

# State Board of Orthotics, Prosthetics, and Pedorthics



[HTTP://OPP.OHIO.GOV](http://opp.ohio.gov)

JOHN R. KASICH, GOVERNOR  
BRIAN W. WEAVER, LPO, BOARD PRESIDENT

HB 326 – 130<sup>th</sup> General Assembly – Senate Commerce and Labor Committee – November 19, 2014

Chairman Baker, Members of the Committee

I am testifying today on behalf of the State Board of Orthotics, Prosthetics, and Pedorthics, the state agency constituted pursuant to action of the 123<sup>rd</sup> General Assembly to administer and enforce Revised Code Chapter 4779, the professions' Practice Act.

I am aware that there are many matters of import and concern before the committee and I do not wish to take up too much of the committee's time, but given both the legislative calendar and the current press of business, I wanted to once more apologize publicly, as I have done in conversation with a number of members on this matter, that the Board was absent from the process on this matter on the House side. We are asking this committee to do some detailed work on this matter that could have and should have been addressed in the House. I cannot change the past but would like to move forward in a cooperatively constructive manner.

To the best of my understanding, before you today is an amendment that was prepared for consideration before the session break. If that is the amendment the committee is considering today, I must respectfully differ from the Sponsor's representation that it addresses the concerns that have been raised by the interested parties who are opposed to the bill's liberal allowances for dispensation of these items.

77 S. High St., 18th floor  
Room #1854  
Columbus, OH 43215-6108

Phone: 614-466-1157  
Fax: 614-387-7347  
Email: [bopp@opp.ohio.gov](mailto:bopp@opp.ohio.gov)

Diabetic Therapeutic Shoes with appropriate inserts or modifications constitute the first line of medical device-related defense against lower limb and lower extremity amputations due to diabetes-related complications. It is an important benefit, but this bill seems to undervalue the important indicators for successful outcomes in utilization.

In fact, the amendment actually lowers the standard provided for in the original draft even further by eliminating the requirement for “assessment” or testing.

The bill with amendment would allow services to be provided:

- By persons who have engaged in no more education or training than that which is provided by an all-online 20-hour course.
- There is no requirement to obtain certification never mind maintain certification.
- There will be no enforceable continuing education requirement.
- There is no criminal background check requirement.
- And perhaps most concerning, there is no emphasis on clinical content of the care to be provided.

The rules of the road for this area of allied healthcare service delivery are essentially established by the US Department of Health and Human Services, CMS both through the facility accreditation protocol and the governance of the DMEPOS / HCPCS accounting system. Facility accreditation standards are based on the CMS Quality Standards for DMEPOS<sup>1</sup>, and those basic guidelines include an **Appendix C** specifying further details for provision of Orthotic and Prosthetic devices, including Therapeutic Shoes and Inserts.

Language specifies:

*The supplier shall be trained in a **broad range of treatment options** to ensure that the item(s) prescribed is/are optimal for the beneficiary’s condition. The provision of custom fabricated or custom fitted devices (i.e., other than off-the-shelf items) **requires access to a facility with the equipment necessary to fulfill the supplier’s responsibility** to provide follow-up treatment, including modification, adjustment, maintenance and repair of the item(s). Individuals supplying the*

---

<sup>1</sup> [http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads//DMEPOS\\_Qual\\_Stand\\_Booklet\\_ICN905709.pdf](http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads//DMEPOS_Qual_Stand_Booklet_ICN905709.pdf)

*item(s) set out in this appendix must possess specialized education, training, and experience in fitting, and certification and/or licensing.*

In the current context, it may be useful to note that these are accreditation standards that a typical pharmacy would not meet. According to testimony provided to date, pharmacies are only interested in providing the single service for which therapeutic shoe fitters are barely trained to offer, not “a broad range of treatment options to ensure that the item(s) prescribed is/are optimal for the beneficiary’s condition.” Neither can they claim “access to a facility with the equipment necessary” to fulfill other responsibilities as indicated.

We would respectfully suggest the Committee, the Senate and this Legislature consider in this context that the state of Ohio recognizes that retail pharmacies and compounding pharmacies are two different types of entities with different standards for service and accountability. The Facility Accreditation standards for DMEPOS suppliers provide a separate set of standards for service and accountability of this important patient benefit – diabetic therapeutic shoes and inserts -- that are not met by either Ohio’s retail or compounding pharmacies.

In addition, observing the manner in which the CMS post-payment and recovery auditors work, it is not difficult to envision a new audit initiative that may be launched to determine strict adherence to these standards by announcing requirements that are supported by the underlying authorizing language but were never previously articulated. I can point to some new indicators in federal regulatory guidelines and claim submission documentation requirements that tend to illustrate that federal authorities are moving in that direction.

- Information at **Medicare.gov**<sup>2</sup> currently states the following regarding eligibility for the benefit and provider qualifications:

***Who's eligible?***

*All people with Medicare who have diabetes and severe diabetic foot disease are covered. Your doctor must certify that you need therapeutic shoes or inserts. A [podiatrist](#) or other qualified doctor must prescribe these items and they must be provided by one these:*

- A podiatrist*
- An orthotist*
- A prosthetist*
- A pedorthist*

- In the current CMS publication Medicare's Coverage of Diabetic Supplies & Services<sup>3</sup>, the following requirements for reimbursement are included:

*p. 14 Therapeutic shoes or inserts (continued)*

***How do I get therapeutic shoes?***

\*\*\*

*Medicare also requires:*

*A podiatrist or other qualified doctor prescribes the shoes*

***A doctor or other qualified individual like a pedorthist, orthotist, or prosthetist fits and provides the shoes***

- In addition, the Local Coverage Article published by the Medicare contractor for the Ohio region has just been updated (effective November 2014<sup>4</sup>) to include the following language:

*Therapeutic Shoes for Persons with Diabetes – Policy Article – **Effective November 2014** (A47129)*

\* \* \*

*The Supplier is the person or entity that actually furnishes the shoe, modification, and/or insert to the beneficiary and that bills Medicare. **The supplier may be a podiatrist, pedorthist, orthotist, prosthetist or other qualified individual.** The Prescribing Physician may be the supplier. The Certifying Physician may only be the supplier if the certifying physician is practicing in a defined rural area or a defined health professional shortage area.*

\* \* \*

**4. Prior to selecting the specific items** that will be provided, the supplier must conduct and document an **in-person evaluation of the beneficiary**. (Refer to the related Local Coverage Determination, Documentation Requirements section, for additional information.)

**5 At the time of in-person delivery to the beneficiary** of the items selected, the supplier must conduct **an objective assessment of the fit of the shoe and inserts and document the results**. **A beneficiary's subjective statements regarding fit as the sole documentation of the in-person delivery does not meet this criterion.**

<sup>2</sup> <http://www.medicare.gov/coverage/therapeutic-shoes-or-inserts.html>

<sup>3</sup> <http://www.medicare.gov/Pubs/pdf/11022.pdf>

<sup>4</sup> [http://www.ngsmedicare.com/ngs/portal/ngsmedicare/newngs/home-lob/pages/medical-policy-center/mpc-search-detail/a47129\\_future\\_110114](http://www.ngsmedicare.com/ngs/portal/ngsmedicare/newngs/home-lob/pages/medical-policy-center/mpc-search-detail/a47129_future_110114)

*If criteria 1–5 are not met, the therapeutic shoes, inserts and/or modifications will be denied as noncovered. When codes are billed without a KX modifier (see Documentation Requirements section in the accompanying Local Coverage Determination), they will be denied as noncovered.*

Thus, while CMS has not stated definitively the qualifications required for dispensing/fitting diabetic therapeutic shoes and inserts, all current indications are that there is an expectation that services are to be performed by persons with significant and substantial education and training for the tasks and processes involved. The bill in its current form with the proposed amendment suggests that the evaluations, procedures and fittings required for successful patient outcomes are merely casual formalities. We believe that perspective does a disservice to diabetic patients.

In addition, exempting these services from licensure runs counter to the current Health Transformation / Minimum Data Set initiative that is being spearheaded by the Health Policy Institute of Ohio. The Board has been working cooperatively to assure inclusion of these rehabilitation and preventive services in the scope of data obtained to assure and direct appropriate utilization and inclusion. We would like to be able to continue toward that goal.

The State Board of Orthotics, Prosthetics and Pedorthics is not a Big Dog among professional licensing agencies, but Ohio has established its recognition of the fields of endeavor as clinically-oriented partners in the provision of allied healthcare services to deserving Ohio consumers and beneficiaries. The Board will work diligently and conscientiously to administer the provisions of law the General Assembly determines are appropriate.

After this committee's last hearing on this matter, we understood our charge to seek consensus and resolution with the bill's sponsor and the supporting parties and met in good faith toward those goals. Along with this testimony, I am providing for the Committee's consideration the correspondence and proposed language we offered to the Sponsor to address what we understood were shared concerns. We would be eager to continue to work with the Sponsor and/or any identified members of this Committee to continue in that manner. Thank you for your consideration and attention.

Mark B. Levy, Board Director, State Board of Orthotics Prosthetics and Pedorthics