

**MINUTES
STATE BOARD OF ORTHOTICS, PROSTHETICS AND PEDORTHICS
ANNUAL BOARD MEETING**

September 11, 2013

This Regular Meeting of the State Board of Orthotics, Prosthetics and Pedorthics (OPP) was held on the above date in the West B&C conference room, 31st floor of the Riffe Center, 77 South High Street, Columbus, Ohio.

I. Call to Order: The meeting scheduled for 2:00 p.m. was called to order at 2:05 p.m. New Board Member Brian Weaver, LPO, was welcomed to the group.

Roll Call:

Members present: Animesh Bhatia, DPM;
Jason Macedonia, LPO – Board Secretary
Bill Neu, LPO – Board President
Brian Weaver, LPO;
Pedorthist seat - Vacant

Members absent: Edwin Niehaus, LP
Robert Reed, consumer

Staff present: Mark B. Levy, Board Director
Meloney Buehl, Office Assistant
Cheryl Hawkinson, Assistant Attorney General

Guests: Levi Tkach, Attorney at Law
Frank Denton, LPED (after Executive Session)
Teresa L. Mantz, Court Reporter (left after hearing)

II. Agenda – Amend/Approve: The agenda as distributed was briefly reviewed, Mr. Levy noted changes/updates from the prior version posted. Notably, the order for consideration of some action items was moved up to assure a quorum would be present, noting two absences and Mr. Neu's need to leave the meeting by 4:45 p.m. After brief discussion and request for questions or additions, motion to approve agenda by Weaver/Macedonia, no further discussion, approved by unanimous vote.

III. Review/Approve Minutes of June 12, 2013, meeting: Minutes having previously been circulated, it was moved/seconded by Bhatia/Weaver to approve without amendment or correction. No further discussion, vote was unanimous in favor.

IV. Record Hearing and Deliberation in re: Notice of Opportunity for Hearing issued to Michael P. Marmer: The regular meeting of the Board was adjourned at 2:07 p.m. to commence the hearing as noted. Mr. Neu presided as Hearing Officer, Ms. Hawkinson presented for the state of Ohio, and Mr. Levy was called as a witness. Board Members present for the hearing, constituting a quorum, were Animesh Bhatia, Jason Macedonia, and Brian Weaver in addition to Bill Neu, presiding. The record was taken by court reporter Teresa L. Mantz. The hearing concluded at 2:33 p.m.

V. Executive Session [ORC § 121.22(G)] -- The regular meeting of the Board was reconvened, and it was moved/seconded by Macedonia/Bhatia to enter Executive Session pursuant to ORC Section 121.22 (G), to consider the appointment, employment, dismissal, discipline, promotion, demotion, or compensation of a public employee or official; to consider the investigation of charges

or complaints against licensees; and to consider matters required to be kept confidential by federal law or regulations or state statutes. Roll Call vote was taken with Bhatia, Macedonia, Neu, and Weaver affirming the motion, requesting staff and AG representative to be excused as well as guests for hearing deliberation. At about 2:50 p.m., staff and AAG were asked back into Executive Session. Unanimous roll call vote to come out of Executive Session occurred at 3:35 p.m.

A short break was taken.

V. 3:40 p.m. Settlements / Charges / Dispositions / Complaints

A. Hearing Disposition– file #13 C 34

Mr. Neu reviewed the evidence presented and gave the Board’s findings of fact and conclusions of law. Based on consideration of all the information available and presented, Mr. Neu advised that all members present and hearing this matter, constituting a quorum, were unanimous in their determination to deny a license in Pedorthics to Mr. Marmer. Members present were polled and all answered in the affirmative regarding their vote, and their votes were recorded by signature on the findings/conclusions document. Mr. Levy was directed to issue an Adjudication Order consistent with the Board’s determination, and the Order, Findings of Fact and Conclusions of Law is attached to these minutes and incorporated by reference.

B. Complaint statuses and tracking

Ms. Buehl was asked to review the status and tracking metrics related to the statistics backing up the charts and graphs presented for the Board’s review. Information is presented as tracked by fiscal year, and it was noted that only two months into the current fiscal year, complaint activity appears to be increasing compared year to year. Relevant charts and graphs are appended to these minutes and incorporated by reference.

The following complaints by tracking number were presented for the Board’s consideration to approve for closure as indicated:

<u>File #</u>	<u>File Subject</u>	<u>Issue addressed</u>	<u>Resolution recommendation</u>
<u>13 C 20</u>	LPED	Supervision; Standard of Care	accept compliance plan / educative
<u>13 C 21</u>	LPED	Standard of Care	no fault found / educative
<u>13 C 35</u>	Retail Shoe Store	Unlicensed Practice	no jurisdiction / no basis
<u>13 C 36</u>	LPED	Standard of Care	in compliance / educative
<u>14 C 01</u>	Out of State DME	Unlicensed Practice	in compliance / educative
<u>14 C 02</u>	DME - Orthotics	Letter of Exemption Request	educative / in compliance
<u>14 C 06</u>	CMS Supplier Directory	Unlicensed Practice	no basis / in compliance

Motion to approve file closure recommendations as indicated on the list was made/seconded by Weaver/Bhatia, no discussion, vote was unanimous in favor.

VII -- Pending License Applications/Licenses Issued:

It was moved/seconded (Macedonia/Weaver) to approve the issuance of licenses as follows:

- **Eric Steinmetz – Temporary/Orthotics** - Masters in O&P from Eastern Michigan University, David DeLuccia, LPO supervisor 2012 – 2013, residency in-state. Needs approval to sit, holds current LP. CRC waived based on currently licensed status.
- **Laura Jackson – Temporary/Orthotics** – Bachelor of Science from University of South Carolina, Leo Godlewski, LPO, in-state supervision in progress; has passed exams, holds ABC CO credential. CRC results in file.
- **Jeremy Farley – Reciprocity/Prosthetics-Orthotics** – Bachelor of Science from The University of Texas, Active LO and LP licenses in Tennessee, passed exams 2006 and 2009, CRC results in file.

No discussion, vote to approve was unanimous.

VIII - 4:10 pm New Business

A. Election of Officers – Nomination and Vote

An election by floor nomination and voice vote was held in accordance with Revised Code § 4779.06, which provides in part "...the board's annual meeting shall be held in this state in September. ... The board shall annually select from its membership a president and a secretary. ..."

1. President -- Bill Neu was nominated from the floor by Dr. Bhatia to continue his current role. Mr. Neu accepted the nomination. No other nominations were made. Vote in favor was unanimous.
2. Secretary – Jason Macedonia was nominated from the floor by Mr. Neu. Mr. Macedonia accepted the nomination. Vote in favor was unanimous.

B. Federal OTS Orthotics and Competitive Bid initiative.

Mr. Levy introduced the topic for consideration going forward without a specific proposal. CMS has recently issued a "final" list – a very long list – of devices it intends to consider to be Off the Shelf devices subject to Competitive Bid, and has indicated an intent to re-write HCPCS narrative descriptions and assign new HCPCS codes for those OTS devices that it has determined may also qualify as custom fit devices when required by patient presentation and appropriate medical findings and orders. Importantly and perhaps positively, information available signals an intent to remove the phrase "includes fitting and adjustment" from the codes to be utilized for OTS devices, which seems to bolster the Board's position that companies billing for the devices under the current language but not performing fitting and adjusting services are billing for services not rendered.

Mr. Levy noted that the Ohio regulatory language governing what may be considered a prefabricated orthotic device that does not require custom fitting by an appropriately trained or licensed professional is differentiated from the subjective, vague federal language. Combined with the fact that CMS has not closed the loop on its charge to clearly articulate the level of education/training/certification required to appropriately dispense and fit certain O&P devices, these reimbursement-related issues come within the Board's purview as a tangent to enforcement of unlicensed practice prohibitions. The Board will need to examine going forward its extended and incomplete effort to review and determine appropriate compliance parameters for certain commonly utilized prefabricated orthotic devices.

Distributed for consideration and future discussion were articles reviewing the issues by stakeholder representatives in O&P (the American Orthotic and Prosthetic Association) as well as the broader medical device sector (Home Medical Equipment Providers).

C. Issue Introduction: Pedorthic Standard of Care – Diabetic Therapeutic Shoes

Noting that issues have been raised and reviewed in the process of addressing a number of complaint/enforcement issues recently, Mr. Levy identified this topic as ripe for the Board's consideration for regulatory guidance to licensees and possible promulgation of rule language clarifying standard of care and scope of practice considerations.

1. CMS Regulatory Language and Gaps – Minimum Standards for provision of DTS services are established by Center for Medicare/Medicaid Services instructive language in the Local Coverage Article (LCA) for Therapeutic Shoes for Persons with Diabetes (A47129) and the companion Local Coverage Determination (LCD) for Therapeutic Shoes for Persons with Diabetes (L27040). Copies were distributed. It was noted that although regulatory treatment of DTS services seems to emulate similar protocols as other DME, certain anomalies and points of difference seem to exist. For example, provision of services is predicated upon a statement from the physician overseeing care and treatment of the patient's diabetic condition, and although language and format for such a statement is suggested in the LCD, separate guidance in the DME MAC Supplier Manual providing specific requirements for Certificates of Medical Necessity and Durable Medical Equipment Information Forms does not address such requirements for DTS services specifically.

2. Clinical tasks and documentation -- In addition, although the regulatory language clearly requires the supplier to engage in a clinical evaluation of foot conditions and device fit and utility, CMS has failed to articulate education/experience/credentialing requirements for suppliers providing the service. In unlicensed jurisdictions, apparently any DME supplier's personnel can be considered qualified to engage in these evaluative processes. Requirements include the ability to review and understand medical records and doctor's narratives pertaining to the condition and comprehensive treatment of the patient, as well as the conduct of an evaluation of the patient's feet for the specific purpose of the service to be provided.

3. Forms appropriate to policy and requirements – the gaps identified above have resulted in suppliers creating combination certification and prescription forms to fulfill both basic requirements. Some suppliers thus consider their paperwork required to support dispensation and reimbursement to be proprietary in nature, and in some cases forms that have come up for Board review seem designed to "drive" physician prescription toward certain DTS service options without allowing for physician choice or direction to provide some allowed services that may be most appropriate for an individual patient's presentation.

Board discussion noted the following requirements and policies that may be appropriate for specific Ohio regulatory reinforcement and guidance, recognizing that Pedorthic Standards of Care as well as DTS policy set a higher bar for suppliers than baseline DME documentation requirements:

- An order for each item billed must be signed and dated by the prescribing physician, kept on file by the supplier, and made available upon request.
- The detailed written order must be signed on or after the date of the visit with the Prescribing Physician
- The supplier must obtain a signed statement from the physician who is managing the patient's systemic diabetes condition (i.e., the certifying physician) specifying that the patient has diabetes mellitus, has one of conditions 2a-2f listed in the related Policy Article, is being treated under a comprehensive plan of care for his/her diabetes, and needs diabetic shoes. This statement must be completed, signed, and dated by the certifying physician.
- The certifying physician must be an M.D. or D.O and may not be a podiatrist, physician assistant, nurse practitioner, or clinical nurse specialist.
- The in-person evaluation of the patient by the supplier at the time of selecting the items that will be provided (refer to related Policy Article, Non-Medical Necessity Coverage and Payment Rules, criterion 4) must include at least the following:
 1. An examination of the patient's feet with a description of the abnormalities that will need to be accommodated by the shoes/inserts/modifications.
 2. For all shoes, taking measurements of the patient's feet.
 3. For custom molded shoes (A5501) and inserts (A5513), taking impressions, making casts, or obtaining CAD-CAM images of the patient's feet that will be used in creating positive models of the feet.
- The in-person evaluation of the patient by the supplier at the time of delivery (refer to related Policy Article, Non-Medical Necessity Coverage and Payment Rules, criterion 5) must be conducted with the patient wearing the shoes and inserts and must document that the shoes/inserts/modifications fit properly.

Samples of forms utilized or recommended by providers, suppliers and manufacturers discovered in research of these issues were distributed for members' review and consideration.

VI. – Consent Agenda: Director's Report

A. Fiscal – Revenue and Expense

Spreadsheet data as presented to the Board is appended.

1. FY13 Performance data – Revenue and Expense - Final
FY13 Revenue - Final: \$111,165.00
FY13 Expense - Final: \$132,338.50

2. FY14 Performance data YTD – Revenue and Expense
FY14 Revenue YTD, 2 months (end of August): \$1,305.00
FY14 Expense YTD, 2 months (end of August): \$22,224.81

3. MBE/EDGE Projections and Participation
 FY13 Participation 23.78%
 FY14 Forecasted Max Participation 43.43%
3. Multi-Function Printer (All-in-one) Replacement/procurement
 Prior Monthly Average (Maintenance & Usage Only): Approx. \$25.00
 Expected Monthly Charges going forward (Lease, Maintenance &
 Usage): Approx. \$85.00

B. Annual Asset Certification -- Statement in Compliance with ORC 117.17 – Letter of Representation

Asset list as certified as of end of FY13 was distributed as attached. In addition, given the recent discussions regarding a likely change of personnel in the Director position within the next few years, Mr. Levy provided a copy of a prepared letter in compliance with ORC §117.17.

C. Legislative Report

1. Legislative Docket / Tracking – appended as presented. No verbal report, no discussion.
2. Practice Act Review – no report.

D. Administrative Docket

1. ODJFS – Rule Revisions and statuses – no report
2. New eLicense Database setup activity – following up on prior progress reports, Mr. Levy advised the Board regarding status of the implementation of a new eLicense system to be rolled out as an enterprise-wide (all state of Ohio entities requiring use of such a licensing/renewal/enforcement tracking system) platform configured for individual agency utilization. Two things generally should be recognized: “Go Live” projections have been re-set from December 2013 until September 2014; Planning and training activities will be demanding an extraordinary investment of staff time.
 - a. Steering Committee participation – Monthly Meetings – This committee was formed from the larger agency Stakeholder group to address fundamental issues about contract compliance, requirements details, implementation re-set scheduling, and providing a focused decision point for change orders and similar issues. Mr. Levy was appointed to provide input and oversight for small agency utilization.
 - b. Training and Testing requirements – general scheduling considerations have been laid out as follows

1. Stakeholder meetings – every two weeks
2. General System Intro Training – 40 hours – 9/30 > 10/04/13
3. User Acceptance Training One – 16-24 hours – Oct > Nov 2013
DAS/IT staff and consultants work one-on-one with OPP to review details of agency system configuration, test data handling and system tools, find any issues or glitches to be addressed.
4. UAT Two – April > June 2014 – agency configuration review to assess system enhancements and compliance with agency requirements
5. UAT Three – July 2014 – final pre-“Go Live” review
6. Go Live -- September 1, 2014

3. Workforce plan approved -- Mr. Levy reported that pursuant to Executive Branch initiative, we previously produced and provided for Board review a Workforce Plan for 2012 documenting agency metrics and compliance with various administrative requirements. That report was recently subject to a review process, and has been formally approved.

4. Recommendation Template submitted: Executive Order 2013-05K: Streamlining the Occupational Licensing Process for Veterans – Distributed and provided for Board review. This is a preliminary report on the agency’s efforts and ability to comply with an Executive Order and companion legislation seeking to enhance civilian workforce re-integration opportunities for military veterans and their spouses.

X. Ethics Review

1. Statewide training opportunities were referenced and reviewed. Board members are encouraged to avail themselves of offerings as their schedules may allow.

- a. OEC trainings – schedule distributed - <http://www.ethics.ohio.gov/education/executiveordertraining.shtml>
- b. OEC Webinars: <http://www.ethics.ohio.gov/education/webinars.shtml>
- c. Auditor of State – Fiduciary Responsibility Webinar- <http://www.auditor.state.oh.us/conferences/FiduciaryTrainingWebinar112812.pdf>

2. OIG Reports – 2012-CA00071 -- A recent report critical of the actions of the Director of a large occupational and facilities licensing agency was distributed and discussed. The investigation centered around the Director’s actions concerning a conflict between the owners of a licensed facility and a licensed subcontractor renting space at the facility. A relative of the contractor had filed a complaint with the Board about the facility, and the facility owners had initiated a process to sever the professional relationship with the related licensee. The Director’s intervention was sought by one or more of the parties. A violation citation had been issued to the facility owners regarding the subject of the

complaint that had been filed with the Board. The Director, in an apparent attempt to facilitate resolution of the dispute offered that the Board, through a public and documented process, could reduce the fine for which the facility could have been found liable in exchange for the owners' agreement to allow the licensed subcontractor additional time to wind down operations at the site and locate another work location. No allegations of personal or compensation-based "favors" were made or found, and the parties signed off on an agreement which was presented to and approved by the Board. However, the Office of the Inspector General of Ohio found that the Director by intervening in the dispute and offering a resolution which entailed actions outside of the agency's formal jurisdiction – the terms of a business agreement between licensed facility owner and licensed subcontractor -- committed a "Wrongful act or omission ... [involving actions] not in accordance with ... such standards of proper governmental conduct as are commonly accepted in the community and thereby subverts, or tends to subvert, the process of government."

XI. - 5:00 pm Old Business

A. Board Continuity –

1. Pedorthist seat vacant – candidate recruitment. Mr. Levy reported on continuing activity in candidate recruitment and review. It was noted that meeting guest Frank Denton, LPED, has submitted an application today with the Governor's office. Mr. Denton is a former Florida practitioner and licensee who has been licensed in Ohio since early 2012 but has been active in the field for 15+ years.
2. Mr. Niehaus' position opens 12/6/2013. Members are greatly encouraged to consider colleagues who may be interested and to assist in recruitment efforts.

B. OPPCE Audit 2013 – final report

1. 46 Licensees were selected for OPPCE Audit (100% of sub group 3)
2. 46 Licensees have responded to the initial request for audit with 100% having completed their CE requirement for the 2010-2012 accrual period

XI. – 5:345 pm Adjournment Motion by Bhatia/Macedonia passed
unanimously without discussion.

Respectfully submitted,

Mark B. Levy
Mark B. Levy
Board Director

William C. Neu, 999
William C. Neu
President

12/11/13
Date