement. In 2007, the General Assembly's Joint Legislative Audit and Review Commission (JLARC) published a report on the likely impact of the bill. The JLARC study is available at http://jlarc.state.va.us/Reports/Rpt358.pdf.

Currently, twelve states regulate OP & P Professionals. Each state requires licenses for Orthotic and/or Prosthetic practitioners. Seven require licenses for Pedorthists, while New Jersey allows for voluntary licensing of Pedorthists. Six require licenses or registration for assistants, technicians and/or fitters and two accredit facilities.

Orthotics, prosthetics and pedorthic devices are non-invasive, however they interact closely with the entire musculoskeletal system. Improperly designed, fabricated or fitted devices can cause skin damage, pain and discomfort, mental distress, or nerve or pulmonary constriction. Additionally, devices may fail leading to injury. OP&P professionals provide both direct patient care and must obtain both professional and product liability insurance.

OP&P professionals often work in independent clinics and shops where they receive reimbursement from government and private insurance providers. CMS estimates that it made approximately $700 million in fraudulent payments to suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS), including fraudulent payments for orthotics and prosthetics.

Recommendations

At its December 17, 2008 meeting, the Regulatory Research Committee voted to recommend not regulating pedorthists at this time. The Board of Health Professions accepted this recommendation at its meeting later that day. At its May 12, 2009 meeting, the Regulatory Research Committee voted to recommend not regulating pedorthists at this time. The Board of Health Professions accepted this recommendation at its meeting later that day.

BACKGROUND & AUTHORITY

By virtue of its statutory authority in §54.1-2510 of the *Code of Virginia* to advise the Governor, the General Assembly, and the Department Director on matters related to the regulation and level of regulation of health care occupations and professions, the Board is beginning an ongoing review of emerging health professions. The study will highlight individual professions selected by the Board for review. The Board selected *Orthotists, Prosthetists* and *Pedorthists* as emerging professions for review in 2008.

To govern evaluative reviews, the Board has developed formal criteria and policies referenced in its publication, *Policies and Procedures for the Evaluation of the Need to Regulate Health Occupations and Professions, 1998.* Among other things, the criteria assess the degree of risk from unregulated practice, the costs and benefits of the various levels of regulation, and the advantages and disadvantages of the various alternatives to regulation that might protect the public. By adopting these criteria and application policies, the Board has endorsed a consistent standard by which to judge the need to regulate any health profession. The aim of this standard is to lead decision-makers to consider the least governmental restriction possible that is consistent with the public's protection. This standard is in keeping with regulatory principles established in Virginia law and is accepted in the national community of regulators.

Study Scope & Methodology

The general scope of this study will be to provide an evaluative review of the policy literature, pertinent state and federal laws, malpractice and disciplinary data, potential economic impact, and public comment concerning the selected emerging health-related occupations and professions in Virginia. The aim is to better understand the scopes of practice of these practitioners and issues relating to the need for adequate safeguards for the public's protection.

The Committee will make recommendations to the full Board concerning the practitioner group(s) to be selected. With the approval of the full Board, the Committee will examine the competencies currently expected of the selected practitioner groups in other jurisdictions to the degree that they exist. The Committee will focus their efforts in determining the answers to the following key questions for each group:

- What is the potential risk for harm to the consumer?
- What specialized skills and training do practitioners possess?
- To what degree is independent judgment required in their practices?
- Is their scope of practice distinguishable from other regulated occupations or professions?
- What would be the economic impact to the public if this group were regulated?
- Are there alternatives other than state regulation of this occupation which would adequately protect the public?

- If the Committee determines that this occupation requires state regulation, what is the least restrictive level that is consistent with the protection of the public's health, safety and welfare?

To answer the key questions, the following steps are recommended:

1. Conduct a review of the general policy literature, if any, related to the regulation of the respective group.
2. Conduct a review of the current relevant states laws and regulations.
3. Review malpractice insurance coverage data (if it is found to exist) in conjunction with other data to address Criterion One - Risk of Harm to the Public.
4. Review available reimbursement data to develop an estimate of how regulating this group may affect costs to address Criterion Five – Economic Impact
5. Prepare an initial draft report to the Board for public comment.
6. Conduct a hearing on the issue of the state regulation of this occupation, including any public health and safety issues germane to current practices as well as the potential fiscal impact which may result from such regulation.
7. Review all public comment, apply the Board's criteria and policies, and consider recommendations for changes in Virginia statute.
8. Prepare a draft with recommendations to the full Board.
9. Review the report and recommendations by the Board, and publish a draft report for consideration by the Department Director and Secretary.
10. If required based on recommendations by the Department Director and Secretary, amend the report and prepare a final report for their approval.

OVERVIEW OF THE PROFESSION

Orthotics, prosthetics and pedorthics (OP&P) is the practice of fabricating and fitting artificial limbs and orthopaedic braces for individual patients. All three disciplines are often considered together (OP&P), however orthotists and prosthetists are often considered as a separate category (O&P). Orthotists focus on orthopaedic braces (orthoses) of the spine and limbs, prosthetists on artificial limbs (prostheses), and pedorthists on therapeutic footwear and inserts.

OP & P professionals work at four levels: practitioners, assistants, technicians and fitters. Practitioners provide direct patient care and manage the treatment plan. Assistants support practitioners, but do not practice independently. (Assistant education and credentialing programs are currently under a moratorium, see below). Technicians fabricate and repair orthoses and prostheses but do not provide direct patient care. Fitters apply and distribute prefabricated or “soft” orthoses and pedorthic devices.

The BLS tracks *Orthotists and Prosthetists* as a distinct occupation (SOC 29-2091) in its Occupational Employment Statistics (OES) series. The latest OES data, which does not include information on self-employed practitioners, is from May, 2007. The BLS defines orthotists and prosthetists as professionals who “assist patients with disabling conditions of limbs and spine or with partial or total absence of limb by fitting

and preparing orthopedic braces or prostheses". As of May 2007, there were 5,600 orthotists and prosthetists employed in the United States. 34.5 percent worked in medical equipment and supply manufacturing, 24.3 percent in health and personal care stores and nine percent in hospitals. Employment figures for Virginia are not available.

The BLS tracks O & P technicians as *Medical Appliance Technicians* (SOC 51-9082). Medical appliance technicians "construct, fit, maintain, or repair medical supportive devices such as braces, artificial limbs, joints, arch supports, and other surgical and medical appliances." As of May 2007, there were 11,900 employed medical appliance technicians in the United States. Most (65 percent) work in medical equipment and supplies manufacturing, 11 percent work in health and personal care stores and 4.5 percent are employed by hospitals. Two hundred and seventy medical appliance technicians are employed in Virginia.

Definitions

Several organizations provide definitions of orthotists, prosthetists and pedorthists. Many professional associations also provide scopes of practice and standards of practice for the professions. A list of definitions appears below. Scopes of practice and standards of practice appear in Appendix A. For information on the organizations providing these standards and definitions, see below.

American Board for Certification in Orthotics, Prosthetics & Pedorthics[1]

Orthotist and Prosthetist Practitioner:

> An ABC certified practitioner is an allied health professional who is specifically educated and clinically trained to manage the provision of comprehensive orthotic and prosthetic care, based upon a clinical assessment and a physician's prescription, to restore physiological function and/or cosmesis.
>
> As the practitioner responsible for all patient care, the certified practitioner independently provides or supervises the provision of comprehensive orthotic and prosthetic care. This includes patient assessment, formulation of a treatment plan, implementation of the treatment plan, follow-up, and practice management. In addition, the certified prosthetist and/or orthotist is obligated to support and conform to the professional responsibilities which promote and assure the overall welfare of the patient and the integrity of the profession.

Pedorthist

> Pedorthics is the design, manufacture, modification of pedorthic devices, to prevent or alleviate foot problems caused by disease, congenital defect, overuse or injury. An ABC Certified Pedorthist is an individual who has

[1] From ABC's Credentialing Page: http://www.abcop.org/Credentialing.asp. Accessed 11/24/2008.

studied foot anatomy and pathology, biomechanics, shoe construction and modification, foot orthosis fabrication and materials, footwear fitting and patient/practice management.

Technician

An ABC registered technician provides all of the technical implementation tasks and services associated with the support of patient care. This includes fabrication, modification and the repair of orthoses and prostheses. The registered technician is obligated to support and conform to professional responsibilities that promote and assure the overall welfare of the patient and the integrity of the profession. Registered technicians participate in the delivery of orthotic and prosthetic care while under the clinical supervision of an ABC-certified practitioner.

Assistant

The registered assistant supports the ABC certified practitioner by assisting in orthotic and prosthetic patient care. Under the guidance and supervision of the ABC certified practitioner, registered assistants may perform orthotic and prosthetic procedures and related tasks in the management of patients. The registered assistant also fabricates, repairs and maintains devices to provide maximum fit, function and cosmesis. ABC registered assistants may not use their credential as independent practitioners engaged in unsupervised patient care. The registered assistant is obligated to support and conform to professional responsibilities that promote and assure the overall welfare of the patient and the integrity of the profession.

The Registered Assistant program is currently on moratorium, and credentialing applications are not being accepted. Individuals maintaining the Registered Assistant credential will not be affected by the moratorium, and will continue to be required to maintain adherence to ABC's Code of Professional Responsibility, obtain continuing education, and remit annual renewal fees.

Orthotic Fitter

An ABC certified fitter-orthotics is an individual trained and qualified to participate in the fitting and delivery of pre-fabricated orthotic devices and/or soft goods. An ABC certified orthotic fitter is competent to practice orthotics within a scope of practice that is specific to fitting prefabricated and off-the-shelf orthoses.

American Medical Association

> Orthotics and prosthetics are applied physical disciplines that address neuromuscular and structural skeletal problems in the human body with a treatment process that includes evaluation and transfer of forces using orthoses and prostheses to achieve optimum function, prevent further disability, and provide cosmesis. The orthotist and prosthetist work directly with the physician and representatives of other allied health professions in the rehabilitation of the physically challenged. The orthotist designs and fits devices, known as orthoses, to provide care to patients who have disabling conditions of the limbs and spine. The prosthetist designs and fits devices, known as prostheses, for patients who have partial or total absence of a limb.

Board for Orthotist/Prosthetist Certification

Pedorthics

> Pedorthics is the practice, pursuant to a written order/prescription when addressing a medical condition, of evaluating, treatment planning, patient managing, measuring, designing, fabricating, assembling, fitting, adjusting or servicing, necessary to accomplish the application of a pedorthic device for the prevention or amelioration of painful and/or disabling conditions related to the lower extremities.

Pedorthic Devices

> "Pedorthic Devices/Modalities" means therapeutic shoes, shoe modifications made for therapeutic purposes, partial foot prostheses ,foot orthoses and below the knee pedorthic modalities. Pedorthic devices do not include nontherapeutic, accommodative inlays and non-therapeutic accommodative footwear, regardless of method of manufacture; unmodified, non-therapeutic over-the-counter shoes; or prefabricated unmodified and/or unmodifiable foot care and footwear products. For purposes of this document, "accommodative" means designed with a primary goal of conforming to the individual's anatomy, and "therapeutic" devices are devices that address a medical condition, while non-therapeutic devices are devices that do not address a medical condition.

The OP&P Process

OP & P practitioners work as part of a team of health professionals managed by a Physiatrist or an Orthopaedic Surgeon. Physiatrists specialize in physical medicine and rehabilitation and coordinate rehabilitation and functionality care for patients suffering from pathologies such as multiple sclerosis, traumatic brain injury, back pain or injury, stroke and amputation. Orthopaedic surgeons specialize in musculoskeletal care and surgery. Practitioners of these specialties receive training in Orthotics and Prosthetics.

Other members of the team include pharmacists, psychologists and physical and occupational therapists.

Physiatrists and orthopedic surgeons, or other licensed medical practitioners, prescribe orthotic, prosthetic or pedorthic devices. Practitioners assess the patient's physical and lifestyle needs and formulate a treatment plan. They then select or design specific devices to meet patient needs. If prefabricated devices are called for, fitters assist patients in getting the right fit. Otherwise, technicians fabricate the devices. Once the device is fabricated, practitioners analyze the device and patient for functionality, ordering adjustments if necessary, and oversee patient education. They often work closely with physical and occupational therapists to help patients adjust to new devices. Orthotic, prosthetic and pedorthic devices require long-term care and follow-up as patient's bodies and lifestyles change. Licensed physicians manage long-term care.

OP & P practitioners often practice independently in outpatient clinics, offices and medical care workshops. In some instances, fabrication is completed offsite by centralized suppliers. Spurred by the Global War on Terror, practitioners have developed advanced rehabilitation centers serving wounded veterans and other patients. These centers combine several rehabilitation functions into one campus. An example is the *Center for the Intrepid* at the Brooke Army Medical Center in San Antonio Texas, constructed using funds from the Intrepid Fallen Heroes Program. The center includes advanced physical, occupational and behavioral therapy services with an advanced prosthetic and orthotic workshop on-site.[2]

Other Virginia Government Studies

The 2007 Virginia General Assembly considered Senate Bill 931 (See below). If passed, Senate Bill 931 would require private insurers to provide coverage for prosthetics at levels at least equivalent to the coverage provided by Medicare. In September 2007, the Joint Audit and Review Commission of the Virginia General Assembly (JLARC) published a report, entitled *Evaluation of Senate Bill 931: Mandated Coverage of Prosthetic Devices,* on the likely impact of the bill. The report provides an overview of the demand and provision of prosthetic services in Virginia and of the likely impact of the bill. The 24-page report is available at http://jlarc.state.va.us/Reports/Rpt358.pdf.

The Report includes the following in its Table of Contents:

- Background
- Medical Efficacy and Effectiveness
- Social Impact
- Financial Impact
- Balancing Medical, Social, and Financial Considerations

[2] The American Medical Association, in their online newsletter amednews.com, has a slideshow of the center. The slideshow provides a good, visual overview of the OP&P process. It is available at http://www0.ama-assn.org/amednews/site/media/intrepid.htm. For more information about the Center for the Intrepid, visit: http://www.fallenheroesfund.org/fallenheroes/about/default.htm.

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PROFESSIONAL ORGANIZATION

Orthotist, prosthetist and pedorthist organizations perform three main functions. Professional associations advance the practice of OP&P. Certification and accreditation boards warrant the competency of professionals, facilities and educational programs. Private trade associations allow members to access reduced prices for insurance, supplies and business services.

Professional Associations

American Academy of Orthotists & Prosthetists

The American Academy of Orthotists & Prosthetists (AAOP) represents practitioners credentialed by the American Board for Certification in Orthotics and Prosthetics (ABC). It promotes high standards of care in the profession through research and educational initiatives. AAOP holds an annual meeting and "State of the Science" conferences. AAOP publishes the Journal of Prosthetics & Orthotics and hosts an online education center. It also offers scholarships to O&P students and hosts an online career guide. Additionally, AAOP advocates for its members in state and federal forums. Grants from the US Department of Education provide funding for many of AAOP's educational and research initiatives. The Academy's headquarters are located in Washington D.C.

Association of Children's Prosthetic-Orthotic Clinics

The Association of Children's Prosthetic-Orthotic Clinics (ACPOC) provides educational, research and networking opportunities to O & P professionals focused on care of children. ACPOC holds an annual conference and publishes a quarterly newsletter.

National Association for the Advancement of Orthotics & Prosthetics

The National Association for the Advancement of Orthotics & Prosthetics (NAAOP) is an advocacy organization that promotes public awareness and lobbies government officials on issues related to O&P. Its lobbying efforts focus on federal level initiatives, and its offices are located in Washington, D.C.

Pedorthic Footwear Association

The Pedorthic Footwear Association (PFA) represents the interests of credentialed pedorthists and promotes standards within the profession. PFA holds an annual symposium and exhibition, publishes a quarterly journal and provides scholarships to students. It also tracks and provides information on current regulations for members, and advocates for members in state and federal agencies.

United States Member Society of the International Society for Prosthetics and Orthotics

The United States Member Society of the International Society for Prosthetics and Orthotics (US ISPO) facilitates orthotic and prosthetic care in underserved populations within the United States and worldwide. US ISPO holds annual conferences, publishes an annual report, provides scholarships to persons in South and Central America and holds seminars and clinics. In conjunction with Medshare International and the Barr Foundation, US ISPO supports the Prosthetic and Orthotic Component Clearinghouse (POCC). POCC collects new and used O&P equipment and distributes them to less developed countries.

Certification and Accreditation

American Board for Certification in Orthotics, Prosthetics & Pedorthics

The American Board for Certification in Orthotics, Prosthetics & Pedorthics (ABC) was formed when the American Board for Certification in Orthotics & Prosthetics merged with the Board for Certification in Pedorthics in 2007. ABC provides comprehensive professional certifications and facility accreditations within the OP&P field. ABC also provides continuing education opportunities and maintains the OandPCARE.org outreach website. ABC maintains offices in Alexandria, Virginia. See Table 1 for a list of ABC's certification and accreditation programs.

Professional Certifications	Facility Accreditation
American Board for Certification	
•Orthotist •Prosthetist •Pedorthics •Technician •Orthotic fitter •Mastectomy Fitter •Therapeutic Shoe Fitter	•Comprehensive O&P •Pedorthics •Post-Mastectomy •Ocular Prosthetics •Custom Fit Orthotics •Off-the-Shelf Orthotics •Non-Custom Therapeutic Shoes •AAD (Durable Medical Equipment
Board for Orthotist/Prosthetist Certification	
•Orthotist •Prosthetist •Pedorthist •Orthotic Fitter •Mastectomy Fitter •Footwear Specialist	DMEPOS Provider

Table 1: Certifications provided by the two OP&P certification boards.

Board for Orthotist/Prosthetist Certification

The Board for Orthotist/Prosthetist Certification (BOC) provides certifications to OP&P professionals and facility accreditation under Centers for Medicaid and Medicare Services (CMS) rules for suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). See Table 1 for a list of BOC's certification and accreditation programs.

Commission on Accreditation of Pedorthic Education

The Commission on Accreditation of Pedorthic Education (CAPE) recognizes pedorthic education programs that meet its standards. CAPE is sponsored by the ABC and PFA.

National Commission on Orthotic and Prosthetic Education

The National Commission on Orthotic and Prosthetic Education (NCOPE) is a sponsor Committee on Accreditation (CoA) of the Commission on Accreditation of Allied Health Education Programs (CAAHEP). The Council for Higher Education Accreditation (CHEA) recognizes the CAAHEP as an accrediting organization for allied health professions. The CAAHEP accredits O & P programs largely based on the review, standards and recommendations of NCOPE. NCOPE also accredits practitioner residency programs. In addition to its accrediting function, NCOPE has performed numerous studies on the practice and workforce of O&P.

Trade Associations

American Orthotics & Prosthetics Association

The American Orthotics & Prosthetics Association (AOPA) provides business services and products to O & P professionals. Its membership consists of both suppliers and patient care facilities. Members receive discounts on a wide array of business and professional products. Additionally, AOPA provides services such as a bi-weekly newsletter of regulatory news and an online insurance coding database. It holds an annual assembly and trade show and educational seminars. AOPA also advocates for O&P professionals within the federal government. AOPA is headquartered in Alexandria, Virginia.

PrimeCare Orthotics & Prosthetics Network

The PrimeCare O& P Network is a private regional association of orthotics and prosthetics facility owners. PrimeCare provides business, marketing and purchasing services to its members. Additionally, PrimeCare credentials all of its members by verifying certification of practitioners, insurance coverage, completion of continuing education and other network requirements. PrimeCare's national membership includes facilities in three of Virginia's border states (Kentucky, North Carolina and Tennessee) but none in Virginia.

OVERLAPPING SCOPES OF PRACTICE

Orthotists, prosthetists and pedorthists have well-developed scopes of practice. The ABC or its predecessors have been certifying orthotists and prosthetists since 1948 and pedorthists since 1973. The Pedorthic Footwear Association has represented Pedorthists since 1958. The American Medical Association lists "Orthotists and

Prosthetists" as one of 77 professions in its annual *Health Care Careers Directory*.[3] As already noted, the Bureau of Labor statistics categorizes orthotists and prosthetists as a separate profession.

Nevertheless, the scopes of practice of orthotists, prosthetists and pedorthists overlap the scopes of practice of occupational and physical therapists, athletic trainers, orthopedic technologists and orthopedic physician's assistants. Suppliers of prefabricated devices may perform some similar functions to practitioners. Finally, advanced research into orthotics, prosthetics and pedorthics often involves cross-disciplinary teams at research institutions.

Occupational and Physical Therapists

Occupational therapists help injured, chronically ill, the elderly or otherwise disabled persons to engage in daily living activities. Physical Therapists assist persons who have limited physical ability, due to injury, illness or birth defect, to gain or regain functionality. The *Social Security Act*, the *Virginia Administrative Code* and the Scope of Practice of the American Physical Therapy Association reference orthotics and prosthetics as within the scope of practice of occupational or physical therapists:

Section 1834(h)(1)(F) iii of the *Social Security Act* lists qualified physical and occupational therapists along with orthotists and prosthetists as practitioners able to receive reimbursement for furnishing prosthetics and custom fabricated orthotics.

Section 18VAC85-80-100 of the *Virginia Administrative Code* lists the design, fabrication and application of orthoses (splints) as one of the individual responsibilities of Occupational Therapists.

The American Occupational Therapy Association's *Scope of Practice* includes the following:

> Assessment, design, fabrication, application, fitting, and training in assistive technology, adaptive devices, and orthotic devices, and training in the use of prosthetic devices.

The American Physical Therapy Association's *Scope of Practice*[4] includes the following:

> 1) examining (history, system review and tests and measures) individuals with impairment, functional limitation, and disability or other health-related conditions in order to determine a diagnosis, prognosis, and intervention; tests and measures may include the following:

[3] See http://www.ama-assn.org/ama/pub/category/14598.html. Accessed 11/24/2008.
[4] Available at http://www.apta.org/AM/Template.cfm?Section=Home&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=46877. Accessed 11/24/2008.

- Assistive and adaptive devices
- Gait, locomotion and balance
- Orthotic, protective, and supportive devices
- Prosthetic requirements

2) alleviating impairment and functional limitation by designing, implementing, and modifying therapeutic interventions that include, but are not limited to

- prescription, application, and, as appropriate, fabrication of devices and equipment (assistive, adaptive, orthotic, protective, supportive, and prosthetic)
- physical agents and mechanical modalities

Athletic Trainers

Athletic trainers practice on physically active persons and prevent or treat injuries related to physical activity. This includes such diverse persons as athletes, performance artists, law enforcement personnel or persons working in physically demanding industries. Athletic trainers provide immediate care for injuries and, under the direction of a physician or physical therapist, provide ongoing care for persons engaged in physical activity. They may design and apply soft or prefabricated orthoses and braces.

Orthopedic Technologists/Orthopedic Physician's Assistants

Orthopedic Technicians and Orthopedic Physician's Assistants assist orthopedic surgeons by applying and removing casts, splints, braces and some orthoses.

Manufacturers and Suppliers

The US Centers for Medicare and Medicaid Services (CMS) classify orthotics and prosthetics under Durable Medical Equipment, Prosthetic, Orthotic and Supplies (DMEPOS) in their reimbursement processes. Manufacturers and suppliers of durable medical equipment also design manufacture and distribute prefabricated orthotics and prostheses for mass production and distribution. Some medical equipment retail and sales businesses provide prefabricated orthoses, prostheses and pedorthic devices directly to consumers.

Biomedical/Rehabilitation Engineering Research

Research and Development of advanced prosthetic, orthotic and pedorthic devices often increases during times of war. The Global War on Terror is no exception. Efforts to design prosthetics, orthotics and other products or procedures that provide increased functionality are underway at medical and academic campuses across the country and within the US Department of Defense. These efforts are often on the cutting edge of human-technology interfaces and provide advances that benefit active duty personnel,

veterans and the public at large[5]. Research in orthoses and braces also takes place in large sports medicine facilities on academic campuses. Some of the programs doing related research in or near Virginia are described below.

Virginia Commonwealth University-Center for Rehabilitation Science and Engineering[6]

The Virginia Commonwealth University-Center for Rehabilitation Science and Engineering (VCU-CERSE) is an interdisciplinary program of VCU's Medicine, Allied Health Professions, Engineering and Education departments. It works in cooperation with the Virginia Department of Rehabilitative Services, the Medical College of Virginia and with the Hunter Holmes Veteran's Administration Medical Center to coordinate research, education and care for persons with disabilities.

Defense Sciences Office[7]:

The Defense Science Office (DSO) of the US Department of Defense provides advanced research for the DoD, including medical services of particular interest to soldiers and veterans. The DSO identifies funds and coordinates projects. The DSO, based in Arlington, Virginia, is currently developing advanced prosthetics and human-assisted neural devices at John Hopkins University in Baltimore.

Virginia Polytechnic Institute and State University[8]

The Department of Engineering at Virginia Tech has worked with the Department of Sports Medicine (which contracts with and employs certified O & P practitioners) to develop advanced materials and orthotics for athletes.

CERTIFICATION

The National Organization for Competency Assurance (NOCA) created the National Commission for Certifying Agencies (NCCA) in 1989 to act as an independent accreditation commission. The NCCA assumed the role of the National Commission for Health Certifying Agencies, which worked closely with the Federal Government to develop standards in voluntary certification programs. The NCCA is a nationally recognized accrediting body for healthcare credentials.[9]

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[5] Dishneau, David. July 17, 2007. "War Fuels Prosthetics Research Blitz" USA Today. http://www.usatoday.com/money/industries/health/2007-07-15-prosthetics_N.htm

[6] For more information, see: http://www.cerse.vcu.edu/index.cfm

[7] For more information, see: http://www.darpa.mil/dso/index.htm and Miles, Donna, February 15, 2008, "Defense Agency Makes Big Advances in Prosthetics Research" *American Forces Press Service News Articles*. http://www.defenselink.mil/news/newsarticle.aspx?id=48987

[8] ScienceDaily. April 1, 2006. "Back in the Game: Orthotics and Prosthetics Experts Use New Materials to Let Injured Athletes Play" http://www.sciencedaily.com/videos/2006/0405-back_in_the_game.htm. Accessed 11/24/2008.

[9] Browning, A.H., Bugbee, A.C., & Mullins, M.A. 1996 *Certification: A NOCA Handbook*. National Organization for Competency Assurance (NOCA). USA. pg. x.

Two organizations, ABC and BOC, provide NCCA accredited certifications for orthotists, prosthetists. ABC also provides NCCA accredited certifications to pedorthists, while BOC's pedorthist certification is unaccredited. Certifications for each discipline (orthotics, prosthetics and pedorthics) are distinct, however many practitioners cross certify in two or more disciplines. No other organizations provide certifications to orthotists, prosthetists or pedorthists. The Centers for Medicare and Medicaid Services (CMS) requires that providers be certified by ABC or BOC before they may be reimbursed for providing prostheses or custom orthoses to beneficiaries.

American Board for Certification in Orthotics, Prosthetics & Pedorthics

ABC provides comprehensive certifications and facility accreditations in the OP&P field. ABC certifies O&P practitioners, pedorthists, technicians and fitters. ABC previously certified registered O&P assistants, however that program is on a moratorium. ABC's practitioner and pedorthist certifications are accredited by the NCCA.

Orthotic and Prosthetic Practitioners[10]

ABC awards the *Certified Orthotist* (CO), *Certified Prosthetist* (CP) and *Certified Prosthetist-Orthotist* (CPO) credentials to candidates that meet eligibility requirements, pass a certification exam, maintain continuing education requirements and conform to ABC's code of professional responsibility. Persons wishing to earn the CPO credential must meet these requirements in each discipline.

To achieve eligibility, candidates may follow one of two pathways: the traditional pathway or the unique qualifications pathways. The traditional pathway requires that either candidates complete a CAAHEP accredited baccalaureate degree or a CAAHEP accredited post-graduate certificate program in prosthetics or orthotics and complete a 1-year NCOPE accredited residency program.

The unique qualifications pathway is for persons who have extensive experience in the field or for persons seeking credentials in a second O&P discipline. A candidate seeking his or her first practitioner credential must have 10 years of clinical experience, 15 credits of college education in specific science courses and have participated in continuing education. Additionally, candidates applying through the unique qualifications pathway must provide comprehensive case history reports on specific types of cases and provide six letters of recommendation. A practitioner seeking his or her second credential only needs five years of experience, with 2,600 hours in the new discipline, but otherwise must meet the same requirements.

Certification exams consist of three parts: a written exam, a written simulation exam and a clinical patient management exam. The written exam is a three-hour, 150-

[10] For more information, see *the ABC Practitioner Certification Book of Rules*, effective December 2003, and the *ABC Unique Qualifications Book of Rules*, effective September 2002. Both are available at: http://www.abcop.org/Credentialing_Practitioners.asp.

question multiple-choice exam. The written simulation exam is a three-hour exam consisting of six simulated case scenarios. The clinical patient management exam is a hands-on exam designed to test clinical and patient care skills. ABC offers the written exams two times per year at testing sites nationally. The clinical exam is also offered twice per year, but in only one location. The exams focus on five domains identified the ABC's *Practice Analysis of Certified Practitioners in the Disciplines of Orthotics and Prosthetics*, a comprehensive job analysis of the O&P field.[11] The five domain areas are:

- Domain I: Patient Assessment
- Domain II: Formulation Of The Treatment Plan
- Domain III: Implementation Of The Treatment Plan
- Domain IV: Follow-Up Treatment Plan
- Domain V: Practice Management

Practitioners credentialed in one discipline must complete 75 hours of continuing education every five years. CPOs must complete 100 hours. Practitioners may complete continuing education hours in two categories. Category I hours consist of ABC approved meetings and courses. Category II hours include completing college courses, giving lectures, publishing articles or reading journals. Only 25 hours of Category II hours may be credited towards continuing education requirements every five years.

The total certification process costs candidates $1,350. This includes a $250 application free, $250 fees for each written exam section and a $600 fee for the clinical exam. Candidates must also pay any travel and lodging expenses for the clinical exam.

Pedorthist

ABC awards the *Certified Pedorthist* (C.Ped) credential to candidates who meet eligibility requirements, pass the certification exam, maintain continuing education requirements and conform to ABC's code of professional responsibility.

To be eligible, candidates must complete a CAPE approved education program. The certification is a written exam held two or three times annually at testing locations nationwide. Candidates must pay a $150 application fee and a $250 exam fee.

C.Peds must complete 55 hours of continuing education over five years. At least 35 credits must be ABC approved Category I hours. The balance may be Category II credits.

[11] ABC's *Practice Analysis of Certified Practitioners in the Disciplines of Orthotics and Prosthetics* was completed in 2007 by the Practice Analysis Task Force. It is available at: http://www.abcop.org/Practice_Analysis.asp

Technicians[12]

ABC awards the *Registered Orthotic Technician* (RTO), *Registered Prosthetic Technician* (RTP) and the *Registered Prosthetic-Orthotic Technician* (RTPO) credentials to candidates who meet eligibility requirements, pass a certification exam, maintain continuing education requirements and conform to ABC's code of professional responsibility. Persons wishing to attain the RTPO credentials must meet the requirements of both disciplines.

To achieve eligibility, candidates must either complete an NCOPE accredited orthotic or prosthetic technician program or have two years experience as a technician under the direct supervision of an ABC certified practitioner.

ABC holds three exams annually at pre-determined locations. The exam consists of a one-hour written multiple-choice exam and a seven-hour practical exam. Exam content is based on domain areas identified in ABC's *Practice Analysis of Certified Practitioners in the Disciplines of Orthotics and Prosthetics.* Candidates must pay a $50 application fee and a $200 examination fee.

Technicians certified in one discipline must complete 30 hours of continuing education every five years. RTPOs must earn 40 hours of continuing education. All continuing education hours may be either Category I or Category II credits.

Orthotic, Mastectomy and Therapeutic Shoe Fitter

ABC awards *Certified Fitter of Orthotics* (CFo), *Certified Fitter of Mastectomy* (CFm) and *Certified Fitter of Therapeutic Shoes* (CFts) credentials. Certified fitters provide patients with pre-fabricated devices or soft goods. Candidates must complete an approved short course or seminar, have experience in their chosen discipline and maintain continuing education requirements. ABC's fitter certifications are not NCCA accredited. Specific information on each fitter certification is available on the ABC website.

Board for Orthotist/Prosthetist Certification

BOC provides certifications and facility accreditations in the OP&P field. BOC certifies O&P practitioners, pedorthists and fitters. The BOC practitioner certifications, and mastectomy and orthotic fitter certifications are NCCA accredited.

Orthotic and Prosthetic Practitioners

BOC awards *Orthotist, BOC-Certified* (BOCO) and *Prosthetist, BOC-Certified* (BOCP) credentials to candidates who meet eligibility requirements, pass a certification exam, maintain continuing education requirements and comply with the BOC's code of

[12] For more information see *Technician Book of Rules*, effective August 2007, available at http://www.abcop.org/Credentialing_Technicians.asp.

ethics. Alternatively, BOC cross-certifies candidates holding appropriate credentials from the following sources:

- State Orthotic and/or Prosthetic Licensing Boards
- American Board for Certification in Orthotic, Prosthetics & Pedorthics
- Canadian Board for Certification of Prosthetists and Orthotists

To be eligible for the BOC exams, candidates must have two years of experience in their chosen discipline and either a bachelor's degree in orthotics or an associate's degree in orthotics or a related field. Alternatively, candidates without formal education must have four years of training or work experience accompanied by intensive study.

Certification exams consist of three parts: a multiple-choice exam, a clinical simulation exam and a video practical exam. The multiple-choice exam is a three-hour, 150 question exam covering nine content areas. The clinical simulation is a paper and pen branching exam that presents clinical simulations. The video practical exam is a self-taped demonstration of six procedures on actual patients in a clinical setting. See Table 2 for an overview of content areas of the multiple-choice exam.

Orthotist Exam			**Prosthetist Exam**		
Content Area	Questions	Percent	Percent	Questions	Content Area
Facilities Management	11	7.33%	5.33%	8	Facilities Management
Professional Practice & Ethics	9	6%	4.67%	7	Professional Practice & Ethics
Patient Assessment & Evaluation	25	16.67%	15.33%	23	Patient Assessment & Evaluation
Communication and Patient Education	20	13.33%	10%	15	Communication & Patient Education
Device Application & Delivery	20	13.33%	14.67%	22	Device Application & Delivery
Patient Follow Up	8	5.33%	10%	15	Patient Follow Up
Patient Preparation & Measurement	18	12%	10%	15	Patient Preparation & Evaluation
Selection of Devices	28	18.67%	10%	15	Design Selection
Fabrication	11	7.33%	10%	15	Fabrication
			10%	15	Application & Evaluation
	150	100%	100%	150	

Table 2: Content Areas of BOC Orthotist and Prosthetist Exams

Practitioners must complete 75 hours of BOC approved continuing education, for each discipline, every five years. BOC assigns a certain number of Category 1 and Category 2 hours for each approved course. For instance, depending on content, a course may be assigned five Category 1 hours and one Category 2 hour. Practitioners must earn at least 15 Category 2 hours.

Certification costs $975 for prosthetists and $1200 for orthotists. The cost includes a $200 application fee, $250 each for the multiple choice and clinical simulation exam and $275 for the video practical exam. Orthotist certification requires an additional $225 international fee.

Pedorthist

BOC awards *BOC Pedorthist* credentials to candidates that meet eligibility requirements, pass a certification exam, maintain continuing education requirements and

comply with the BOC's code of ethics. BOC also cross certifies candidates with a state license or other current certification. The BOC Pedorthist certification is not accredited.

To be eligible for the BOC Pedorthist exam candidates must have successfully completed a CAPE approved education program and have 1,000 hours of supervised fitting experience. The exam is a

three-hour, 100-question exam. See Table 3 for content areas.

Content Area	Questions
Facilities Management	7
Professional Practice & Ethics	7
Patient Assessment & Evaluation	20
Communication & Patient Education	10
Device Application & Delivery	20
Follow-up	9
Patient Preparation & Measurement	7
Selection of Devices	20
Total:	100

Table 3: Content areas of the BOC Pedorthist exam.

BOC Pedorthists must complete 40 continuing education hours every five years. Eight must be Category 2 hours as described in the Practitioner section. The fee for the certification exam is $350. The fee includes a $150 application fee and a $200 fee for the exam.

Orthotic and Mastectomy Fitters, and Footwear Specialist

BOC awards *Certified Orthotic Fitter* (COF), *Certified Mastectomy Fitter*(CMF) and *BOC Footwear Specialist* (BOCFS) credentials. Certified fitters and footwear specialists provide patients with pre-fabricated devices or soft goods. Candidates must complete an approved short course or seminar, have experience in their chosen discipline and maintain continuing education requirements. BOC's orthotic and mastectomy fitter certifications are NCCA accredited. The footwear specialist certification is not accredited. Specific information on fitter and footwear specialist certifications is available on the BOC website.

At a Glance

Table 4 provides an overview of practitioner, technician and pedorthist certifications:

	Accredited	Education	Experience	CEU (5 years)	Fee
Practitioner					
ABC: CO/CP	NCCA	Baccalaureate or Graduate	**… and** 1 year Residency	75	$1,350
BOC: BOCO/BOCP	NCCA	Associates or baccalaureate	**…or** 4 years	75	BOCO: $1,200 BOCP: $975
Technician					
ABC: RTO/ RTP	NA	NCOPE accredited	**. . .or** two years	30	$250
Pedorthist					
ABC: C.Ped	NCCA	CAPE approved	NA	55	$400
BOC Pedorthist	NA	CAPE approved	**…and** 1,000 hours	40	$350

Table 4: Overview of ABC and BOC certifications for practitioners, technicians and pedorthists.

FACILITY ACCREDITATION

The *Medicare Improvements for Patients and Providers Act of 2008* (MIPPA) limited reimbursement for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) to accredited facilities. MIPPA allowed the Centers for Medicare & Medicaid Services (CMS) to grant deeming authority to private accreditation organizations for this purpose. To receive reimbursement, facilities must be accredited by September 30th, 2009.

MIPPA also exempts certain practitioners from the September 30th, 2009 deadline, and allows CMS to exempt other practitioners at its discretion. These practitioners are exempt unless or until CMS develops rules specific to these practitioners. Physical therapists, occupational therapists, orthotists and prosthetists are among the exempted practitioners. Pedorthists and fitters are not exempt.[13] CMS intends to develop specific rules for orthotists and prosthetists in 2009.

CMS has granted deeming authority for the provision of orthotics, prosthetics and therapeutic shoes to several facility accreditation organizations. Among the quality standards CMS has set for accredited facilities are that "individuals supplying the(se) item(s) … must possess specialized education, training, and experience in fitting, *and certification and/or licensing*" (emphasis added)[14]. This means providers of prefabricated devices must be certified to at least the fitter level. CMS has granted deeming authority to suppliers of orthotics and prosthetics to the following organizations[15]:

- American Board for Certification in Orthotics & Prosthetics, Inc
- Board of Orthotist/Prosthetist Certification
- The Joint Commission
- National Board for Accreditation for Orthotic Suppliers
- Commission on Accreditation of Rehabilitation Facilities
- Community Health Accreditation Program
- HealthCare Quality Association on Accreditation (Orthotics only)
- Accreditation Commission for Healthcare, Inc (Orthotics only)
- National Association of the Board of Pharmacies (Non-custom only)
- The Compliance Team (Mail order or home delivery only)

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[13] See CMS "Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Accreditation Fact Sheet" at http://www.cms.hhs.gov/MedicareProviderSupEnroll/Downloads/DMEPOSAccreditationMIPPA-FactSheet.pdf. Accessed 11/26/2008.

[14] Centers for Medicare & Medicaid Services. October 2008. "Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Quality Standards." http://www.cms.hhs.gov/MedicareProviderSupEnroll/Downloads/DMEPOSAccreditationStandards.pdf. Accessed 11/26/2008.

[15] See CMS, Feb. 7, 2008, "Deemed Accreditation Organizations for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies" http://www.cms.hhs.gov/MedicareProviderSupEnroll/Downloads/DeemedAccreditationOrganizations.pdf

The granting of deeming authority to organizations that have not traditionally dealt with prosthetics or custom orthotics was controversial. Review of the rules surrounding DMEPOS reimbursement, facility accreditation and certifications are ongoing.

EDUCATION

Educational programs for orthotists and prosthetists come in three levels: baccalaureate degrees, post-graduate certificates and masters degrees. Baccalaureate and masters degrees prepare students for residencies in both orthotics and prosthetics. Certificate programs are tailored to one or the other discipline. Based on the advice of the National Commission on Orthotic and Prosthetic Education (NCOPE), the Commission on Accreditation of Allied Health Education Programs (CAAHEP) accredits O&P educational programs.

Pedorthic educational programs are accredited by the Commission on Accreditation of Pedorthic Education (CAPE). CAPE is sponsored by both the American Board for Certification of Orthotists, Prosthetists & Pedorthists (ABC) and the Pedorthic Footwear Association (PFA). CAPE accredited programs are not recognized by the CAAHEP or any other national or regional accreditation board.

National Commission on Orthotic and Prosthetic Education

The National Commission on Orthotic and Prosthetic Education (NCOPE) is a sponsoring Committee on Accreditation (CoA) of the Commission on Accreditation of Allied Health Education Programs (CAAHEP). The CAAHEP is recognized by the Council for Higher Education Accreditation (CHEA), and accredits programs with the advice of the NCOPE. The NCOPE accredits three types of programs: O&P Practitioners, O&P Technicians and Fitters (Orthotic, Mastectomy and Therapeutic Shoe Fitters). NCOPE also accredits practitioner residency programs

Currently, the NCOPE accredits baccalaureate and masters degree programs, and post-graduate certificate programs. By 2012, the NCOPE will only accredit programs enrolling students for master's degrees. NCOPE accredited practitioner programs must include clinical as well as classroom experience. Institutions are able to justify differing program lengths, but the NCOPE recommends that programs include 30 semester hours, or 900 real hours, in each discipline. Programs must include a minimum of 250 hours of clinical experience in each discipline.

Programs must cover following core content:

- Basic Sciences
- Patient Evaluation
- Formulation and implementation of a Treatment Plan
- Practice Management
- Specific Prosthetics and Orthotics Content Areas
    - This content area has extensive and detailed requirements

- Research Methods
- Clinical Experience

The NCOPE accreditation process is an extensive process that takes about 13 months to complete. Programs must reaccredit every five years. Initial accreditation costs $1000, while continuing accreditation costs $500. In either case, programs must cover the expenses of on-site evaluators. Additionally, accredited programs must pay a $750 annual fee. The NCOPE Accreditation Manual lists the following six steps in the accreditation process:

1. Letter of Intent
2. Self Study Report
3. Report reviewed by evaluators
4. Trained Evaluators conduct an on-site visit
5. Evaluator team prepares an evaluation report, which is reviewed by the program for factual accuracy
6. The Commission reviews all reports to make determination of an accreditation recommendation to CAAHEP

Institution	Location	Degrees Offered
California State University	CA	Baccalaureate, Postbaccalaureate Certificate
Newington Certificate Program	CT	Postbaccalaureate Certificate
Georgia Institute of Technology	GA	Master's Degree
Eastern Michigan University	MI	Master's Degree
Century College	MN	Postbaccalaureate Certificate
University of Texas Southwestern Medical Center	TX	Baccalaureate Degree
University of Washington	WA	Baccalaureate Degree
Northwestern University	IL	Postbaccalaureate Certificate
St. Petersburg College	FL	**Developing Program:** Baccalaureate

Table 5: NCOPE accredited O&P programs.

NCOPE also accredits residency sites. To achieve accreditation, residency sites must be ABC accredited, be directed by an ABC certified practitioner, employ one practitioner for every two residents and provide experience in a specified list of orthotic or prosthetic procedures, among other requirements. There are eleven accredited residency sites in Virginia:

- Coastal Prosthetics & Orthotics (Norfolk)
- Eastern Cranial Affiliates dba Infinite Technologies O&P (Arlington)
- Hanger P & O, Inc. (Newport News)
- Hanger Prosthetics & Orthotics (Lynchburg)
- Progressive Prosthetic & Orthotic Services, Inc. (Virginia Beach)
- Tidewater Prosthetic Center, Inc. (Suffolk)
- University of Virginia Div. of Prosthetics & Orthotics (Charlottesville)
- Virginia Prosthetics, Inc. (Roanoke)

- Williamsburg O & P (Newport News)[16]

Commission on Accreditation of Pedorthic Education

The American Board for Certification in Orthotics, Prosthetics & Pedorthics and the Pedorthic Footwear Association (PFA) sponsor the Commission on Accreditation of Pedorthic Education (CAPE) to ensure that Pedorthic educational programs meet the pre-certification guidelines required by the ABC.

To meet ABC standards, candidates applying for certification must first complete 120 hours of accredited education, including 54 hours of lab or "hands on" education. Alternatively, previously credentialed health professionals, such as medical doctors, certified orthotists or physical therapists, must complete only 84 hours of education before sitting for the exam. Non-Lab hours may be completed online.

Students may "mix and match" their education by attending multiple institutions and seminars, or they may attend a dedicated program. However, all students must complete a required number of hours in specified subject areas (see Table 6).

Subject Area	Total Hours	Lab Hours
Practice Management	4	-
Patient Management	4	-
Pathology of Diseases	16	-
Anatomy	4	-
Biomechanics	8	-
Orthotics	31	22
Modifications of Footwear	31	22
Footwear	11	6
Pedorthic Assessment	11	4

Table 6: Content areas for CAPE accredited programs

Accreditation is achieved by mailed application, including a Self Study. A $500 fee for new courses, or a $250 fee for annual renewals, must accompany applications. Properly credentialed instructors must teach all courses and content must meet the requirements set by the BCP Role Delineation Study. Accredited programs are subject to audit and surveys of students. Additionally, CAPE maintains a grievance procedure that can result in investigations. Accredited programs must undergo a comprehensive review at least once every ten years.

The CAPE website lists the following 11 accredited programs:

- Contemporary Pedorthics (Online with traveling lab component)
- Northwestern University (Illinois)
- Finch University (Illinois)
- Pro-Learn, LLC (Oklahoma)
- Foot Solutions (Georgia)
- Oklahoma State University (Oklahoma)
- Medical college of Wisconsin (Wisconsin)
- Temple University School of Podiatric Medicine (Pennsylvania)
- New York College of Podiatric Medicine (New York)

[16] NCOPE. "Residency Programs in the United States", http://www.ncope.org/info_residents/residency_programs_us.asp?st=va

- Xtra Depth University (New York)
- The Robert M. Palmer, M.D., Institute of Biomechanics, Inc. (Indiana)

ECONOMIC IMPACT

Salary Information

The Bureau of Labor Statistics' (BLS) Occupational Employment Statistics (OES) survey tracks salary information on orthotists and prosthetists in the category O*rthotists and Prosthetists* (SOC 29-2091) and on technicians in the category *Medical Appliance Technicians* (SOC 51-9082). The OES survey only tracks employed (not self-employed or unemployed) workers. The latest OES data is from May, 2007. In addition to the BLS, the American Orthotic & Prosthetic Association (AOPA) provides salary information on practitioners, technicians and residents and the American Medical Association provides information on practitioners. The Pedorthic Footwear Association (PFA) conducts an annual survey of certified pedorthists.

O&P Practitioners

The BLS provides state level data on salaries, as well as information on salary ranges. Table 7 provides an overview of BLS salary data for orthotists and prosthetists working in Virginia, Virginia's border states, and nationally. It also includes the 90th and 10th percentile ranges for practitioners employed in Virginia. The BLS data does not include self-employed practitioners, who may earn significantly different amounts.

State	Work force	Hourly mean wage	Annual Mean Wage
North Carolina	140	$21.26	$44,210
Tennessee	200	$22.33	$46,450
Maryland	30	$27.61	$57,440
Kentucky	NA	$29.07	$60,480
Virginia	**NA**	**$31.99**	**$66,550**
10th percentile		$18.95	$39,420
90th percentile		$50.66	$105,370
National	5,600	$30.90	$64,280

Table 7: Employment and salary information for orthotists and prosthetists from the Bureau of Labor Statistics.

The AOPA's 2007 Operating Performance & Compensation Survey found that ABC certified orthotists/prosthetists with 15 years of experience earned $89,334 annually. Entry-level practitioners completing their one-year NCOPE accredited residencies earned $33,742.[17] The AOPA's 2000 Business and Salary Survey Report found significant pay differences between BOC and ABC certified practitioners over the course of their careers. The results of the 2000 survey are reported in Table 8. Care should be taken when considering these findings, however. The AOPA reports that the 2000 survey suffered from a low response rate and that large firms were overrepresented in the sample.[18]

[17] As reported on the American Academy of Orthotists & Prosthetists career information website, www.opcareers.org. See http://www.opcareers.org/employment/. Accessed 12/1/2008.
[18] See http://www.aopanet.org/advance_your_career/job_listings/

	< 2 Years Experience	2-5 Years Experience	5+ Years Experience
BOC Certified	$36,527	$46,993	$57,880
ABC Certified	$48,760	$64,857	$91,455

Table 8: AOPA Salary information on BOC and ABC practitioner certifications. The AOPA survey suffered from a low response rate and overrepresentation by large employers.

The American Medical Association reports on its Health Care Career website that orthotists and prosthetists earned between $42,000 and $60,000, on average, in 2003. Starting salaries for orthotists and prosthetists were between $22,000 and $35,000 on average.[19]

All of these surveys use differing methodologies of varying validity and they survey different populations. Care should be taken when generalizing findings, especially when comparing the market value of different certifications. Nevertheless, the surveys report similar results for average and entry level salaries, lending support to the validity of average and entry-level salary estimates.

Technicians

The BLS provides state level data on salaries and salary ranges for medical appliance technicians. According to BLS data, Virginia is the top paying state for medical appliance technicians. Table 9 provides an overview of BLS salary data for medical appliance technicians working in Virginia, Virginia's border states, and nationally. It also includes the 90th and 10th percentile ranges for technicians employed in Virginia.

State	Work force	Hourly mean wage	Annual Mean Wage
West Virginia	70	$15.15	$31,500
North Carolina	330	$18.08	$37,610
Tennessee	90	$15.10	$31,420
Maryland	160	$18.86	$39,220
Kentucky	100	$14.63	$30,420
Virginia	**270**	**$24.70**	**$51,370**
10th percentile		$10.25	$21,320
90th percentile		$45.11	$93,830
National	11,900	$17.31	$36,010

Table 9: Employment and salary data on medical appliance technicians from the BLS.

The AOPA's 2007 Operating Performance & Compensation Survey found that ABC Registered Technicians earned $43,786 on average[20], or over 20 percent more than the national average for medical appliance technicians reported by the BLS.

Pedorthists

The BLS does not track pedorthists as a separate category. Beginning in 2006, however, the Pedorthic Footwear Association (PFA) began conducting annual surveys of

[19] See American Medical Association "Health Care Career Income Ranges" at http://www.ama-assn.org/ama/pub/category/6038.html. Accessed 12/1/2008.
[20] As reported on the American Academy of Orthotists & Prosthetists career information website, www.opcareers.org. See http://www.opcareers.org/employment/. Accessed 12/1/2008.

certified pedorthists. The survey does not include information on non-certified practitioners. Salaries for non-certified pedorthists may vary significantly from certified pedorthists. In 2007, PFA sent out 2,270 surveys and received 473 responses. The PFA reports a ± 4 percent margin of error at a 95 percent confidence level, indicating that the results are statistically reliable for the population surveyed.

The PFA survey results indicate that certified pedorthists earn, on average, $57,174 annually. Pedorthists certified for less than three years earned, on average, $51,880 annually. Table 10 provides an overview of the salary results. Certified Pedorthists that owned their own businesses had significantly higher incomes. Business incomes averaged $381,590. [21]

Years Certified in Pedorthics	Annual Income
Up to 3	$51,880
4 to 6	$52,060
7 to 15	$59,945
16 to 25	$70,500
More than 25	$82,495
Overall	$57,174

Table 10: Salaries of certified pedorthists from the PFA

Economic Effect of Certifications

Although the earnings potential of orthotists, prosthetists, pedorthists and technicians are significant, the costs of certification can be high for entry-level professionals. Table11 provides an overview of the cost of certifications in hours worked for some entry-level salaries provided from the salary surveys. An entry-level salary estimation for pedorthists is not available.

	Hourly Salary	Cost: ABC Certification	Cost: BOC Certification
O&P Practitioner		*$1,350*	*$1200/$975*
BLS: 10th Percentile (Virginia)	$18.95	71 hrs	63 / 51 hrs
AOPA: Resident Salary	$16.22	83 hrs	74 / 60 hrs
Technician		*$250*	*NA*
BLS: 10th percentile (Virginia)	$10.25	24.39	NA

Table 11: The cost of certification in hours worked for various entry-level wage levels. All hour amounts are rounded. The hourly salary for AOPA: Resident Salary is based on a 40-hour work week.

It is difficult to gauge the earnings incentives of certifications for orthotists, prosthetists and pedorthists. Earnings of practitioners were similar in AOPA, AMA and BLS surveys. While the 2000 Business and Salary Survey Report conducted by the AOPA indicates significant differences in earnings between those with BOC and ABC certifications, the survey suffered from a small, non-representative sample. The PFA survey only included certified pedorthists. However, practitioners must be certified to receive reimbursement for prosthetics and custom-made orthotics by Medicare or Medicaid, indicating increased earnings potential for certified practitioners.

[21] Pedorthic Footwear Association. September 2007. "2007 Industry Profile Survey of Certified Pedorthists: Final Results" SmithBucklin Corporation: The Market Research & Statistics Group. See page 5 for survey information and page 9 and 11 for income information. http://www.pedorthics.org/portals/0/2007_PFA_Survey.pdf

Clearer information exists for Registered Technicians. The average salary of Registered Technicians reported by the AOPA was $9,776, or over 20 percent, higher than the average salary of all medical appliance technicians as reported by the BLS.

Certification for orthotists, prosthetists and pedorthists is likely to become more important as CMS standards for prefabricated DMEPOS facility accreditations become effective on September 30, 2009 (See above). Certification is already required for custom devices. Though orthotists and prosthetists are exempt from the September 30, 2009 deadline, CMS plans to issue rules and a new deadline for orthotists and prosthetists sometime in 2009. CMS quality standards require that "individuals supplying the(se) item(s) … must possess specialized education, training, and experience in fitting, *and certification and/or licensing*" (emphasis added).[22] Additionally, many insurance companies already require facility accreditation, while many that do not at this time may adopt CMS rules in 2009.[23] Thus, the earnings potential of non-certified practitioners is likely to decrease in the future.

CURRENT REGULATIONS

Federal

Social Security Act

Section 1834(h) of the *Social Security Act*, as amended, requires that Medicare Part B reimburse costs for prosthetics or custom-fabricated orthotics only when these items are:

1. Furnished by a qualified practitioner
2. Fabricated by a practitioner or qualified supplier
3. At a facility that meets criteria established by the Secretary

Qualified Practitioners are:

1. Qualified Physical Therapists and Occupational Therapists
2. Licensed Orthotists and Prosthetists in states where these professions are licensed
3. In states not requiring licensure, Certified by the ABC or the BOC or another credentialing organization approved by the Secretary.

Qualified Suppliers are facilities that are accredited by the ABC or the BOC or other accrediting agency determined by the Secretary.

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[22] Centers for Medicare & Medicaid Services. October 2008. "Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Quality Standards." http://www.cms.hhs.gov/MedicareProviderSupEnroll/Downloads/DMEPOSAccreditationStandards.pdf. Accessed 11/26/2008.

[23] See the American Board for Certification in Orthotics, Prosthetics & Pedorthics, May 31, 2005, "ABC Accreditation: A Growing Requirement for Insurance Reimbursement" and Feb. 22, 2005, "ABC Selected as the Accreditation Standard for Linkia Managed Care Organization." Available at: http://www.abcop.org/News.asp. Accessed 12/01/2008.

Medicare Improvements for Patients and Providers Act of 2008

The *Medicare Improvements for Patients and Providers Act of 2008* (MIPPA) requires that suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) be accredited before receiving reimbursement. See below

Virginia

Department of Medical Assistance Services

The Virginia Department of Medical Services (DMAS) oversees Medicaid services, including extending Medicaid Benefits for prosthetic devices.

Prosthetics:

The DMS maintains a Prosthetic Device Manual, and its contents are included in participation agreements with prosthetic suppliers. In addition to complying with Federal and State laws and regulations, the Prosthetic Device Manual lists the following certification requirement specific to prosthetic providers:

> "A participating provider is a supplier of prosthetic devices that is certified by the American Board for Certification in Orthotics and Prosthetics and has a current, signed participation agreement with the Department of Medical Assistance Services (DMAS)."[24]

Prosthetics benefits must be pre-authorized before they are extended. The Medicaid benefit is extended to medically necessary prosthetic arms, legs, eyes, breasts and the provision of internal (implant) body parts prescribed by a licensed practitioner. It explicitly excludes orthotics, organ transplants, orthopedic footwear, and shoe modifications. Both the prescribing physician and the prosthetist must provide a Certificate of Need form.

Orthotics:

Orthotics are regulated as described in the Durable Medical Equipment and Supplies Manual. Orthotics are defined as:

> "Orthotic device services include devices that support or align extremities to prevent or correct deformities or improve functioning and services necessary to design the device, including measuring, fitting, and instructing the recipient in its use."[25]

[24] Prosthetic Device Manual, Provider Participation Requirements, Pg. 1. revised 10-01-2004.
[25] Durable Medical Equipment and Supplies Manual, Covered Services and Limitations, Pg. 46. revised 10-27-2007

Supplies used in the course of treatment at the practitioner's office, such as Ace Bandages, splints or slings, are covered normally. Similarly, items made by an occupational therapist such as slings or supports, are covered as part of an approved outpatient rehabilitation visit.

Other Orthotics, however, are specifically excluded from coverage unless the recipient is participating in an approved Intensive Rehabilitation Program. Intensive Rehabilitation Programs must be ordered by a physician. To be covered, Orthotics must be directly related to the rehabilitation program, prescribed by a doctor and receive preauthorization from DMS.

Orthotic suppliers have no specific certification or licensure requirements beyond that of being a participating provider with a signed participation agreement.

Prosthetic Parity Senate Bill 1116

With the past decade, coalitions of patients, trade associations, advocacy groups and concerned citizens have begun Prosthetic Parity campaigns at the national and state level. Prosthetic parity refers to the campaigns' attempts to mandate third-party coverage of prosthetics, repairs and replacements through legislation, putting prosthetic care "on par with other critical medical devices."[26] Federal insurance programs, including Medicare, Medicaid and the Veterans Administration, cover prosthetics and the long-term care of prosthetics. Additionally, traumatic care insurance providers, such as automobile or workers compensation insurance, cover prosthetic devices. However, many private third-party payers and health maintenance organizations do not cover prosthetics or do not cover repair or replacement of worn or damaged prosthetics.

Colorado, Maine, New Hampshire, Rhode Island, Massachusetts, California and Oregon have all passed prosthetic parity laws. Twenty-eight states are considering bills, including Virginia. The Virginia General Assembly first considered a prosthetic parity law in 2007. Following study into the potential impact of the bill, provisions that required coverage equal to coverage provided by Medicare were removed. The modified bill was enacted effective July 01, 2009 as Chapter 839 or the Acts of Assembly. The text of the law appears in Appendix C.

State Regulations

Currently, twelve states regulate OP & P Professionals. Each state requires licenses for Orthotic and/or Prosthetic practitioners. Seven require licenses for Pedorthists, while New Jersey allows for voluntary licensing of Pedorthists. Six require licenses or registration for assistants, technicians and/or fitters and two accredit facilities.

[26] Amputee Coalition of America, "Prosthetic Coverage is Good Medicine for Working Families." Washington D.C. http://www.amputee-coalition.org/advocacy/fact_sheets/campaign_fact_sheet.pdf Accessed 12/2/2008.

Eleven states accept or require ABC certifications, have license requirements equivalent to ABC certification or use the ABC exam as the license exam. Three states accept or require BOC certifications, though none accept the non- NCCA accredited BOC Pedorthist certification. Residency and experience requirements tend to be in line with certification requirements, though Ohio requires and additional 8 months of supervised experience. All states have continuing education requirements, ranging from 12 to 15 annually per discipline, except for Tennessee and Georgia which are still in the process of promulgating rules.

State	Level	ABC	BOC	Other	Experience	Fees	Renewal	Fee	CEU
Alabama	License	Y	Y	Exam		$675/975	1 yr	Same	17/22
Pedorthist	License	Y				$675	1 yr	Same	
Assistant	License	Y	Y	Exam		$425	1 yr	Same	
Supplier	Register					$500	1 yr	Same	
Facility	Accredit	Y	Y				1 yr		
Arkansas	License	Y				$300	2 yr		15/20
Pedorthist	License	Y				$300	2 yr		11
Assistant	Certify				5 yrs	$100	2 yr		7.5/10
Florida	License	Y			1900 hrs	$1005	2 yr	$500	15
Pedorthist	License	Y			80 hrs	$1005	2 yr	$500	15
Orthotic Fitter	License			SAI/TAIT	3800 hrs	$1005	2 yr	$500	10
Fitter Asstistant	License			SAI/TAIT		$1005	2 yr	$500	5
Georgia-2007	License	Y				$200/300	2 yr		
Illinois	License	Y				$400/800	2 yr	$125	15
Pedorthist	License	Y			80 hr	$400	2 yr	$125	15
CEU Sponsor	Authorize					$500	2 yr	$250	
New Jersey	License	Y			1900 hr	$675	2 yr	$350	15/20
Pedorthist	Voluntary	Y					2 yr		
Assistant	License			Exam & 40 hrs education	1900 hr	$475	2 yr	$150	6/8
Facility				Required Equipment					
Ohio	License	Y			8 months/ 1900hr	$125	1 yr	$300	15/25
Pedorthist	License	Y							11
Oklahoma	License	Y	Y			$250	2 yr	$125	15
Pedorthist	License	Y				$150	1 yr		11
Technician	Register	Y	Y			$50	2 yr	$50	3
Assistant	Register	Y	Y			$75	2 yr	$75	5
Rhode Island	License	Y	Y			$330	2 yr	$170	Cert.
Tennessee-2008	License	Y				$310			
Pedorthists	License	Y				$310			
Texas	License			Post Grad, Exam	1900 hrs	$312/412	2 yr	Same	12/20
Assistant	License			Assoc, Exam	1000 hrs	$212/262	2 yr	Same	6/10
Technician	Register				1000 hrs	$108/160	2 yr	Same	3/5
Facility	Accredit					$420/532	2 yr	Same	
Washington	License	Y			1900 hrs	$250/ discount	1 yr	$50	15/20

Table 11: Overview of state regulations. All states listed license practitioners. Fees and CEU requirements for single discipline or combined O&P licenses are separated by a "/".

HARM

Complications[27]

Orthotic, prosthetic and pedorthic devices are not invasive. However, their impact human function and motion can affect the entire musculoskeletal system. Poorly designed devices can result in device failure, decreased functionality, arthritis or other pain, skin breakdown, discomfort or increased mental distress (often associated with a loss of limb).

Additionally, their close contact with skin and flesh and the requirement for a tight fit can cause skin, nerve or pulmonary complications. Practitioners must be able to differentiate normal skin adaptations from serious skin or pulmonary disorders. This is especially true for weight-bearing lower limb prosthetic and pedorthic devices and orthotics for the spine.

The weight of a person using a weight-bearing prosthetic is borne by tissues not generally adequate for that purpose. Sockets must fit well to prevent further damage to the residual limb and to avoid discomfort and pain. In some cases, practitioners may design sockets to reshape the residual limb.

In addition to normal complications, improper or inappropriate use of orthotics may result in decreased use of functional limbs. This can result in muscle atrophy, osteopenia (loss of bone density), decreased pulmonary capacity or physical or psychological dependency on the device.

Fraud

Orthotists, Prosthetists and Pedorthists often work independently and maintain their own clinics and businesses. Medicare and other insurance providers reimburse practitioners directly for services and devices prescribed by a physician. This makes the practice of orthotists, prosthetists and pedorthists vulnerable to fraud.

In January 2007, the US General Accountability Office (GAO) published a report on the effectiveness of contractors hired to detect Medicare fraud in the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) area. The report notes that the CMS estimates it made approximately $700 million in improper payments for DMEPOS between April 1, 2005 and March 31, 2006.

Among improper claims, the GAO noted that Medicare had paid over $2 million from October 2002 and March 2005 for orthotic braces for beneficiaries who, according to Medicare payment records, had already received prosthetics for the same limb (i.e. Medicare paid for braces for limbs that did not exist or for prosthetics for limbs that did.)

[27] See Kelly, Brian, DO November 2, 2007, "Lower Limb Prosthetics" and Kulkarni, Shantanu, DO, "Spinal Orthotics" on eMedicine: Physical Medicine and Rehablitation Section. http://www.emedicine.com/pmr/index.shtml. Accessed 12/2/2008.

Over the same period, CMS paid $500,000 for beneficiaries to receive multiple (more than two) of the same prosthetic limb with one year.[28]

A notable case occurred in Florida in 2004. Forty-eight small durable medical equipment suppliers conspired to charge Medicare for prosthetics that beneficiaries did not need or receive. Before federal prosecutors broke the case, the companies had received $122 million in fraudulent charges. None of these suppliers were licensed or certified to provide custom prosthetic or orthotics, as required by Florida law.[29]

A 1997 Study conducted by the US Department of Health and Human Services noted that 68 percent of questionable Medicare billings for orthotics involve durable medical suppliers, while only 35 percent involved orthotists. The same study found that 19 percent of orthotic devices paid for by Medicare are medically unnecessary.[30]

Malpractice Insurance

Orthotists, prosthetists and pedorthists are unique in that they provide direct patient care *and* fabricate and provide medical equipment and devices. Thus OP & P practitioners need both professional and product liability coverage.

Several insurance companies provide coverage specifically tailored to OP & P facilities:

Cailor-Fleming Insurance

Cailor-Fleming Insurance is an Ohio-based company exclusively endorsed by ABC, BOC, PrimeCare, NAAOP and several state chapters of the AAOP. The application requires information on facilities, experience, equipment used, staff, certification and professional memberships. It also requests sales information on five categories of sales: Practitioner Patient Care, manufacturing, wholesale distribution, retail customers, medical equipment repair.

Chittenden Insurance Group

In partnership with The Hartford Insurance Co, Chittenden provides comprehensive insurance for O&P including general liability, worker's compensation insurance and professional liability. The company maintains offices in NH, VT and MA. The application seeks information on facilities, staffing, professional memberships, equipment used and automobiles used. It also requests sales information on five sales categories: Practitioner Patient Care, Manufacturing, Wholesale Distribution, Retail Countersales and Other.

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[28] US Government Accountability Office, January 2007, *Medicare: Improvements Needed to Address Improper Payments for Medical Equipment and Supplies.* Report to the Ranking Minority Member, Committee on Finance, U.S. Senate. GAO-07-59. http://www.gao.gov/new.items/d0759.pdf

[29] The O&P Edge. "Florida Fraud Costs Medicare" OandP.com. http://www.oandp.com/edge/issues/articles/NEWS_2005-05-11_01.asp. Accessed 12/2/2008.

[30] US Department of Health and Human Services, Office of the Inspector General, October, 1997, *Medicare Orthotics*, OEI-02-95-00380

McNeil & Company

This New York Company provides HOMed O&P Plus insurance to O&P providers. The HOMed series of coverages specializes in Home Medical equipment dealers. It provides property, crime, employee, umbrella and commercial liability. Commercial liability coverage includes professional, products and contractual liability. It provides up to $3 million of aggregate liability.

AOPA Insurance Program

The American Orthotic & Prosthetic Association's Insurance Program is underwritten by AIG, Inc and AON Infinity. It provides general, product and professional liability coverage. It also provides worker's compensation coverage.

VGM Insurance

VGM provides O&P specific "OPGA Group Insurance." Standard coverage includes product liability, professional liability and general liability. Property and automobile insurance is also available. Coverage up to $5 million is available.

The application requests information on experience, facilities, employees, incidence of surgery, previous claims and certifications. It also seeks information of four sales categories: Patient Care Sales, Supplier/Distributor, Supplier/Manufacturer, DME-Durable Medical Equipment & Soft Goods.

AON Infinity Insurance Services Inc (Pedorthists)

Aon Infinity insurance provides the only insurance program endorsed by the Pedorthic Footwear Association. It provides up to $3 million annual aggregate insurance (Product, professional and premises). It also provides up to $5 million of Umbrella coverage. The application requests information on facilities, association membership, certifications and staffing, and experience. It also requests revenue information on three sources: Sales of shoes, orthotics and Accessories, repairs, and other.

Criticality Survey

As part of its effort to determine the risk of harm to consumers from the practice of orthotists and prosthetists, staff surveyed two members of the Board of Health Professions thought to have expert knowledge of the subject matter. Dr. Juan M. Montero, II, M.D. and Mr. Damien Howell, P.T. were asked to quantify the risk of harm associated with tasks listed in the Practice Analysis by the American Board for Certification in Orthotics, Prosthetics & Pedorthics, Inc.[31] In a survey of a small number of

[31] American Board for Certification in Orthotics, Prosthetics & Pedorthics, Inc. 2007. *Practice Analysis of Certified Practitioners in the Disciplines of Orthotics and Prosthetics*. *http://www.abcop.org/Assets/PDF/PracticeAnalysis_SS04.pdf*

experts, a strong concensus between the experts is necessary to ensure the validity of the results. This was not achieved, rendering the results inconclusive. The survey, and an overview of the results, appears in Appendix D.

PUBLIC COMMENT

The American Board for Certification in Orthotics, Prosthetics & Pedorthics, Inc. (ABC) provided written comment in support of licensure of orthotists, prosthetists and pedorthists using ABC certification as a condition of licensure. The comments emphasized that BOC certifications do not require a degree or a residency program. The comments also indicated that the board may wish to consider fitters. Lastly, the comments suggested recognition of ABC certifications as a possible alternative to licensure.

The Pedorthic Footwear Association (PFA) provided written comments in support of licensure of pedorthists. Their comments included background and justification for licensure, noting the growth of elderly and diabetic populations and legislative initiatives at federal and state levels. The comments also note that while Medicare requires certification, many pedorthists do not participate in Medicare programs, leaving a gap in coverage. Both groups provided model licensure legislation.

The Virginia Occupational Therapy Association (VOTA) provided comments opposed to licensure. VOTA does not support licensure of activities already included in the scopes of practice of occupational and physical therapy, or any regulation that would limit the existing scopes of practice for occupational or physical therapists or require additional licenses.

POLICY OPTIONS

When examining other health professions regulated within the Department of Health Professions' health regulatory boards, the key factors that are associated with each form of professional regulation are: educational requirements, examination requirements, scope of practice, discipline, and continuing education. To assist the Committee in its review, Table 9, below, provides an essential overview of each factor in relation to the form of traditional state regulation. It indicates whether the factor is necessarily required or associated with the form of regulation (Y), is optional (O), or is not required (N).

Form of Regulation	Educational Requirement	Examination Requriement	Discipline	Standards of Practice	Continuing Education
Licensure	O	O	Y	Y	O
Voluntary Certification	O	Y	Y	Y	O
Registration	N	N	Y	Y	O

Option 1-Licensure

Licensure is the most restrictive level of state regulation and largely confers a monopoly to the group in question. Licensure ensures that the scope-of-practice and the professional title are reserved to individuals who meet certain minimal competencies to safely practice. To select this option for Orthotist, Prosthetists or Pedorthists, all six Criteria must be met.

(1) There must be a high risk of harm to the consumer that results from the practices inherent in the profession, the characteristics of the clients served, and/or the setting or supervisory arrangements for health service delivery.
(2) The profession must be viewed as requiring special skills and training.
(3) Practitioners must generally practice autonomously.
(4) The scope of practice is distinguishable from other health professions and occupations.
(5) The economic costs to the public of regulation and the potential reduction of supply are justified.
(6) Alternatives such as strengthening inspections and injunctions, disclosure requirements and consumer protection laws and regulations are insufficient to address the risk of harm to the public from the unregulated practice of the profession.

Option 2 – Voluntary Certification

This is the second most restrictive level of regulation. It presumes a moderate potential for risk of harm to the public that is attributable to the nature of the practice, client vulnerability, or practice setting and level of supervision. It requires that all of the Criteria listed above be met, except #3 (Autonomous Practice). Voluntary certification provides assurances for the public that the individual practitioner who obtains certification has at least a minimal level of competency to safely practice. It affords discipline of the certificate holder. The scope-of-practice is not restricted, but the use of the professional titles or credentials would be reserved to those meeting the certification requirements. This method affords consumers and employers with a means of identifying competent practitioners but does not restrict the performance of their duties only to those certified.

Option 3 – Registration

Registration simply requires that all practitioners be registered as individual practitioners. Discipline could be taken against the registrant and not simply the facility. There is no test of minimal competency. This option provides accountability of the individual without the potential economic impact of restricting the supply of practitioners. Clients, supervisors, and others would be able to track disciplinary history of the individual which should preclude incompetent or unscrupulous practitioners from leaving one area in Virginia only to go to another. Criteria #1, #4, #5 and #6 must be met.

For Options #1, #2 or #3, the regulation of practitioners should be housed within a recognized board that can assure competency, set appropriate standards of care, and take disciplinary action when necessary.

Option 4 – No Professional Regulation

To select this option, the work of practitioners must be considered safe, ordinary work, with no special, distinguishable knowledge or skill required to adequately protect the public's health, safety and welfare.

Note: In addition to these options, the Board may wish to consider regulation of technicians or fitters, or to consider facility accreditation.

RECOMMENDATIONS

Noting an insufficiency of evidence, the Regulatory Research Committee determined that the risk of harm to consumers does not outweigh the economic costs of a licensure program, including direct costs to taxpayers, regulatory burden and restriction of supply, at this time.

At their December 17, 2008 meeting, following a properly seconded motion by Dr. Boone, the Regulatory Research Committee voted unanimously to recommend not regulating pedorthists at this time. At the meeting of the full Board of Health Professions, held on the same day, the board voted to accept the recommendation following a properly seconded motion by Dr. Chadwick.

At their May 12, 2009 meeting, following a properly seconded motion by Ms. Seymour, the Regulatory Research Committee voted unanimously to recommend not regulating orthotists or prosthetists at this time. At the meeting of the full Board of Health Professions, held on the same day, the board voted to accept the recommendation following a properly seconded motion by Ms. Hughes.

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American Academy of Orthotists & Prosthetists: www.oandp.org

American Academy of Physical Medicine and Rehabilitation: www.aapmr.org

American Board for Certification in Orthotics, Prosthetics & Pedorthics: www.abcop.org

American Medical Association: www.ama-assn.org

Amputee Coalition of America: www.amputee-coaltion.org

American Orthotics & Prosthetics Association: www.aopanet.org

American Physical Therapy Association: www.apta.org
Arkansas Department of Health: www.healthyarkansas.com

Association of Children's Prosthetic-Orthotic Clinics: www.acpoc.org

Board for Orthotist/Prosthetist Certification: www.bocusa.org

Bureau of Labor Statistics: www.bls.gov
Centers for Medicare & Medicaid Services, Durable Medical Equipment Center: www.cms.hhs.gov/center/dme.asp

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New Jersey, Board of Orthotics and Prosthetics Examiners: www.state.nj.us/lps/ca/medical/orthotic.htm

O&P Edge: www.oandp.com

Oklahoma State Board of Medical Licensure and Supervision: www.okmedicalboard.org/medboard/index.php

Ohio Board of Orthotics, Prosthetics and Pedorthics: www.ohio.gov/bop

Orthotics & Prosthetics Careers: www.opcareers.org

Pedorthic Footwear Association: www.pedorthics.org

PrimeCare Orthotics & Prosthetics Network: www.primecareop.com

Rhode Island Division of Health Professions Regulation:
www.health.state.ri.us/hsr/professions/

Social Security Online: www.ssa.gov

Tennessee Department of Health, Health Related Boards: www.tennessee.gov/health/

Texas Board of Orthotics and Prosthetics: www.dshs.state.tx.us/op/

United States Member Society of the International Society for Prosthetics and Orthotics:
www.usispo.org

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www.cerse.vcu.edu

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APPENDICES
Appendix A

Scopes of Practice

American Board for Certification in Orthotics, Prosthetics and Pedorthics

Certified Pedorthists
Effective January 1, 1997 (Revised March 17, 2003)*
* This Scope of Practice is that of the former Board for Certification in Pedorthics (BCP). It remained unchanged after the integration of the ABC and the BCP.

Practice of Pedorthics:
Pedorthics is the practice, pursuant to a written order/prescription when addressing a medical condition, of evaluating, treatment planning, patient managing, measuring, designing, fabricating, assembling, fitting, adjusting or servicing, necessary to accomplish the application of a pedorthic device for the prevention or amelioration of painful and/or disabling conditions of the foot and ankle.

Certified Pedorthist (C.Ped.):
A certified pedorthist (C.Ped.) is a professional whose competence in the practice of pedorthics is credentialed by the American Board for Certification in Orthotics, Prosthetics and Pedorthics, Inc. To become certified, a pedorthist must meet initial educational requirements and pass a comprehensive written exam given by the American Board for Certification in Orthotics, Prosthetics and Pedorthics (ABC) which is accredited by the National Commission for Certifying Agencies. Once certified, a pedorthist must meet continuing education and annual renewal requirements to maintain pedorthic certification. The certified pedorthist must also adhere to the ABC *Code of Professional Responsibility* to ensure the highest scope of professional competence and deportment. The practice of pedorthics by a certified pedorthist inherently includes both prescriptive and nonprescriptive work because of the universal use of footwear. As a member of the health care team, a C.Ped. plays an important role in the patient's foot care; however, absent another professional certification or credential, a certified pedorthist shall not diagnose, prescribe, provide medical prognosis, or perform invasive procedures. A written order/prescription is required for any pedorthic device, modification, and/or prefabricated below the knee anatomical support addressing a medical condition. A C.Ped's activities must reflect his/her certification and education. A C.Ped fits, fabricates, adjusts, modifies, or transfers devices which reflect his/her certification.

Pedorthic devices:
"Pedorthic devices" means therapeutic shoes, shoe modifications made for therapeutic purposes, partial foot prostheses (L5000), foot orthoses and subtalar-control foot orthoses (SCFO, see below). Pedorthic devices do not include non-therapeutic, accommodative inlays and non-therapeutic accommodative footwear, regardless of method of

manufacture; unmodified, non-therapeutic over-the-counter shoes; or prefabricated foot care products. For purposes of this document, "accommodative" means designed with a primary goal of conforming to the individual's anatomy, and "therapeutic" devices are devices that address a medical condition, while non-therapeutic devices are devices that do not address a medical condition.

Subtalar -Control Foot Orthosis (SCFO)

Subtalar-Control Foot Orthosis (SCFO): a lower extremity orthosis designed to manage the function of the anatomy distal to the ankle joint* by controlling the range of motion of the subtalar joint**. The proximal length of a SCFO does not extend beyond the musculotendonis junction of the gastrocnemius and the calcaneal (Achilles) tendon. A SCFO is a method of treatment of conditions related to the foot demanding additional surface area to control forces. A SCFO does not include a supramalleoli orthosis.

*Ankle Joint

Ankle Joint Articulations

- Talus
  - o Talar trochlea
- Tibia
  - o Inferior articular surface
  - o Articular surface of the medial malleolus
- Fibula
  - o Articular surface of the inferior lateral malleolus

Ankle Joint Function: The ankle joint is a single plane joint consisting of the sagital motions of plantar flexion and dorsiflexion

**Subtalar Joint

Subtalar Joint Articulations

- Calcaneous
  - o Middle articular surface
  - o Posterior articular surface
- Talus
  - o Talo-calcaneal
  - o Talo-navicular

Subtalar Joint Function: The subtalar joint is a multi-plane or tri-plane motion joint consisting of the frontal plane motion of inversion/eversion, the transverse plane motion of abduction/adduction, and the sagital plane motion of flexion/extension.

Orthotics & Prosthetics: Scope of Practice

From the Report prepared by the Scope of Practice Task Force of the American Board for Certification in Orthotics and Prosthetics, Inc.
http://www.abcop.org/Assets/PDF/ScopeOfPractice.pdf

FOREWORD

The Board of Directors of the American Board for Certification in Orthotics and Prosthetics, Inc., (ABC) commissioned a task force to develop an *Orthotic and Prosthetic Scope of Practice* document for use by orthotic and prosthetic professionals, consumers, members of the rehabilitation team and health care decision makers. To write this consensus document, the task force used a variety of resources including the *1996 Report of the Task Force on the Scope of Practice in Orthotics and Prosthetics* and the *PracticeAnalysis of the Disciplines of Orthotics and Prosthetics.* In addition, the task force conducted both a survey of the profession as well as interviews with credentialed individuals.

This *Orthotic and Prosthetic Scope of Practice* document defines several aspects of the orthotic and prosthetic professions, including the scope of comprehensive orthotic and prosthetic care, the specific tasks performed by orthotic and prosthetic professionals and the common terms used in the profession. This document also delineates the levels of orthotic and prosthetic supervision and identifies where orthotists and prosthetists work as well as what devices they provide.
Any scope of practice document should be revised periodically, and it is the intent of ABC to revise this document as the practice of orthotics and prosthetics changes.

This publication represents the shared efforts of many dedicated individuals. ABC is grateful for the commitment of the task force members and staff who devoted their time and effort to this project.

Jack E. Uellendahl, CPO
President

INTRODUCTION

Orthotics and prosthetics is a specialized health care profession, which combines a unique blend of clinical and technical skills. Orthotists and prosthetists evaluate patients and custom design, fabricate and fit orthoses and prostheses. Orthotic patients have neuromuscular and musculoskeletal disorders, and prosthetic patients have a partial or total absence of a limb. Orthotists and prosthetists give their patients the ability to lead more active and independent lives by working with other members of the rehabilitation team to create a treatment plan and custom device. This work requires substantial clinical and technical judgment.
The practice of orthotics and prosthetics has its history in the artisans and other skilled craftsmen of the past.Many of the developments of the 20th century in both professions came out of the world wars and the polio epidemics of the 1950s. Today’s practitioners work in a variety of settings and use innovative materials and techniques to restore function and provide relief for many impairments.
The principles of biomechanics, pathomechanics, gait analysis, kinesiology, anatomy and physiology are crucial to the practitioner’s ability to provide comprehensive patient care

and a positive clinical outcome. Patient assessment, treatment and education are part of the practitioner's responsibility and require collaborative communication skills.
The professions of orthotics and prosthetics have advanced together, as the same skills and knowledge base are necessary to evaluate for and design custom orthoses and prostheses.
The scope of orthotic and prosthetic practice is delineated in this publication to assist those with an interest in the professions or with a need to describe the professions to other interested parties.

EDUCATION AND EXPERIENCE QUALIFICATIONS

Individuals interested in an education in orthotics and prosthetics attend schools with curriculum specific programs accredited by the Commission on Accreditation of Allied Health Education Programs (CAAHEP) and the National Commission on Orthotic and Prosthetic Education (NCOPE). The accredited educational programs meet standards of quality designed to prepare individuals to enter the orthotic and prosthetic professions at all levels.

Orthotic and prosthetic assistants and technicians may attend associate degree or certificate level programs that include hands-on experience and emphasize the technical and assistive aspects of the profession. Assistants, technicians and fitters also enter the field through on-the-job training.
Orthotic and prosthetic practitioners receive their baccalaureate or post-baccalaureate education at colleges or universities. Post-baccalaureate clinical experience is required through a structured residency program. NCOPE accredited residency sites provide the orthotic and prosthetic resident with qualified experience that extends the education and training process into the patient management setting.

CREDENTIALING

Orthotic and prosthetic board certification and registration are available to members of the profession through the American Board for Certification in Orthotics and Prosthetics, Inc., (ABC). Established in 1948, ABC's credentialing program seeks to recognize those who have met specific educational and residency standards and who have demonstrated a level of knowledge and clinical skills through successfully completing the certification or registration examinations.
ABC credentialed individuals must obtain mandatory continuing education credits to maintain their certification/registration at a five-year renewal cycle. They are also bound by a code of ethical conduct that provides a framework for professional conduct in consideration of the patient, allied health colleagues and the profession.
ABC credentialing requirements were established to maintain improved quality of care, assure patient safety and promote the appropriate utilization of orthotic and prosthetic services.
The following credentials are awarded by ABC:

CO, Certified Orthotist

CP, Certified Prosthetist
CPO, Certified Prosthetist-Orthotist
ROA, Registered Orthotic Assistant
RPA, Registered Prosthetic Assistant
RPOA, Registered Prosthetic-Orthotic Assistant
RTO, Registered Orthotic Technician
RTP, Registered Prosthetic Technician
RTPO, Registered Prosthetic-Orthotic Technician
RFO, Registered Fitter-Orthotics
RFM, Registered Fitter-Mastectomy
RFOM, Registered Fitter-Orthotics/Mastectomy

PRACTICE SETTINGS

The practice of orthotics and prosthetics is carried out in many settings, including the following:

☛ Orthotic and prosthetic facilities

☛ Hospitals

☛ Specialty clinics

☛ Acute care facilities

☛ Rehabilitation facilities

☛ University and research facilities

☛ Rural outreach clinics

☛ Home health settings

☛ Skilled nursing facilities

AREAS OF RESPONSIBILITY PERFORMED BY ABC CREDENTIALED ORTHOTIC AND PROSTHETIC PROFESSIONALS

Patient Assessment
Perform a comprehensive assessment of the patient to obtain an understanding of the patient's orthotic/prosthetic needs:

☛ Review patient's prescription/referral.

☛ Take a comprehensive patient history, including demographic characteristics, family dynamics, previous use of an orthosis/prosthesis, diagnosis, work history, avocational activities, signs and symptoms, medical history (including allergies to materials), reimbursement status, patient expectations, results of diagnostic evaluations.

☛ Assist in formulating the treatment plan by performing a diagnosis-specific functional clinical examination, including manual muscle testing, gait assessment and evaluation of

sensory function, cognitive ability, range of motion, joint stability, skin integrity and compliance.

☛ Consult with other health care professionals and caregivers about patient's condition to assist in formulating a treatment plan.

☛ Communicate with patient and/or caregiver about the recommended treatment plan, and any optional plans, to involve them in orthotic or prosthetic care; include disclosure of potential risks/benefits.

☛ Verify patient care by documenting history, ongoing care and follow-up, using established record-keeping techniques.

☛ Refer patient, if appropriate, to other health care professionals (e.g., psychologist, therapist, physician) for intervention beyond orthotic/prosthetic scope of practice.

Formulation of the Treatment Plan

Create a comprehensive orthotic/prosthetic treatment plan to meet the needs and goals of the patient:

☛ Evaluate the findings to determine an orthotic/prosthetic recommendation.

☛ Formulate treatment goals and expected orthotic/prosthetic outcomes to reduce pain/increase comfort, enhance function and independence, provide stability, prevent deformity, address cosmesis and/or promote healing.

☛ Consult with physician/referral source to modify, if necessary, the original prescription and/or treatment plan.

☛ Identify material, design and components to support anticipated outcome.

☛ Develop a plan for patient needs, including patient education and follow-up.

☛ Document treatment plan using established record-keeping techniques to verify patient care.

☛ Inform patient or responsible parties of their financial responsibilities, pertaining to proposed treatment plan.

Implementation of the Treatment Plan

Perform the necessary procedures to deliver the appropriate orthotic/prosthetic services, which may include fabrication of the orthosis/prosthesis:

☛ Inform patient, family and/or caregiver of the orthotic/prosthetic procedure, possible risks and time involved in the procedure.

☛ Select appropriate material/techniques to implement treatment plan.

☛ Provide patient with preparatory care for orthotic/prosthetic treatment (e.g., diagnostic splint, residual limb shrinker).

☛ Prepare patient for procedure required to initiate treatment plan (e.g., take impression, digitize, delineate, scan).

☛ Implement procedure (e.g., take impression, digitize, delineate, scan).

☛ Select appropriate materials, components and specifications for orthosis/prosthesis based on patient criteria to ensure optimum strength, durability and function as required (e.g., choose ankle or knee joints, feet, knee units; choose material of components, lamination layups).

☛ Consult technical component/material resources as required.

☛ Prepare delineation/impression/template for modification/fabrication (e.g., prepare impression/reverse delineation, seal and fill impression/pour cast, digitize, strip model, download shape to carver or modification software).

☛ Modify and prepare patient model for fabrication.

☛ Fabricate/assemble prescribed device by assembling selected materials/components to prepare for fitting and/or delivery (e.g., laminate/vacuum-form, remove socket/orthosis from model, smooth and finish orthosis/prosthesis, contour side bars to model/delineation, smooth and finish side bars, bench align components to socket, strap orthosis/prosthesis as necessary, perform final assembly of orthosis/prosthesis for patient fitting/delivery).

☛ Assess device for structural safety and ensure that manufacturers' guidelines have been followed prior to patient fitting/delivery (e.g., torque values, patient weight limits).

☛ Assess/align orthosis/prosthesis for accuracy in sagittal, transverse and coronal planes to provide maximum function/comfort.

☛ Provide gait training/functional-use training.

☛ Ensure that materials, design and components are fit/delivered as prescribed.

☛ Complete fabrication process after achieving optimal fit of orthosis/prosthesis (e.g., convert test socket to definitive orthosis/prosthesis).
☛Educate/counsel patient and/or caregiver about the use and maintenance of the orthosis/prosthesis (e.g., wear schedules, therapy, other instructions).
☛Reassess orthosis/prosthesis for structural safety prior to patient delivery (e.g., screws tightened, cover attached).
☛Document treatment using established record-keeping techniques to verify implementation of treatment plan.

Follow-up Treatment Plan
Provide continuing patient care and periodic evaluation to assure/maintain/document optimal fit and function of the orthosis/prosthesis:
☛Solicit subjective feedback from patient and/or caregiver to determine status (e.g., wear schedule/tolerance, comfort, perceived benefits, perceived detriments, ability to don and doff, proper usage and function, overall patient satisfaction).
☛Assess patient's functional level.
☛Assess patient's skin condition (e.g., integrity, color, temperature, volume).
☛Assess patient's general health, height, and weight, and note any changes.

☛Assess patient's psychosocial status, and note any changes (e.g., family status, job, caregiver).
☛Assess fit of orthosis/prosthesis with regard to strategic contact (e.g., three-point force systems, total contact) to determine need for changes relative to initial treatment goals.
☛Assess fit of orthosis/prosthesis with regard to anatomical relationships to orthosis/prosthesis (e.g., trimlines, static/dynamic alignment) to determine need for changes relative to initial treatment goals.
☛Formulate plan to modify orthosis/prosthesis based on findings; inform patient and/or caregiver of plan to modify orthosis/prosthesis.
☛Make or delegate modifications to orthosis/prosthesis (e.g., relieve pressure, change range of motion, change alignment, change components, add pressure-sensitive pad).
☛Assess modified device for structural safety, and ensure that manufacturers' guidelines (e.g., torque values, patient weight limits) have been followed.
☛Evaluate modifications to orthosis/prosthesis, including static and dynamic assessment to confirm that goals and objectives of modifications have been met.
☛Reassess patient knowledge and understanding of goals and objectives to ensure proper use of orthosis/prosthesis relative to modifications.
☛Document all findings and actions and communicate with appropriate health care professionals (e.g., referral sources, colleagues, supervisor) to ensure patient status is updated.

Practice Management

Develop, implement and/or monitor policies and procedures regarding human resource management, physical environment management, business/financial management and organizational management:
☛Plan, implement, evaluate and document policies and procedures in compliance with all applicable federal and state laws and regulations as well as professional and ethical guidelines (e.g., FDA, ADA, OSHA, MSDS, ABC Canon of Ethics).
☛Develop and implement personnel policies and procedures (e.g., benefits, training, incentives, staff recognition, regular performance appraisals).
☛Establish procedures for patient care that comply with accepted medical/legal requirements, and maintain current education in those areas.
☛Demonstrate proper documentation of patient history and financial records by using established record-keeping techniques to verify patient care and other pertinent information.
☛Communicate roles and expectations of employer and employees by providing documentation to create a professional, cooperative working environment and improve patient care.

Promotion of Competency and Enhancement of Professional Practice

Participate in personal and professional development through continuing education, training, research and organizational affiliations:
☛Participate in continuing education and/or provide such education for other health care professionals, orthotic and prosthetic practitioners, assistants, technicians, fitters and office staff (e.g., publications, seminars, case studies).
☛Participate in education for residents, students and trainees.

☞Conduct or participate in product development research, clinical trials and outcome evaluation studies.
☞Participate in the development, implementation and monitoring of public policy regarding orthotics/prosthetics (e.g., provide testimony/information to legislative/ regulatory bodies, serve on professional committees and regulatory agencies).
☞Participate in/with consumer organizations and nongovernmental organizations to promote competency and enhancement of orthotic/prosthetic profession.

COMMONLY USED ORTHOSES
Foot orthosis (FO)
Ankle-foot orthosis (AFO)
Knee orthosis (KO)
Knee-ankle-foot orthosis (KAFO)
Fracture orthosis
Hip orthosis (HO)
Hip-knee-ankle-foot orthosis (HKAFO)
Lumbosacral orthosis (LSO)
Thoracolumbosacral orthosis (TLSO)
Thoracolumbar orthosis (TLO)
Cervicothoracolumbosacral orthosis (CTLSO)
Cervical orthosis (CO)
Cranial remolding orthosis (CRO)
Cervicothoracic orthosis (CTO)
Halo cervical orthosis
Hand orthosis (HdO)
Wrist-hand orthosis (WHO)
Wrist orthosis (WO)
Elbow orthosis (EO)
Elbow-wrist-hand orthosis (EWHO)
Shoulder-elbow-wrist-hand orthosis (SEWHO)
Shoulder orthosis (SO)
Custom shoes
Diabetic footwear
Gradient compression hose
Custom seating

COMMONLY USED PROSTHESES
Postoperative prosthesis
Partial foot prosthesis
Symes prosthesis
Transtibial prosthesis
Knee disarticulation prosthesis
Transfemoral prosthesis
Hip disarticulation prosthesis
Hemi-pelvectomy prosthesis

Partial hand prosthesis
Wrist disarticulation prosthesis
Transradial prosthesis
Elbow disarticulation prosthesis
Transhumeral prosthesis
Shoulder disarticulation prosthesis
Cosmetic restoration prosthesis
Mastectomy prosthesis
Myoelectric prosthesis
Microprocessor prosthesis
Programmable function prosthesis

ORTHOTIC AND PROSTHETIC PATIENT CARE AND SERVICE PROVIDERS

ABC Certified Orthotist and/or Prosthetist

An ABC certified orthotist or prosthetist is an allied health professional who is specifically trained and educated to manage the provision of comprehensive orthotic and prosthetic care, based upon a clinical assessment and a physician's prescription, to restore physiological function and/or cosmesis.

The ABC certified practitioner independently provides or supervises the provision of comprehensive orthotic and prosthetic care. This includes patient assessment, formulation of a treatment plan, implementation of the treatment plan, follow-up and practice management.

The practitioner certified by the American Board for Certification in Orthotics and Prosthetics, Inc., (ABC) is bound by the ABC Canons of Ethical Conduct, which are enforced by a Professional Discipline program. The certified practitioner is obligated to support and conform to professional responsibilities that promote and assure the overall welfare of the patient and the integrity of the profession. The time-limited certification is based on participation in the Mandatory Continuing Education program.

ABC Registered Assistant

An ABC registered assistant is an individual trained and qualified to participate in the delivery of orthotic and prosthetic care while under the clinical supervision of an ABC certified practitioner.

The registered assistant supports the ABC certified practitioner by assisting in orthotic and prosthetic patient care. Under the guidance and supervision of the ABC certified practitioner, registered assistants may perform orthotic and prosthetic procedures and related tasks in the management of patients. The registered assistant also fabricates, repairs and maintains devices to provide maximum fit, function and cosmesis.

ABC registered assistants may not use their credentials as independent practitioners engaged in unsupervised patient care. The registered assistant is bound by the ABC Canons of Ethical Conduct, which are enforced by a Professional Discipline program. The registered assistant is obligated to support and conform to professional responsibilities that promote and assure the overall welfare of the patient and the integrity

of the profession. The time-limited registration is based on participation in the Mandatory Continuing Education program.

ABC Registered Technician

An ABC registered technician is an individual who supports the ABC certified practitioner by providing the technical implementation tasks and services associated with the support of patient care. Under the supervision of and in consultation with the practitioner, the registered technician fabricates, repairs and maintains devices to provide maximum fit, function and cosmesis. The registered technician is expected to keep abreast of all new fabricating techniques,must be familiar with the properties of pertinent materials and must be skilled in the use of appropriate equipment.

ABC registered technicians may not use their credentials as independent practitioners engaged in direct patient care. The registered technician is bound by the ABC Canons of Ethical Conduct, which are enforced by a Professional Discipline program. The registered technician is obligated to support and conform to professional responsibilities that promote and assure the overall welfare of the patient and the integrity of the profession.

The time-limited registration is based on participation in the Mandatory ContinuingEducation program.

ABC Registered Fitter-Orthotics

An ABC registered fitter-orthotics is an individual trained and qualified to participate in the fitting and delivery of prefabricated orthotic devices and/or soft goods. An ABC registered fitter-orthotics is competent to practice orthotics within a scope of practice that is specific to fitting prefabricated and off-the-shelf orthoses as described below:

- Cervical orthoses not requiring more than minor modification
- Pressure gradient hose
- Trusses
- Prefabricated spinal orthoses, except those used in the treatment of scoliosis, rigid body jackets made of thermoformable materials, and halo devices
- Prefabricated orthoses of upper and lower extremities, except those used in the treatment of bone fractures

The registered fitter-orthotics is bound by the ABC Canons of Ethical Conduct, which are enforced by a Professional Discipline program. The registered fitter-orthotics is obligated to support and conform to professional responsibilities that promote and assure the overall welfare of the patient and the integrity of the profession. The time-limited registration is based on participation in the Mandatory Continuing Education program.

ABC Registered Fitter-Mastectomy

An ABC registered fitter-mastectomy is an individual trained and qualified to participate in the fitting and delivery of breast prostheses and mastectomy products and services. An ABC registered fitter-mastectomy is competent to practice within a scope of practice that is specific to fitting breast prostheses and mastectomy products and services. The

registered fitter-mastectomy is bound by the ABC Canons of Ethical Conduct, which are enforced by a Professional Discipline program. The registered fitter-mastectomy is obligated to support and conform to professional responsibilities that promote and assure the overall welfare of the patient and the integrity of the profession. The timelimited registration is based on participation in the Mandatory Continuing Education program.

Other Personnel

Other personnel who work within the orthotic and prosthetic facility and under the supervision of an ABC certified practitioner should be employed under the appropriate title such as aide, office support personnel, etc. Any involvement with the provision of patient care must be within the scope of the individual's education and experience and must be directly supervised by the ABC certified practitioner.

LEVELS OF SUPERVISION OF ORTHOTIC AND PROSTHETIC PATIENT CARE

Direct Supervision

The caregiver is qualified to provide patient care under the direct on-site supervision of an ABC certified practitioner. The supervisor must be available for consultation throughout the patient care process,must review the results of care rendered by the supervised individual and is responsible for countersigning within 15 days all entries by the caregiver in the patient's clinical record.

Indirect Supervision

The caregiver is qualified to provide patient care as delegated by the ABC certified practitioner. The supervisor is not required to be on-site but must be available for immediate consultation during the delivery of care. The supervisor must review and countersign within 15 days all entries in the patient's clinical record.

The levels of supervision required per practice domain are summarized below:

Domain	Registered Assistant	Registered Technician	Other Personnel*
Patient Assessment	Direct	N/A	N/A
Formulation of the Treatment Plan	Direct	N/A	N/A
Implementation of the Treatment Plan	Indirect	Direct	Direct
Follow-up Treatment Plan	Indirect	Direct	Direct
Practice Management	N/A	N/A	Direct
Promotion of Competency and Enhancement of Professional Practice	Indirect	Direct	Direct

*The registered fitter working for an ABC accredited facility is indirectly supervised. All registered fitters must provide patient care services strictly within their limited scope of practice.

THE FUTURE OF ORTHOTICS AND PROSTHETICS

The number of people requiring orthotic and prosthetic care is expected to increase as the proportion of the population in the age groups at highest risk for orthotic and prosthetic care increases. In conjunction with an increased demand for orthotic and prosthetic professionals, there are certain areas of orthotic and prosthetic expertise that will need to be expanded. Developments such as computer-aided design, osteointegration and electronically powered and computer-controlled components for hands, elbows and knees are challenging orthotists and prosthetists to expand their knowledge base.

There continues to be an expansion in the materials and complex designs available for orthotic and prosthetic use. This also requires that orthotists and prosthetists have a better understanding of material science so that these materials can be used in the most effective manner. The practice of orthotics and prosthetics is increasingly more clinically based. This requires better analytical problem-solving skills, keener interpersonal communication skills, greater knowledge of computers and a larger emphasis on outcomes of patient care.

Board of Orthotist/Prosthetist Certification

Scope of Practice ~ BOC Pedorthist

http://www.bocusa.org/CMS/Files/Scope_Of_Practice_BOC_Pedorthist.pdf

I. Definitions

A. Practice of Pedorthics

Pedorthics is the practice, pursuant to a written order/prescription when addressing a medical condition, of evaluating, treatment planning, patient managing, measuring, designing, fabricating, assembling, fitting, adjusting or servicing, necessary to accomplish the application of a pedorthic device for the prevention or amelioration of painful and/or disabling conditions related to the lower extremities.

B. BOC Pedorthist

A Pedorthist is a professional whose competence in pedorthics is evaluatedand verified by the Board for Orthotist/Prosthetist Certification.

C. Pedorthic Devices

“Pedorthic Devices/Modalities” means therapeutic shoes, shoe modifications made for therapeutic purposes, partial foot prostheses ,foot orthoses and below the knee pedorthic modalities. Pedorthic devices do not include nontherapeutic, accommodative inlays and non-therapeutic accommodative footwear, regardless of method of manufacture; unmodified, non-therapeutic over-the-counter shoes; or prefabricated unmodified and/or unmodifiable foot care and footwear products. For purposes of this document, “accommodative” means designed with a primary goal of conforming to the individual’s
anatomy, and “therapeutic” devices are devices that address a medical condition, while non-therapeutic devices are devices that do not address a medical condition.

II. General Requirements for a BOC Pedorthist

To become certified in pedorthics, a pedorthist must meet initial educational requirements and pass a comprehensive written exam given by the Board for Orthotist/Prosthetist Certification (BOC), which is accredited by the National Commission for Certifying Agencies. Once certified, a pedorthist must meet continuing education and annual renewal requirements to maintain pedorthic certification. The BOC Pedorthist must also adhere to a code of ethics designed to ensure a comprehensive scope of professional competence and deportment. The practice of pedorthics by a BOC Pedorthist inherently includes prescriptive and non-prescriptive work because of the universal use of footwear. A written order/prescription is required for any pedorthic device, modification and/or prefabricated below the knee anatomical support addressing a medical condition. A pedorthist's activities must reflect his/her certification(s) and education. A pedorthist fits, adjusts, modifies, and transfers devices which reflect his/her certification(s).

III. Roles of a Pedorthist

There are several areas that are specific to a pedorthist as a practitioner certified by BOC. They include:

A. Pedorthic Assessment

Ascertain physician/clinician's diagnosis; gather information; examine patient's current footwear and assess patient's feet; evaluate patient using generally accepted pedorthic methods; determine patient's realistic expectations; consult with clinician as appropriate. A clinician is defined as any healthcare provider who has the legal and/or licensed authority in the state to order or prescribe medical care.

B. Implementation

Select appropriate pedorthic device(s); create appropriate models; fabricate appropriate foot orthoses, partial foot prostheses and below the knee orthoses. Modify footwear; conduct trial fittings; facilitate patient's understanding; and conduct appropriate follow-up. A pedorthist is authorized to treat primary diagnoses as provided by the physician/clinician to treat medical conditions related to the lower extremity.

C. Practice Management

Comply with universal precaution procedures, occupational safety and health rules; document all patient matters; communicate with other professionals; maintain a proficient staff and suitable facility; follow a quality assurance plan and a pedorthic practice in accordance with sound business principles and governmental requirements in order to ensure fairness to patients and other stakeholders.

D. Professional Development and Responsibility

Adhere to legal and ethical Scope of Practice; participate in continuing education; fulfill civic responsibilities; participate in research as appropriate; educate the public and health professionals on available pedorthic services.

Appendix B

Position Statements of O&P Organizations on Licensure from Organization Websites

The American Academy of Orthotist and Prosthesists
http://www.oandp.org/about/positions/

4. On the Minimum Education Essentials & Credentialing for Providers of Comprehensive Orthotic and Prosthetic Services

It is the position of the AAOP that the delivery of comprehensive orthotic and prosthetic services should appropriately match the "minimum" education and experience requirements required by the ABC for orthotic and prosthetic practitioners. These currently accepted ABC standards are embodied within the "Essentials and Guidelines for an Accredited Educational Program for the Orthotist and Prosthetist" developed by the National Commission on Orthotic and Prosthetic Education (NCOPE). These "Essentials and Guidelines" were developed with the support and cooperation of the AAOP, the American Orthotic and Prosthetic Association (AOPA) and the American Medical Association (AMA). They serve as the foundation for the "minimum" education and experience established by the ABC for individuals wishing to pursue a career pathway in orthotics and prosthetics, as an ABC Certified Prosthetist and/or Orthotist.

The development of the NCOPE's "Essentials and Guidelines for an Accredited Educational Program for the Orthotist and Prosthetist" led to formal recognition of Orthotics and Prosthetics as an allied health occupation by the AMA's Council on Medical Education in 1992. This in turn led to a collaborative relationship with the AMA's Commission on Allied Health Education and Accreditation (CAHEA) in the accreditation of educational programs in the profession of orthotics and prosthetics which eventually led to formal recognition of NCOPE's "Essentials and Guidelines" by the AMA's Council on Medical Education in 1993. CAHEA, which is now known as the Commission on Accreditation of Allied Health Education Programs (CAAHEP), is the most widely recognized independent non-profit allied health education accreditation organization in the United States.

In that regard, ABC credentialed orthotic and prosthetic practitioners provide to disabled and/or injured persons a unique medical rehabilitation service that involves a clinical evaluation and assessment that leads to the custom designing, fitting and/or development of an orthosis or prosthesis. An "orthosis" by definition is an external supportive and/or assistive device interfaced externally to the human body for the treatment of neuromuscular and/or musculoskeletal deficit secondary to disease, trauma or a congenital disorder involving the arms, legs and/or spine. A "prosthesis" by definition is an external supportive and/or assistive device interfaced externally to the human body for the replacement of a limb absence secondary to disease, trauma or a congenital disorder involving the arms and/or legs. Given the unique blend of medical and engineering

sciences, as well as technical skills that one must possess to ensure competency in the delivery of comprehensive O&P services, the Academy supports the maintenance of minimum education and credentialing requirements of the American Board for Certification in Orthotics and Prosthetics. The Academy further supports the ABC's ethical standard that requires O&P services be prescribed by a physician or an appropriately licensed health care provider.

5. Position Statement on State Licensure

As the pre-eminent professional organization in orthotics and prosthetics, it is the mission of the American Academy of Orthotists and Prosthetists (AAOP) to promote high standards of patient care through education, patient advocacy, literature and research. In keeping with this mission, and as the ONLY professional organization representing practitioners credentialed by the American Board for Certification in Orthotics and Prosthetics Inc. (ABC), the Academy is supportive of the highest standards for providers to ensure quality comprehensive orthotic and prosthetic services for patients.

The Academy believes:

Licensure requirements benefit the patient requiring orthotic or prosthetic services by demanding established criteria for minimum education essentials and experiential requirements. The standards we endorse are embodied within the "Standards and Guidelines for an Accredited Educational Program for the Orthotist and Prosthetist" developed by the National Commission on Orthotic and Prosthetic Education (NCOPE), and are required for certification by the American Board for Certification in Orthotics and Prosthetics (ABC). These standards were also recognized by the American Medical Association's Council on Medical Education in 1993, and by the Commission on Accreditation of Allied Health Education Programs (CAAHEP).

Licensure requirements are in the best interests of the profession in that they give official status to the practice of the profession, establish a recognized scope of practice for Orthotists and Prosthetists, and will be recognized by other healthcare practitioners in the crossover of patient care responsibilities.

Therefore, the Academy endorses state licensure of Orthotists and Prosthetists as the preferred method of establishing patient protection mechanisms through legislated state standards, provided those standards are equivalent to those developed by the National Commission on Orthotic and Prosthetic Education and recognized by the Commission on Accreditation of Allied Health Education Programs.

National Association for the Advancement of Orthotics & Prosthetics
http://www.naaop.org/alerts.asp?alert_id=10000060

Issue #2 – O&P State Licensure

NAAOP supports state licensure because it protects the O&P patient by demonstrating that only practitioners with sufficient education, experience, and appropriate patient care facilities can provide complex O&P patient care. It also gives the O&P consumer legal recourse for substandard care. Medicare currently requires licensure as a condition for participation in the Medicare program for states that have licensure, but this may be modified in pending regulations.

Appendix C

CHAPTER 839

An Act to amend and reenact § 38.2-4319 of the Code of Virginia and to amend the Code of Virginia by adding a section numbered 38.2-3418.15, relating to health insurance coverage for prosthetic devices and components.

[S 1116]

Approved April 8, 2009

Be it enacted by the General Assembly of Virginia:

1. That § 38.2-4319 of the Code of Virginia is amended and reenacted and that the Code of Virginia is amended by adding a section numbered 38.2-3418.15 as follows:

§ 38.2-3418.15. Coverage for prosthetic devices and components.

A. Notwithstanding the provisions of § 38.2-3419, each insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical, or major medical coverage on an expense-incurred basis; each corporation providing individual or group accident and sickness subscription contracts; and each health maintenance organization providing a health care plan for health care services shall offer and make available coverage for medically necessary prosthetic devices, their repair, fitting, replacement, and components, as follows:

1. As used in this section:

"Component" means the materials and equipment needed to ensure the comfort and functioning of a prosthetic device.

"Limb" means an arm, a hand, a leg, a foot, or any portion of an arm, a hand, a leg, or a foot.

"Prosthetic device" means an artificial device to replace, in whole or in part, a limb.

2. Prosthetic device coverage does not include repair and replacement due to enrollee neglect, misuse, or abuse. Coverage also does not include prosthetic devices designed primarily for an athletic purpose.

3. An insurer shall not impose any annual or lifetime dollar maximum on coverage for prosthetic devices other than an annual or lifetime dollar maximum that applies in the aggregate to all items and services covered under the policy. The coverage may be made subject to, and no more restrictive than, the provisions of a health insurance policy that apply to other benefits under the policy.

4. An insurer shall not apply amounts paid for prosthetic devices to any annual or lifetime dollar maximum applicable to other durable medical equipment covered under the policy other than an annual or lifetime dollar maximum that applies in the aggregate to all items and services covered under the policy.

5. No insurer, corporation, or health maintenance organization shall impose upon any person receiving benefits pursuant to this section any coinsurance in excess of 30 percent of the carrier's allowable charge for such prosthetic device or services when such device or service is provided by an in-network provider.

6. An insurer, corporation, or health maintenance organization may require preauthorization to determine medical necessity and the eligibility of benefits for prosthetic devices and components, in the same manner that prior authorization is required for any other covered benefit.

B. The requirements of this section shall apply to all insurance policies, contracts, and plans delivered, issued for delivery, reissued, or extended in the Commonwealth on and after January 1, 2010, or at any time thereafter when any term of the policy, contract, or plan is changed or any premium adjustment is made.

C. This section shall not apply to short-term travel, accident-only, limited or specified disease, or individual conversion policies or contracts, nor to policies or contracts designed for issuance to persons eligible for coverage under Title XVIII of the Social Security Act, known as Medicare, or any other similar coverage under state or federal governmental plans.

§ 38.2-4319. Statutory construction and relationship to other laws.

A. No provisions of this title except this chapter and, insofar as they are not inconsistent with this chapter, §§ 38.2-100, 38.2-136, 38.2-200, 38.2-203, 38.2-209 through 38.2-213, 38.2-216, 38.2-218 through 38.2-225, 38.2-229, 38.2-232, 38.2-305, 38.2-316, 38.2-322, 38.2-400, 38.2-402 through 38.2-413, 38.2-500 through 38.2-515, 38.2-600 through 38.2-620, Chapter 9 (§ 38.2-900 et seq.), §§ 38.2-1016.1 through 38.2-1023, 38.2-1057, Article 2 (§ 38.2-1306.2 et seq.), § 38.2-1306.1, § 38.2-1315.1, Articles 3.1 (§ 38.2-1316.1 et seq.), 4 (§ 38.2-1317 et seq.) and 5 (§ 38.2-1322 et seq.) of Chapter 13, Articles 1 (§ 38.2-1400 et seq.) and 2 (§ 38.2-1412 et seq.) of Chapter 14, §§ 38.2-1800 through 38.2-1836, 38.2-3401, 38.2-3405, 38.2-3405.1, 38.2-3407.2 through 38.2-3407.6:1, 38.2-3407.9 through 38.2-3407.16, 38.2-3411.2, 38.2-3411.3, 38.2-3411.4, 38.2-3412.1:01, 38.2-3414.1, 38.2-3418.1 through ~~38.2-3418.14~~ *38.2-3418.15*, 38.2-3419.1, 38.2-3430.1 through 38.2-3437, 38.2-3500, subdivision 13 of § 38.2-3503, subdivision 8 of § 38.2-3504, §§ 38.2-3514.1, 38.2-3514.2, 38.2-3522.1 through 38.2-3523.4, 38.2-3525, 38.2-3540.1, 38.2-3542, 38.2-3543.2, Article 5 (§ 38.2-3551 et seq.) of Chapter 35, Chapter 52 (§ 38.2-5200 et seq.), Chapter 55 (§ 38.2-5500 et seq.), Chapter 58 (§ 38.2-5800 et seq.) and § 38.2-5903 of this title shall be applicable to any health maintenance organization granted a license under this chapter. This chapter shall not apply to an insurer or health services plan licensed and regulated in conformance with the insurance laws or Chapter

42 (§ 38.2-4200 et seq.) of this title except with respect to the activities of its health maintenance organization.

B. For plans administered by the Department of Medical Assistance Services that provide benefits pursuant to Title XIX or Title XXI of the Social Security Act, as amended, no provisions of this title except this chapter and, insofar as they are not inconsistent with this chapter, §§ 38.2-100, 38.2-136, 38.2-200, 38.2-203, 38.2-209 through 38.2-213, 38.2-216, 38.2-218 through 38.2-225, 38.2-229, 38.2-232, 38.2-322, 38.2-400, 38.2-402 through 38.2-413, 38.2-500 through 38.2-515, 38.2-600 through 38.2-620, Chapter 9 (§ 38.2-900 et seq.), §§ 38.2-1016.1 through 38.2-1023, 38.2-1057, § 38.2-1306.1, Article 2 (§ 38.2-1306.2 et seq.), § 38.2-1315.1, Articles 3.1 (§ 38.2-1316.1 et seq.), 4 (§ 38.2-1317 et seq.) and 5 (§ 38.2-1322 et seq.) of Chapter 13, Articles 1 (§ 38.2-1400 et seq.) and 2 (§ 38.2-1412 et seq.) of Chapter 14, §§ 38.2-3401, 38.2-3405, 38.2-3407.2 through 38.2-3407.5, 38.2-3407.6 and 38.2-3407.6:1, 38.2-3407.9, 38.2-3407.9:01, and 38.2-3407.9:02, subdivisions 1, 2, and 3 of subsection F of § 38.2-3407.10, 38.2-3407.11, 38.2-3407.11:3, 38.2-3407.13, 38.2-3407.13:1, and 38.2-3407.14, 38.2-3411.2, 38.2-3418.1, 38.2-3418.2, 38.2-3419.1, 38.2-3430.1 through 38.2-3437, 38.2-3500, subdivision 13 of § 38.2-3503, subdivision 8 of § 38.2-3504, §§ 38.2-3514.1, 38.2-3514.2, 38.2-3522.1 through 38.2-3523.4, 38.2-3525, 38.2-3540.1, 38.2-3542, 38.2-3543.2, Chapter 52 (§ 38.2-5200 et seq.), Chapter 55 (§ 38.2-5500 et seq.), Chapter 58 (§ 38.2-5800 et seq.) and § 38.2-5903 shall be applicable to any health maintenance organization granted a license under this chapter. This chapter shall not apply to an insurer or health services plan licensed and regulated in conformance with the insurance laws or Chapter 42 (§ 38.2-4200 et seq.) of this title except with respect to the activities of its health maintenance organization.

C. Solicitation of enrollees by a licensed health maintenance organization or by its representatives shall not be construed to violate any provisions of law relating to solicitation or advertising by health professionals.

D. A licensed health maintenance organization shall not be deemed to be engaged in the unlawful practice of medicine. All health care providers associated with a health maintenance organization shall be subject to all provisions of law.

E. Notwithstanding the definition of an eligible employee as set forth in § 38.2-3431, a health maintenance organization providing health care plans pursuant to § 38.2-3431 shall not be required to offer coverage to or accept applications from an employee who does not reside within the health maintenance organization's service area.

F. For purposes of applying this section, "insurer" when used in a section cited in subsections A and B of this section shall be construed to mean and include "health maintenance organizations" unless the section cited clearly applies to health maintenance organizations without such construction.

Appendix D

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Virginia Board of Health Professions

As part of the ongoing emerging professions review, the Regulatory Research Committee is evaluating the need to regulate orthotists and prosthetists. The "gateway" criterion for regulation of professions is the *Risk for Harm to the Consumer.* For any level of regulation to be justified, the unregulated practice of orthotists and prosthetists must pose some public health risk.

> **Criterion One: Risk for Harm to the Consumer**
> The unregulated practice of the health occupation will harm or endanger the public health, safety or welfare. The harm is recognizable and not remote or dependent on tenuous argument. The harm results from: (a) practices inherent in the occupation, (b) characteristics of the clients served, (c) the setting or supervisory arrangements for the delivery of health services, or (d) from any combination of these factors.
>
> (Board of Health Professions: *Policies and Procedures for the Evaluation of the Need to Regulate Health Occupations and Professions.)*

Evidence of actual harm is lacking. However, this does not rule out the existence of a *risk* of harm. To assist in determining the risk of harm, the Regulatory Research Committee requested that members of the Board of Health Professions with relevant knowledge perform a preliminary criticality analysis of orthotists and prosthetists. In a criticality analysis, experts evaluate the extent of harm and the probability of harm occurring of individual tasks performed in the profession. Dr. Carter has suggested that you have the appropriate expertise to properly judge the risk of harm for Orthotists & Prosthetists. The Regulatory Research Committee would graciously appreciate your assistance in this matter.

The attached survey lists 57 tasks identified in a practice analysis performed by the American Board for Certification of Orthotics, Prosthetics and Pedorthics, Inc. The survey asks you to determine how much harm the performance of the task may cause, and the probability of the harm occurring for a certified and uncertified practitioner. Additionally, and most importantly, the survey asks you to summarize your opinion on the risk of harm from practice within six domain areas. Further instructions are available in the survey instrument.

Thank you,

Justin Crow

Survey: Orthotists & Prosthetists

The following survey is designed to assist the Regulatory Research Committee in determining the risk of harm the unregulated practice of orthotics and prosthetics. The survey lists 57 individual tasks, divided into six large domain areas. A column adjacent to each task, "Magnitude of Harm", further divides the rows into levels of harm. You are asked to determine the probability that the performance of each task, by a certified and by an uncertified practitioner, will result in each level of harm.

Though the survey asks for exact numbers, your analysis will necessarily be subjective. The Committee is interested in your professional judgment of the risk of harm, so your subjective evaluation of the probability for risk is appropriate. Additionally, a "Summary/Comments" section follows each domain area. Please use the survey portion as a guide to providing your professional insight into the risk of harm for each area. Since the survey is only going out to a few persons, quantitative analysis of the results in not appropriate. Rather, the survey portion acts as a guide to qualitative analysis. This makes your comments all the more important.

The "Magnitude of Harm" divides each task into four levels of harm: none, minor, moderate, and severe.

None: No injury, or minimal financial loss or inconvenience.

Minor: Financial loss or inconvenience, or injury which is likely to be completely reversed.

Moderate: Debilitating injury where physical and/or emotional harm occurs immediately or in the future, which may lead to a permanent loss of function.

Severe: A life threatening injury.

For each task, please indicate the probability, in percentages, of the performance of the task resulting in each level of harm in the third and fourth column. For all four levels, the results should add up to 100. Please consider the probability for *each instance the task is performed* rather than determining the frequency of the tasks occurring. The practice analysis by the American Board for Orthotists, Prosthetists & Pedorthists has already determined the frequency practitioners perform each task. If you do not feel comfortable completing any question or portion, simply leave it blank.

The third and fourth columns differentiate between certified and uncertified practitioners. This may lead you to automatically increase the probability for harm for uncertified practitioners. However, uncertified practitioners may not necessarily be

incompetent, only less thoroughly trained, educated and tested. For purposes of this survey, certified and uncertified practitioners should be considered:

Certified practitioners: Have met minimum skill levels through education *equivalent to* a one-year post-graduate certificate in either orthotics or prosthetics and a corresponding one-year residency. Certified practitioners have demonstrated their knowledge, skills and abilities in a rigorous certification exam that includes both written and clinical simulations. Additionally, certified practitioners must complete continuing education to keep abreast of current best practices.

Uncertified practitioners: Have the knowledge, skills and abilities to perform routine tasks on a day-to-day basis, but lack structured or comprehensive education and experience. Uncertified practitioners may be unable to pass a rigorous certification exam, and may lack comprehension of complex procedures or knowledge of unusual occurrences and best practices.

Please feel free to complete the survey electronically and return it to me by email (Justin.Crow@dhp.virginia.gov). If you would prefer to fill out a printed copy, let me know and I will mail you a survey with a self-addressed stamped envelope.

The survey is long, so please take your time in completing it. You may wish to take a break and come back to it another day if filling in the survey begins to feel "repetitive". The results will be presented at the next meeting of the Regulatory Research Committee on May 12, so the surveys do not need to be returned until the end of April. I will send a reminder email in mid-April if the surveys have not been returned by then.

Please contact me if you have any questions or comments.

Thank you,

Justin Crow

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Instructions: For each level of harm associated with each task, please indicate the probability that a certified and an uncertified practitioner could create harm. Total probability for each task should add up to 100%.

Domain 1: Patient Assessment
Perform a comprehensive assessment of the patient to obtain an understanding of the patient's orthotic/ prosthetic needs.

Task	Magnitude of Harm	Probability: Certified	Probability: Uncertified
Review patient's prescription/referral	None		
	Minor		
	Moderate		
	Severe		
Take a comprehensive patient history, including demographic characteristics, family dynamics, previous use of an orthosis/ prosthesis, diagnosis, work history, avocational activities, signs and symptoms, medical history (including allergies to materials, current medications), reimbursement status, patient expectations, patient compliance with ancillary care, results of diagnostic evaluations	None		
	Minor		
	Moderate		
	Severe		
Perform a diagnosis-specific functional clinical and cognitive ability examination that includes manual muscle testing, gait analysis, and evaluation of sensory function, range of motion, joint stability, and skin integrity	None		
	Minor		
	Moderate		
	Severe		
Consult with other health care providers and caregivers, when appropriate, about patient's condition in order to formulate a treatment plan	None		
	Minor		
	Moderate		
	Severe		
Verify patient care by documenting history, ongoing care, and follow-up, using established record-keeping techniques	None		
	Minor		
	Moderate		
	Severe		
Refer patient, if appropriate, to other health care providers for intervention beyond orthotic/prosthetic scope of practice	None		
	Minor		
	Moderate		
	Severe		

Summary/Comments:

Domain 2: Formulation of the Treatment Plan

Analyze and integrate information from patient assessment to create a comprehensive orthotic/ prosthetic treatment plan to meet the needs and goals of the patient.

Task	Magnitude of Harm	Probability: Certified	Probability: Uncertified
Evaluate the findings to determine an orthotic/prosthetic treatment plan	None		
	Minor		
	Moderate		
	Severe		
Formulate treatment goals and expected orthotic/prosthetic outcomes to reduce pain, increase comfort, provide stability, prevent deformity, address aesthetic factors, and/or promote healing to enhance function and independence	None		
	Minor		
	Moderate		
	Severe		
Consult with physician/referral source/appropriately licensed health care provider to modify, if necessary, the original prescription and/or treatment plan	None		
	Minor		
	Moderate		
	Severe		
Identify design, materials, and components to support treatment plan	None		
	Minor		
	Moderate		
	Severe		
Develop a treatment plan based on patient needs, including patient education and follow-up	None		
	Minor		
	Moderate		
	Severe		
Communicate to patient and/or caregiver about the recommended treatment plan and any optional plans, including disclosure of potential risks/benefits in orthotic/prosthetic care	None		
	Minor		
	Moderate		
	Severe		
Document treatment plan using established record-keeping techniques	None		
	Minor		
	Moderate		
	Severe		
Ensure patient or responsible parties are informed of their financial responsibilities (for example, insurance verification/ authorization, deductibles, co-pays) as they pertain to proposed treatment plan	None		
	Minor		
	Moderate		
	Severe		

Summary/Comments:

Domain 3: Implementation of the Treatment Plan

Perform the procedures necessary to provide the appropriate orthotic/prosthetic services, including fabrication.

Task	Magnitude of Harm	Probability: Certified	Probability: Uncertified
Inform patient, family, and/or caregiver of the orthotic/prosthetic procedure, possible risks, and time involved in the procedure	None		
	Minor		
	Moderate		
	Severe		
Provide patient with preparatory care for orthotic/prosthetic treatment (e.g., diagnostic splint, compression garment)	None		
	Minor		
	Moderate		
	Severe		
Select appropriate materials/techniques in order to obtain a patient model/image	None		
	Minor		
	Moderate		
	Severe		
Prepare patient for procedure required to initiate treatment plan (e.g., measure, take impression, delineate, scan, digitize)	None		
	Minor		
	Moderate		
	Severe		
Perform procedure (e.g., measure, take impression, delineate, scan, digitize)	None		
	Minor		
	Moderate		
	Severe		
Refer to manufacturer's specifications and other technical resources regarding components/materials	None		
	Minor		
	Moderate		
	Severe		
Select appropriate materials and components for orthosis/prosthesis based on patient criteria to ensure optimum strength, durability, and function (e.g., ankle or knee joints, feet, knee units, lamination layups)	None		
	Minor		
	Moderate		
	Severe		
Prepare delineation/impression/template for modification/fabrication (e.g., prepare impression/reverse delineation, digitize)	None		
	Minor		
	Moderate		
	Severe		
Rectify and prepare patient model/image for fabrication	None		
	Minor		
	Moderate		
	Severe		
Fabricate/assemble orthosis/prosthesis in order to prepare for initial or diagnostic fitting and/or delivery	None		
	Minor		
	Moderate		
	Severe		
Assess device for structural safety and ensure manufacturers' guidelines have been followed prior to patient fitting/delivery (e.g., torque values, patient weight limits)	None		
	Minor		
	Moderate		
	Severe		

Task	Magnitude of Harm	Probability: Certified	Probability: Uncertified
Assess/align orthosis/prosthesis for accuracy in sagittal, transverse, and coronal planes in order to provide maximum function/comfort	None		
	Minor		
	Moderate		
	Severe		
Ensure materials, design, and components are provided as specified in the treatment plan	None		
	Minor		
	Moderate		
	Severe		
Complete fabrication process after achieving optimal fit and function of orthosis/prosthesis (e.g., convert test socket to definitive orthosis/prosthesis)	None		
	Minor		
	Moderate		
	Severe		
Educate patient and/or caregiver about the use and maintenance of the orthosis/prosthesis (e.g., wearing schedules, other instructions)	None		
	Minor		
	Moderate		
	Severe		
Re-assess orthosis/prosthesis for structural safety prior to patient delivery	None		
	Minor		
	Moderate		
	Severe		
Document treatment using established record-keeping techniques to verify implementation of treatment plan	None		
	Minor		
	Moderate		
	Severe		
Refer patient to appropriate health care providers (e.g., nurse practitioners, therapists) for necessary ancillary care	None		
	Minor		
	Moderate		
	Severe		

Summary/Comments:

Domain 4: Follow-up Treatment Plan

Provide continuing patient care and periodic evaluation to assure/maintain/document optimal fit and function of the orthosis/prosthesis.

Task	Magnitude of Harm	Probability: Certified	Probability: Uncertified
Obtain feedback from patient and/or caregiver to evaluate outcome (e.g., wear schedule/tolerance, comfort, perceived benefits, perceived detriments, ability to don and doff, proper usage and function, overall patient satisfaction)	None		
	Minor		
	Moderate		
	Severe		
Assess patient's function and note any changes	None		
	Minor		
	Moderate		
	Severe		
Assess patient's skin condition (e.g., integrity, color, temperature, volume) and note any changes	None		
	Minor		
	Moderate		
	Severe		
Assess patient's general health, height, and weight, and note any changes	None		
	Minor		
	Moderate		
	Severe		
Assess patient's psychosocial status (e.g., family status, job, or caregiver), and note any changes	None		
	Minor		
	Moderate		
	Severe		
Assess fit of orthosis/prosthesis with regard to strategic contact (e.g., multiple force systems, total contact) to determine need for changes relative to initial treatment goals	None		
	Minor		
	Moderate		
	Severe		
Assess fit of orthosis/prosthesis with regard to anatomical relationships to orthosis/prosthesis (e.g., trimlines, static/dynamic alignment) to determine need for changes relative to initial treatment goals	None		
	Minor		
	Moderate		
	Severe		
Assess patient's achievement of planned treatment outcomes	None		
	Minor		
	Moderate		
	Severe		
Formulate plan to modify orthosis/prosthesis based on assessment of outcomes and inform patient and/or caregiver of plan to modify orthosis/prosthesis as necessary	None		
	Minor		
	Moderate		
	Severe		
Make or supervise modifications to orthosis/prosthesis (e.g., relieve pressure, change range of motion, change alignment, change components, add pressure-sensitive pad)	None		
	Minor		
	Moderate		
	Severe		
Assess modified device for structural safety	None		
	Minor		
	Moderate		
	Severe		

Task	Magnitude of Harm	Probability: Certified	Probability: Uncertified
Evaluate results of modifications to orthosis/prosthesis, including static and dynamic assessment	None		
	Minor		
	Moderate		
	Severe		
Reassess patient knowledge of goals and objectives to ensure proper use of orthosis/prosthesis relative to modifications	None		
	Minor		
	Moderate		
	Severe		
Document all findings and actions and communicate with physicians, referral sources, appropriately licensed health care providers to ensure patient status is updated	None		
	Minor		
	Moderate		
	Severe		
Develop long-term follow-up plan	None		
	Minor		
	Moderate		
	Severe		

Summary/Comments:

Domain 5: Practice Management

Develop, implement, and/or monitor policies and procedures regarding human resources, the physical environment, business and financial practices, and organizational management.

Task	Magnitude of Harm	Probability: Certified	Probability: Uncertified
Plan, implement, evaluate, and document policies and procedures in compliance with all applicable federal and state laws and regulations and professional and ethical guidelines (e.g., CMS, HIPPA, FDA, ADA, OSHA, ABC Code of Professional Responsibility)	None		
	Minor		
	Moderate		
	Severe		
Develop and implement personnel policies and procedures (e.g., benefits, training, incentives, staff recognition, regular performance evaluations)	None		
	Minor		
	Moderate		
	Severe		
Establish procedures for patient care that comply with current medical/legal requirements	None		
	Minor		
	Moderate		
	Severe		
Demonstrate proper documentation of patient history and financial records using established record-taking techniques	None		
	Minor		
	Moderate		
	Severe		
Create a professional, cooperative working environment to improve patient care	None		
	Minor		
	Moderate		
	Severe		

Summary/Comments:

Domain 6: Promotion of Competency and Enhancement of Professional Practice
Participate in personal and professional development through continuing education, training, research, and organizational affiliations.

Task	Magnitude of Harm	Probability: Certified	Probability: Uncertified
Participate in continuing education and/or provide such education for other health care providers, orthotic and prosthetic practitioners, pedorthists, assistants, fitters, technicians, and office staff (e.g., publications, seminars, case studies)	None		
	Minor		
	Moderate		
	Severe		
Participate in education of residents, students and trainees	None		
	Minor		
	Moderate		
	Severe		
Conduct or participate in product development research, clinical trials, and outcome studies	None		
	Minor		
	Moderate		
	Severe		
Participate in the development, implementation, and monitoring of public policy regarding orthotics/prosthetics (e.g., provide testimony/ information to legislative/regulatory bodies, serve on professional committees and regulatory agencies)	None		
	Minor		
	Moderate		
	Severe		
Participate in/with consumer organizations and nongovernmental organizations in order to promote competency and enhancement of orthotic/prosthetic profession	None		
	Minor		
	Moderate		
	Severe		

Summary/Comments:

Thank You!

Harm Factor Calculation:

None:	Answer x 0
Minor:	+ Answer x 1
Moderate:	+ Answer x 2
Severe:	+ Answer x 3
Harm Factor	Sum

* Potential for moderate harm
** Potential for severe harm

Domain 1: Patient Assessment

Perform a comprehensive assessment of the patient to obtain an understanding of the patient's orthotic/ prosthetic needs.

Task	Montero			Howell		
	Certified	Uncertified	Difference	Certified	Uncertified	Difference
Review patient's prescription/referral	10	10	**0**	5	10	**-5**
Take a comprehensive patient history, including demographic characteristics, family dynamics, previous use of an orthosis/ prosthesis, diagnosis, work history, avocational activities, signs and symptoms, medical history (including allergies to materials, current medications), reimbursement status, patient expectations, patient compliance with ancillary care, results of diagnostic evaluations	10	10	**0**	5	10	**-5**
Perform a diagnosis-specific functional clinical and cognitive ability examination that includes manual muscle testing, gait analysis, and evaluation of sensory function, range of motion, joint stability, and skin integrity	25*	70*	**-45**	15*	20*	**-5**
Consult with other health care providers and caregivers, when appropriate, about patient's condition in order to formulate a treatment plan	20*	90*	**-70**	0	0	**0**
Verify patient care by documenting history, ongoing care, and follow-up, using established record-keeping techniques	10	40	**-30**	0	10	**-10**
Refer patient, if appropriate, to other health care providers for intervention beyond orthotic/prosthetic scope of practice	20	90*	**-70**	15*	20*	**-5**

Comments:

Dr. Montero: I believe that the certified practitioner has a definite broader understanding of patient assessment because of the curriculum requirement for certification such as better understanding of anatomy, physiology and biomechanics. The uncertified practitioner relies mainly on "on the job" experience.

Mr. Howell: Small risk when performing clinical exam on a diabetic amputee of causing a skin lesion which may be very difficult to heal and/or risk of not following infection precautions resulting in serious infection

Domain 2: Formulation of the Treatment Plan

Analyze and integrate information from patient assessment to create a comprehensive orthotic/ prosthetic treatment plan to meet the needs and goals of the patient.

Task	Montero			Howell		
	Certified	Uncertified	Certified	Uncertified	Certified	Uncertified
Evaluate the findings to determine an orthotic/prosthetic treatment plan	10	40	**-30**	15*	20*	**-5**
Formulate treatment goals and expected orthotic/prosthetic outcomes to reduce pain, increase comfort, provide stability, prevent deformity, address aesthetic factors, and/or promote healing to enhance function and independence	10	80*	**-70**	15*	30*	**-15**
Consult with physician/referral source/appropriately licensed health care provider to modify, if necessary, the original prescription and/or treatment plan	25*	95**	**-70**	15*	30*	**-15**
Identify design, materials, and components to support treatment plan	5	70*	**-65**	15*	30*	**-15**
Develop a treatment plan based on patient needs, including patient education and follow-up	5	70*	**-65**	15*	30*	**-15**
Communicate to patient and/or caregiver about the recommended treatment plan and any optional plans, including disclosure of potential risks/benefits in orthotic/prosthetic care	25*	95**	**-70**	15*	30*	**-15**
Document treatment plan using established record-keeping techniques	5	30	**-25**	15*	60*	**-45**
Ensure patient or responsible parties are informed of their financial responsibilities (for example, insurance verification/ authorization, deductibles, co-pays) as they pertain to proposed treatment plan	5	30	**-25**	15*	60*	**-45**

Comments:

Dr. Montero: The treatment plan is critical in the differentiation between certified and uncertified practitioners for this is a reflection of required education and training that certified practitioners undergo.

Mr. Howell: The probability of uncertified practitioner equipment sales personnel having poor record keeping or record keeping not meeting standards of Medicare would be high.

Domain 3: Implementation of the Treatment Plan

Perform the procedures necessary to provide the appropriate orthotic/prosthetic services, including fabrication.

Task	Montero			Howell		
	Certified	Uncertified	Certified	Uncertified	Certified	Uncertified
Inform patient, family, and/or caregiver of the orthotic/prosthetic procedure, possible risks, and time involved in the procedure	5	5	**0**	7*	30*	**-23**
Provide patient with preparatory care for orthotic/prosthetic treatment (e.g., diagnostic splint, compression garment)	5	5	**0**	7*	30*	**-23**
Select appropriate materials/techniques in order to obtain a patient model/image	5	30	**-25**	15*	30*	**-15**
Prepare patient for procedure required to initiate treatment plan (e.g., measure, take impression, delineate, scan, digitize)	5	20	**-15**	7*	30*	**-23**
Perform procedure (e.g., measure, take impression, delineate, scan, digitize)	5	20	**-15**	15*	30*	**-15**
Refer to manufacturer's specifications and other technical resources regarding components/materials	25	100*	**-75**	7*	30*	**-23**
Select appropriate materials and components for orthosis/prosthesis based on patient criteria to ensure optimum strength, durability, and function (e.g., ankle or knee joints, feet, knee units, lamination layups)	5	5	**0**	15*	30*	**-15**
Prepare delineation/impression/template for modification/fabrication (e.g., prepare impression/reverse delineation, digitize)	5	5	**0**	15*	30*	**-15**
Rectify and prepare patient model/image for fabrication	5	30*	**-25**	15*	60*	**-45**
Fabricate/assemble orthosis/prosthesis in order to prepare for initial or diagnostic fitting and/or delivery	5	30	**-25**	15*	60*	**-45**
Assess device for structural safety and ensure manufacturers' guidelines have been followed prior to patient fitting/delivery (e.g., torque values, patient weight limits)	5	30	**-25**	15*	60*	**-45**

Task	Montero			Howell		
	Certified	Uncertified	Certified	Uncertified	Certified	Uncertified
Assess/align orthosis/prosthesis for accuracy in sagittal, transverse, and coronal planes in order to provide maximum function/comfort	5	30	**-25**	15*	60*	**-45**
Ensure materials, design, and components are provided as specified in the treatment plan	5	30	**-25**	15*	60*	**-45**
Complete fabrication process after achieving optimal fit and function of orthosis/prosthesis (e.g., convert test socket to definitive orthosis/prosthesis)	25*	70*	**-45**	15*	60*	**-45**
Educate patient and/or caregiver about the use and maintenance of the orthosis/prosthesis (e.g., wearing schedules, other instructions)	5	30	**-25**	15*	60*	**-45**
Re-assess orthosis/prosthesis for structural safety prior to patient delivery	Na	Na	**Na**	15*	60*	**-45**
Document treatment using established record-keeping techniques to verify implementation of treatment plan	5	30	**-25**	15*	60*	**-45**
Refer patient to appropriate health care providers (e.g., nurse practitioners, therapists) for necessary ancillary care	5	30	**-25**	15*	60*	**-45**

Comments:

Dr. Montero: From what I can gather, manufacturers provide continuing educational courses wherein only certified practitioners are invited. This is critical to assist with optimum decision making of the practitioner to obtain quality care for the patient.

Domain 4: Follow-up Treatment Plan

Provide continuing patient care and periodic evaluation to assure/maintain/document optimal fit and function of the orthosis/prosthesis.

Task	Montero			Howell		
	Certified	Uncertified	Certified	Uncertified	Certified	Uncertified
Obtain feedback from patient and/or caregiver to evaluate outcome (e.g., wear schedule/tolerance, comfort, perceived benefits, perceived detriments, ability to don and doff, proper usage and function, overall patient satisfaction)	5	30	**-25**	15*	60*	**-45**
Assess patient's function and note any changes	5	30	**-25**	15*	60*	**-45**
Assess patient's skin condition (e.g., integrity, color, temperature, volume) and note any changes	25*	70*	**-45**	15*	30*	**-15**
Assess patient's general health, height, and weight, and note any changes	5	5	**0**	15*	30*	**-15**
Assess patient's psychosocial status (e.g., family status, job, or caregiver), and note any changes	5	20	**-15**	15*	30*	**-15**
Assess fit of orthosis/prosthesis with regard to strategic contact (e.g., multiple force systems, total contact) to determine need for changes relative to initial treatment goals	25*	60*	**-35**	15*	30*	**-15**
Assess fit of orthosis/prosthesis with regard to anatomical relationships to orthosis/prosthesis (e.g., trimlines, static/dynamic alignment) to determine need for changes relative to initial treatment goals	25*	60*	**-35**	15*	30*	**-15**
Assess patient's achievement of planned treatment outcomes	5	5	**0**	15*	30*	**-15**
Formulate plan to modify orthosis/prosthesis based on assessment of outcomes and inform patient and/or caregiver of plan to modify orthosis/prosthesis as necessary	30*	70*	**-40**	15*	30*	**-15**
Make or supervise modifications to orthosis/prosthesis (e.g., relieve pressure, change range of motion, change alignment, change components, add pressure-sensitive pad)	5	5	**0**	15*	30*	**-15**
Assess modified device for structural safety	5	5	**0**	15*	30*	**-15**

Task	Montero			Howell		
	Certified	Uncertified	Difference	Certified	Uncertified	Difference
Evaluate results of modifications to orthosis/prosthesis, including static and dynamic assessment	5	5	**0**	15*	30*	**-15**
Reassess patient knowledge of goals and objectives to ensure proper use of orthosis/prosthesis relative to modifications	5	5	**0**	15*	30*	**-15**
Document all findings and actions and communicate with physicians, referral sources, appropriately licensed health care providers to ensure patient status is updated	5	5	**0**	15*	30*	**-15**
Develop long-term follow-up plan	5	5	**0**	15*	30*	**-15**

Comments:

Dr. Montero: In this section, I believe that the non-certified practitioner who has limited knowledge and experience will have less options to correct problems when they arise.

Dr. Howell: There is relatively small likelihood of inconvenience, injury or infection in some clients more than others from treatment & follow up treatment as a result of poorly applied interventions in a certified provider & the risk is greater in a non-certified provider.

Domain 5: Practice Management
Develop, implement, and/or monitor policies and procedures regarding human resources, the physical environment, business and financial practices, and organizational management.

Task	Montero			Howell		
	Certified	Uncertified	Certified	Uncertified	Certified	Uncertified
Plan, implement, evaluate, and document policies and procedures in compliance with all applicable federal and state laws and regulations and professional and ethical guidelines (e.g., CMS, HIPPA, FDA, ADA, OSHA, ABC Code of Professional Responsibility)	5	5	0	2	5	-3
Develop and implement personnel policies and procedures (e.g., benefits, training, incentives, staff recognition, regular performance evaluations)	5	5	0	2	5	-3
Establish procedures for patient care that comply with current medical/legal requirements	5	5	0	2	5	-3
Demonstrate proper documentation of patient history and financial records using established record-taking techniques	5	5	0	2	5	-3
Create a professional, cooperative working environment to improve patient care	5	5	0	2	5	-3

Comments:

Dr. Montero: I see no difference in this section.

Mr. Howell: I would expect a distinguishing factor would be whether the provider was billing Medicare or not, rather than whether they were certified or not certified. A provider who is billing Medicare will meet higher standards of practice management. If a provider is not billing Medicare there may be an advantage to requiring certification in order to decrease risk associated with practice management.

Domain 6: Promotion of Competency and Enhancement of Professional Practice
Participate in personal and professional development through continuing education, training, research, and organizational affiliations.

Task	Montero			Howell		
	Certified	Uncertified	Certified	Uncertified	Certified	Uncertified
Participate in continuing education and/or provide such education for other health care providers, orthotic and prosthetic practitioners, pedorthists, assistants, fitters, technicians, and office staff (e.g., publications, seminars, case studies)	5	20	-15	2	5	-3
Participate in education of residents, students and trainees	5	20	-15	2	5	-3
Conduct or participate in product development research, clinical trials, and outcome studies	5	20	-15	2	5	-3
Participate in the development, implementation, and monitoring of public policy regarding orthotics/prosthetics (e.g., provide testimony/ information to legislative/regulatory bodies, serve on professional committees and regulatory agencies)	5	20	-15	2	5	-3
Participate in/with consumer organizations and nongovernmental organizations in order to promote competency and enhancement of orthotic/prosthetic profession	5	20	-15	2	5	-3

Comments:

Dr. Montero: I understand that continuing medical education is mandatory to maintain certification. Obviously the non-certified practitioner may or may not stay abreast of the state of the art.

Thank You!

	Dr. Montero		
Domain 1 Patient Assessment	**Magnitude of Harm**	**Probability: Certified**	**Probability: Uncertified**
	None	90	90
	Minor	10	10
	Moderate	0	0
Review patient's prescription/referral	Severe	0	0
Harm Factor			
	None	90	90
	Minor	10	10
	Moderate	0	0
Take a comprehensive patient history, etc....	Severe	0	0
Harm Factor			
Perform a diagnosis-specific functional clinical and cognitive ability examination that includes manual muscle testing, gait analysis, and evaluation of sensory function, range of motion, joint stability, and skin integrity	None	80	50
	Minor	15	30
	Moderate	5	20
	Severe	0	0
	None	85	40
	Minor	10	30
Consult with other health care providers and caregivers, when appropriate, about patient's condition in order to formulate a treatment plan	Moderate	5	30
	Severe	0	0
	None	90	70
	Minor	10	20
Verify patient care by documenting history, ongoing care, and follow-up, using established record-keeping techniques	Moderate	0	10
	Severe	0	0
	None	80	40
	Minor	20	30
Refer patient, if appropriate, to other health care providers for intervention beyond orthotic/prosthetic scope of practice	Moderate	0	30
	Severe	0	0

Domain 2: Formulation of the Treatment Plan	**Magnitude of Harm**	**Probability: Certified**	**Probability: Uncertified**
	None	90	60
	Minor	10	40
Evaluate the findings to determine an orthotic/prosthetic treatment plan	Moderate	0	0
	Severe	0	0

Formulate treatment goals and expected orthotic/prosthetic outcomes to reduce pain, increase comfort, provide stability, prevent deformity, address aesthetic factors, and/or promote healing to enhance function and independence	None	90	40
	Minor	10	40
	Moderate	0	20
	Severe	0	0
Consult with physician/referral source/appropriately licensed health care provider to modify, if necessary, the original prescription and/or treatment plan	None	80	40
	Minor	15	30
	Moderate	5	25
	Severe	0	5
Identify design, materials, and components to support treatment plan	None	95	40
	Minor	5	50
	Moderate	0	10
	Severe	0	0
Develop a treatment plan based on patient needs, including patient education and follow-up	None	95	50
	Minor	5	30
	Moderate	0	20
	Severe	0	0
Communicate to patient and/or caregiver about the recommended treatment plan and any optional plans, including disclosure of potential risks/benefits in orthotic/prosthetic care	None	80	40
	Minor	15	30
	Moderate	5	25
	Severe	0	5
Document treatment plan using established record-keeping techniques	None	95	70
	Minor	5	30
	Moderate	0	0
	Severe	0	0
Ensure patient or responsible parties are informed of their financial responsibilities (for example, insurance verification/ authorization, deductibles, co-pays) as they pertain to proposed treatment plan	None	95	70
	Minor	5	30
	Moderate	0	0
	Severe	0	0

Domain 3: Implementation of the Treatment Plan	**Magnitude of Harm**	**Probability: Certified**	**Probability: Uncertified**
Inform patient, family, and/or caregiver of the orthotic/prosthetic procedure, possible risks, and time involved in the procedure	None	95	95
	Minor	5	5
	Moderate	0	0
	Severe	0	0

Provide patient with preparatory care for orthotic/prosthetic treatment (e.g., diagnostic splint, compression garment)	None	95	95
	Minor	5	5
	Moderate	0	0
	Severe	0	0
Select appropriate materials/techniques in order to obtain a patient model/image	None	95	70
	Minor	5	30
	Moderate	0	0
	Severe	0	0
Prepare patient for procedure required to initiate treatment plan (e.g., measure, take impression, delineate, scan, digitize)	None	95	80
	Minor	5	20
	Moderate	0	0
	Severe	0	0
Perform procedure (e.g., measure, take impression, delineate, scan, digitize)	None	95	80
	Minor	5	20
	Moderate	0	0
	Severe	0	0
Refer to manufacturer's specifications and other technical resources regarding components/materials	None	80	30
	Minor	15	40
	Moderate	5	30
	Severe	0	0
Select appropriate materials and components for orthosis/prosthesis based on patient criteria to ensure optimum strength, durability, and function (e.g., ankle or knee joints, feet, knee units, lamination layups)	None	95	95
	Minor	5	5
	Moderate	0	0
	Severe	0	0
Prepare delineation/impression/template for modification/fabrication (e.g., prepare impression/reverse delineation, digitize)	None	95	95
	Minor	5	5
	Moderate	0	0
	Severe	0	0
Rectify and prepare patient model/image for fabrication	None	80	50
	Minor	20	40
	Moderate	0	10
	Severe	0	0
Fabricate/assemble orthosis/prosthesis in order to prepare for initial or diagnostic fitting and/or delivery	None	95	95
	Minor	5	5
	Moderate	0	0
	Severe	0	0

Assess device for structural safety and ensure manufacturers' guidelines have been followed prior to patient fitting/delivery (e.g., torque values, patient weight limits)	None	95	95
	Minor	5	5
	Moderate	0	0
	Severe	0	0
Assess/align orthosis/prosthesis for accuracy in sagittal, transverse, and coronal planes in order to provide maximum function/comfort	None	95	90
	Minor	5	10
	Moderate	0	0
	Severe	0	0
Ensure materials, design, and components are provided as specified in the treatment plan	None	95	95
	Minor	5	5
	Moderate	0	0
	Severe	0	0
Complete fabrication process after achieving optimal fit and function of orthosis/prosthesis (e.g., convert test socket to definitive orthosis/prosthesis)	None	80	50
	Minor	15	30
	Moderate	5	20
	Severe	0	0
Educate patient and/or caregiver about the use and maintenance of the orthosis/prosthesis (e.g., wearing schedules, other instructions)	None	95	95
	Minor	5	5
	Moderate	0	0
	Severe	0	0
Re-assess orthosis/prosthesis for structural safety prior to patient delivery	None	-	-
	Minor	-	-
	Moderate	-	-
	Severe	-	-
Document treatment using established record-keeping techniques to verify implementation of treatment plan	None	95	95
	Minor	5	5
	Moderate	0	0
	Severe	0	0
Refer patient to appropriate health care providers (e.g., nurse practitioners, therapists) for necessary ancillary care	None	95	95
	Minor	5	5
	Moderate	0	0
	Severe	0	0

Domain 4: Follow-up treatment plan	**Magnitude of Harm**	**Probability: Certified**	**Probability: Uncertified**
Obtain feedback from patient and/or caregiver to evaluate	None	95	95

outcome (e.g., wear schedule/tolerance, comfort, perceived benefits, perceived detriments, ability to don and doff, proper usage and function, overall patient satisfaction)	Minor	5	5
	Moderate	0	0
	Severe	0	0
Assess patient's function and note any changes	None	90	80
	Minor	10	20
	Moderate	0	0
	Severe	0	0
Assess patient's skin condition (e.g., integrity, color, temperature, volume) and note any changes	None	80	50
	Minor	15	30
	Moderate	5	20
	Severe	0	0
Assess patient's general health, height, and weight, and note any changes	None	95	95
	Minor	5	5
	Moderate	0	0
	Severe	0	0
Assess patient's psychosocial status (e.g., family status, job, or caregiver), and note any changes	None	95	80
	Minor	5	20
	Moderate	0	0
	Severe	0	0
Assess fit of orthosis/prosthesis with regard to strategic contact (e.g., multiple force systems, total contact) to determine need for changes relative to initial treatment goals	None	80	55
	Minor	15	30
	Moderate	5	15
	Severe	0	0
Assess fit of orthosis/prosthesis with regard to anatomical relationships to orthosis/prosthesis (e.g., trimlines, static/dynamic alignment) to determine need for changes relative to initial treatment goals	None	80	55
	Minor	15	30
	Moderate	5	15
	Severe	0	0
Assess patient's achievement of planned treatment outcomes	None	95	95
	Minor	5	5
	Moderate	0	0
	Severe	0	0
Formulate plan to modify orthosis/prosthesis based on assessment of outcomes and inform patient and/or caregiver of plan to modify orthosis/prosthesis as necessary	None	75	50
	Minor	20	30
	Moderate	5	20
	Severe	0	0
Make or supervise modifications to orthosis/prosthesis	None	95	95

(e.g., relieve pressure, change range of motion, change alignment, change components, add pressure-sensitive pad)	Minor	5	5
	Moderate	0	0
	Severe	0	0
	None	95	95
	Minor	5	5
	Moderate	0	
Assess modified device for structural safety	Severe	0	
	None	95	95
	Minor	5	5
	Moderate	0	0
Evaluate results of modifications to orthosis/prosthesis, including static and dynamic assessment	Severe	0	0
	None	95	95
	Minor	5	5
Reassess patient knowledge of goals and objectives to ensure proper use of orthosis/prosthesis relative to modifications	Moderate	0	0
	Severe	0	0
	None	95	95
	Minor	5	5
Document all findings and actions and communicate with physicians, referral sources, appropriately licensed health care providers to ensure patient status is updated	Moderate	0	0
	Severe	0	0
	None	95	95
	Minor	5	5
	Moderate	0	0
Develop long-term follow-up plan	Severe	0	0

Domain 5: Practice Management	**Magnitude of Harm**	**Probability: Certified**	**Probability: Uncertified**
Plan, implement, evaluate, and document policies and procedures in compliance with all applicable federal and state laws and regulations and professional and ethical guidelines (e.g., CMS, HIPPA, FDA, ADA, OSHA, ABC Code of Professional Responsibility)	None	95	95
	Minor	5	5
	Moderate	0	0
	Severe	0	0
	None	95	95
	Minor	5	5
Develop and implement personnel policies and procedures (e.g., benefits, training, incentives, staff recognition, regular performance evaluations)	Moderate	0	0
	Severe	0	0
	None	95	95
	Minor	5	5
Establish procedures for patient care that comply with current medical/legal requirements	Moderate	0	0

	Severe	0	0
Demonstrate proper documentation of patient history and financial records using established record-taking techniques	None	95	95
	Minor	5	5
	Moderate	0	0
	Severe	0	0
Create a professional, cooperative working environment to improve patient care	None	95	95
	Minor	5	5
	Moderate	0	0
	Severe	0	0

Domain 6: Promotion of Competency and Enhancement of Professional Practice	**Magnitude of Harm**	**Probability: Certified**	**Probability: Uncertified**
Participate in continuing education and/or provide such education for other health care providers, orthotic and prosthetic practitioners, pedorthists, assistants, fitters, technicians, and office staff (e.g., publications, seminars, case studies)	None	95	80
	Minor	5	20
	Moderate	0	0
	Severe	0	0
Participate in education of residents, students and trainees	None	95	80
	Minor	5	20
	Moderate	0	0
	Severe	0	0
Conduct or participate in product development research, clinical trials, and outcome studies	None	95	80
	Minor	5	20
	Moderate	0	0
	Severe	0	0
Participate in the development, implementation, and monitoring of public policy regarding orthotics/prosthetics (e.g., provide testimony/ information to legislative/regulatory bodies, serve on professional committees and regulatory agencies)	None	95	80
	Minor	5	20
	Moderate	0	0
	Severe	0	0
Participate in/with consumer organizations and nongovernmental organizations in order to promote competency and enhancement of orthotic/prosthetic profession	None	95	80
	Minor	5	20
	Moderate	0	0
	Severe	0	0

Mr. Howell

Domain 1 Patient Assessment	Magnitude of Harm	Probability: Certified	Probability: Uncertified
	None	95	90
	Minor	5	10
	Moderate	0	0
Review patient's prescription/referral	Severe	0	0
Harm Factor			
	None	95	90
	Minor	5	10
	Moderate	0	0
Take a comprehensive patient history, etc....	Severe	0	0
Harm Factor			
Perform a diagnosis-specific functional clinical and cognitive ability examination that includes manual muscle testing, gait analysis, and evaluation of sensory function, range of motion, joint stability, and skin integrity	None	90	85
	Minor	5	10
	Moderate	5	5
	Severe	0	0
	None	100	100
Consult with other health care providers and caregivers, when appropriate, about patient's condition in order to formulate a treatment plan	Minor	0	
	Moderate	0	
	Severe	0	
	None	100	100
Verify patient care by documenting history, ongoing care, and follow-up, using established record-keeping techniques	Minor	0	10
	Moderate	0	0
	Severe	0	0
	None	90	85
Refer patient, if appropriate, to other health care providers for intervention beyond orthotic/prosthetic scope of practice	Minor	5	10
	Moderate	5	5
	Severe	0	0

Domain 2: Formulation of the Treatment Plan	Magnitude of Harm	Probability: Certified	Probability: Uncertified
	None	90	85
	Minor	5	10
Evaluate the findings to determine an orthotic/prosthetic treatment plan	Moderate	5	5
	Severe	0	0
Formulate treatment goals and expected orthotic/prosthetic outcomes to reduce pain, increase	None	90	80
	Minor	5	10

comfort, provide stability, prevent deformity, address aesthetic factors, and/or promote healing to enhance function and independence	Moderate	5	10
	Severe	0	0
Consult with physician/referral source/appropriately licensed health care provider to modify, if necessary, the original prescription and/or treatment plan	None	90	80
	Minor	5	10
	Moderate	5	10
	Severe	0	0
Identify design, materials, and components to support treatment plan	None	90	80
	Minor	5	10
	Moderate	5	10
	Severe	0	0
Develop a treatment plan based on patient needs, including patient education and follow-up	None	90	80
	Minor	5	10
	Moderate	5	10
	Severe	0	0
Communicate to patient and/or caregiver about the recommended treatment plan and any optional plans, including disclosure of potential risks/benefits in orthotic/prosthetic care	None	90	80
	Minor	5	10
	Moderate	5	10
	Severe	0	0
Document treatment plan using established record-keeping techniques	None	90	60
	Minor	5	20
	Moderate	5	20
	Severe	0	0
Ensure patient or responsible parties are informed of their financial responsibilities (for example, insurance verification/ authorization, deductibles, co-pays) as they pertain to proposed treatment plan	None	90	60
	Minor	5	20
	Moderate	5	20
	Severe	0	0

Domain 3: Implementation of the Treatment Plan	**Magnitude of Harm**	**Probability: Certified**	**Probability: Uncertified**
Inform patient, family, and/or caregiver of the orthotic/prosthetic procedure, possible risks, and time involved in the procedure	None	89	80
	Minor	5	10
	Moderate	1	10
	Severe	0	0
Provide patient with preparatory care for orthotic/prosthetic treatment (e.g., diagnostic splint,	None	89	80
	Minor	5	10

compression garment)	Moderate	1	10
	Severe	0	0
	None	90	80
	Minor	5	10
Select appropriate materials/techniques in order to obtain a patient model/image	Moderate	5	10
	Severe	0	0
	None	89	80
	Minor	5	10
Prepare patient for procedure required to initiate treatment plan (e.g., measure, take impression, delineate, scan, digitize)	Moderate	1	10
	Severe	0	0
	None	90	80
	Minor	5	10
Perform procedure (e.g., measure, take impression, delineate, scan, digitize)	Moderate	5	10
	Severe	0	0
	None	89	80
	Minor	5	10
Refer to manufacturer's specifications and other technical resources regarding components/materials	Moderate	1	10
	Severe	0	0
	None	90	80
	Minor	5	10
Select appropriate materials and components for orthosis/prosthesis based on patient criteria to ensure optimum strength, durability, and function (e.g., ankle or knee joints, feet, knee units, lamination layups)	Moderate	5	10
	Severe	0	0
	None	90	80
	Minor	5	10
Prepare delineation/impression/template for modification/fabrication (e.g., prepare impression/reverse delineation, digitize)	Moderate	5	10
	Severe	0	0
	None	89	80
	Minor	5	10
	Moderate	1	10
Rectify and prepare patient model/image for fabrication	Severe	0	0
	None	90	80
	Minor	5	10
Fabricate/assemble orthosis/prosthesis in order to prepare for initial or diagnostic fitting and/or delivery	Moderate	5	10
	Severe	0	0
Assess device for structural safety and ensure manufacturers' guidelines have been followed prior to	None	90	80
	Minor	5	10

patient fitting/delivery (e.g., torque values, patient weight limits)	Moderate	5	10
	Severe	0	0
Assess/align orthosis/prosthesis for accuracy in sagittal, transverse, and coronal planes in order to provide maximum function/comfort	None	90	80
	Minor	5	10
	Moderate	5	10
	Severe	0	0
Ensure materials, design, and components are provided as specified in the treatment plan	None	90	80
	Minor	5	10
	Moderate	5	10
	Severe	0	0
Complete fabrication process after achieving optimal fit and function of orthosis/prosthesis (e.g., convert test socket to definitive orthosis/prosthesis)	None	90	80
	Minor	5	10
	Moderate	5	10
	Severe	0	0
Educate patient and/or caregiver about the use and maintenance of the orthosis/prosthesis (e.g., wearing schedules, other instructions)	None	90	80
	Minor	5	10
	Moderate	5	10
	Severe	0	0
Re-assess orthosis/prosthesis for structural safety prior to patient delivery	None	90	80
	Minor	5	10
	Moderate	5	10
	Severe	0	0
Document treatment using established record-keeping techniques to verify implementation of treatment plan	None	90	80
	Minor	5	10
	Moderate	5	10
	Severe	0	0
Refer patient to appropriate health care providers (e.g., nurse practitioners, therapists) for necessary ancillary care	None	90	80
	Minor	5	10
	Moderate	5	10
	Severe	0	0

Domain 4: Follow-up treatment plan	**Magnitude of Harm**	**Probability: Certified**	**Probability: Uncertified**
Obtain feedback from patient and/or caregiver to evaluate outcome (e.g., wear schedule/tolerance, comfort, perceived benefits, perceived detriments, ability to don	None	90	80
	Minor	5	10
	Moderate	5	10

and doff, proper usage and function, overall patient satisfaction)	Severe	0	0
Assess patient's function and note any changes	None	90	80
	Minor	5	10
	Moderate	5	10
	Severe	0	0
Assess patient's skin condition (e.g., integrity, color, temperature, volume) and note any changes	None	90	80
	Minor	5	10
	Moderate	5	10
	Severe	0	0
Assess patient's general health, height, and weight, and note any changes	None	90	80
	Minor	5	10
	Moderate	5	10
	Severe	0	0
Assess patient's psychosocial status (e.g., family status, job, or caregiver), and note any changes	None	90	80
	Minor	5	10
	Moderate	5	10
	Severe	0	0
Assess fit of orthosis/prosthesis with regard to strategic contact (e.g., multiple force systems, total contact) to determine need for changes relative to initial treatment goals	None	90	80
	Minor	5	10
	Moderate	5	10
	Severe	0	0
Assess fit of orthosis/prosthesis with regard to anatomical relationships to orthosis/prosthesis (e.g., trimlines, static/dynamic alignment) to determine need for changes relative to initial treatment goals	None	90	80
	Minor	5	10
	Moderate	5	10
	Severe	0	0
Assess patient's achievement of planned treatment outcomes	None	90	80
	Minor	5	10
	Moderate	5	10
	Severe	0	0
Formulate plan to modify orthosis/prosthesis based on assessment of outcomes and inform patient and/or caregiver of plan to modify orthosis/prosthesis as necessary	None	90	80
	Minor	5	10
	Moderate	5	10
	Severe	0	0
Make or supervise modifications to orthosis/prosthesis (e.g., relieve pressure, change range of motion, change alignment, change components, add pressure-sensitive	None	90	80
	Minor	5	10
	Moderate	5	10

pad)	Severe	0	0
	None	90	80
	Minor	5	10
	Moderate	5	10
Assess modified device for structural safety	Severe	0	0
	None	90	80
	Minor	5	10
	Moderate	5	10
Evaluate results of modifications to orthosis/prosthesis, including static and dynamic assessment	Severe	0	0
	None	90	80
	Minor	5	10
	Moderate	5	10
Reassess patient knowledge of goals and objectives to ensure proper use of orthosis/prosthesis relative to modifications	Severe	0	0
	None	90	80
	Minor	5	10
	Moderate	5	10
Document all findings and actions and communicate with physicians, referral sources, appropriately licensed health care providers to ensure patient status is updated	Severe	0	0
	None	90	80
	Minor	5	10
	Moderate	5	10
Develop long-term follow-up plan	Severe	0	0

Domain 5: Practice Management	**Magnitude of Harm**	**Probability: Certified**	**Probability: Uncertified**
Plan, implement, evaluate, and document policies and procedures in compliance with all applicable federal and state laws and regulations and professional and ethical guidelines (e.g., CMS, HIPPA, FDA, ADA, OSHA, ABC Code of Professional Responsibility)	None	98	90
	Minor	2	5
	Moderate	0	0
	Severe	0	0
Develop and implement personnel policies and procedures (e.g., benefits, training, incentives, staff recognition, regular performance evaluations)	None	98	90
	Minor	2	5
	Moderate	0	0
	Severe	0	0
Establish procedures for patient care that comply with current medical/legal requirements	None	98	90
	Minor	2	5
	Moderate	0	0
	Severe	0	0

Demonstrate proper documentation of patient history and financial records using established record-taking techniques	None	98	90
	Minor	2	5
	Moderate	0	0
	Severe	0	0
Create a professional, cooperative working environment to improve patient care	None	98	90
	Minor	2	5
	Moderate	0	0
	Severe	0	0

Domain 6: Promotion of Competency and Enhancement of Professional Practice	**Magnitude of Harm**	**Probability: Certified**	**Probability: Uncertified**
Participate in continuing education and/or provide such education for other health care providers, orthotic and prosthetic practitioners, pedorthists, assistants, fitters, technicians, and office staff (e.g., publications, seminars, case studies)	None	98	90
	Minor	2	5
	Moderate	0	0
	Severe	0	0
Participate in education of residents, students and trainees	None	98	90
	Minor	2	5
	Moderate	0	0
	Severe	0	0
Conduct or participate in product development research, clinical trials, and outcome studies	None	98	90
	Minor	2	5
	Moderate	0	0
	Severe	0	0
Participate in the development, implementation, and monitoring of public policy regarding orthotics/prosthetics (e.g., provide testimony/ information to legislative/regulatory bodies, serve on professional committees and regulatory agencies)	None	98	90
	Minor	2	5
	Moderate	0	0
	Severe	0	0
Participate in/with consumer organizations and nongovernmental organizations in order to promote competency and enhancement of orthotic/prosthetic profession	None	98	90
	Minor	2	5
	Moderate	0	0
	Severe	0	0