Chairman Hackett, Vice-Chair Tavares, Members of the Committee, thank you for the opportunity to appear before you today. My name is Mark Levy, and I have enjoyed the honor and challenge to serve as Director of the State Board of Orthotics, Prosthetics and Pedorthics, since 2002.

The State Board of Orthotics, Prosthetics and Pedorthics was established as a Professional and Occupational Licensing Board by enactment of the 123rd General Assembly. We are a very small agency within the state of Ohio structure and may not be very familiar to many members. The professions the Board counts as its constituent stakeholders are not so numerous that they can sponsor a legislative presence such as that offered by many of the other allied healthcare professions.

Nonetheless, the state of Ohio through enactment of Chapter 4779 has recognized that O&P (Orthotic and Prosthetic) Practitioners are specialized caregivers within the allied healthcare community who bring value and accountability to what would otherwise be treated as “you paid for it, you deal with it, buyer beware” commodity sales. As more funding of healthcare services moves toward the public sector with state and federal treasuries on the hook for reimbursement, provider-based accountability in a structure that seeks to assure patient-centered and outcome-oriented approaches becomes more crucial.
Without licensing of O&P professionals, accountability for these devices is measured only by proof of device delivery, often by drop-ship from an out of state (and out of reach) business, or from point of sale by a cashier or clerk. In such settings, continuity of care is often documented only by robo-call digital telephone logs.

With licensing comes a code of professional responsibility, scope of practice delineation, and a local, state-based process to address those consumer issues.

The Board’s purpose is common to other licensing agencies: to assure the competence of persons licensed to provide the regulated services as a means to protect the public. The Board’s licensees are physical rehabilitation specialists. They engage in custom fabricating and fitting devices and they engage as partners in continuity of care and treatment team approaches to assure proper fit, utility and positive outcomes for their patients:

1. Orthotists are medical bracing specialists; the practice of Orthotics is much more expansive than what is commonly labeled in the commercial realm as shoe inserts. It includes devices fitted literally head-to-toe, including pediatric cranial remolding helmets, HALO bracing for neurosurgical interventions, back braces (TLO, TLSO), knee-ankle-foot bracing (KAFO), and others, including customized shoe inserts and orthopedic footwear.

2. Prosthetists have expertise in artificial limb design, customizing and fitting; Prosthetic design increasingly incorporates sophisticated electronic componentry, including myoelectric devices that are interactive with the body’s neuromuscular systems

3. Pedorthists offer a limited subset of Orthotic interventions: fitting diabetic therapeutic shoes, footwear customized to address foot abnormalities and injuries, and specialized below-the-ankle bracing

The Board regulates professional practices that are classified within the federal healthcare regulatory matrix in the sector known as DMEPOS – which stands for Durable Medical Equipment, Prosthetics and Orthotics, and Supplies.
As the House subcommittee we testified before last month requested response to a number of questions regarding the Governor’s recommendations, I am attaching those questions and answers as submitted on the House side to more fully inform this written testimony.

As indicated in response to question #4 in that document, we believe the proposed consolidation with the OT-PT-AT Board to form a new State Physical Health Services Board could provide an appropriate basis for maintenance of professional licensure for this allied healthcare sector. We recognize the opportunities to gain operational efficiencies and lowering of costs, both to the state and our applicants and licensees. If given the opportunity, we would suggest some further engagement with the language to improve both the transition and administrative efficiencies once completed, and so would respectfully offer our subject matter expertise and request notification of any such opportunity for constructive input.

We have run a projection of budgetary information for FY2018. HB49’s proposed allocation of $122,574 for operations from July 1, 2017 through January 21, 2018, appears to be adequate to cover currently-anticipated costs. The budget proposal we originally submitted in accordance with directives and requirements suggested a funding level of $199,182 per fiscal year for FY18-19.

Thank you for your consideration. I welcome the opportunity to answer any questions Members may have, or to stand on these writings as presented.

Respectfully submitted,

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Questions and Responses for Submission with Agency Budget Testimony

1. What is your department’s primary purpose and objectives?

The Board’s purpose is to protect the public by assuring that persons who perform custom fabrication and custom fitting of Orthotic, Prosthetic, and Pedorthic devices to Ohio consumers have appropriate minimum qualifications by virtue of recognized or demonstrated background, education, experience, and training in keeping with the requirements detailed by the legislature in Chapter 4779 of the Revised Code.

2. What is your department’s past and anticipated workload, the number of staff required to complete that workload, and the department’s total number of staff? Also provide a breakdown of how many staff work in administration, customer service, or in the field.

Chapter 4779 of the Revised Code provides for the creation of an uncompensated seven-member board (three vacancies currently exist) and requires the board to establish by Administrative Code rules requirements for licensing and regulation that are consistent with the statutory directives. With a small constituent licensed population of about 400 persons and a staff currently consisting of a single FTE in the Board Director’s position and a part-time permanent office assistant, the board understands it is still responsible not only to administer and enforce the Practice Act, but also to fulfill the programmatic and reporting requirements assumed by all agencies of state government.

The office assistant position is focused largely on fiscal processing and bookkeeping requirements that meet the expectations of DAS, OBM, and the Auditor of State, as well as providing clerical and general office support to the Director. The Assistant needs to be skilled in utilization of the primary components of the Office software suite, as well as the functionality of the electronic rule filing system (ERF) platform and specialized software, the basic components of the eLicense system, and the BI reporting tools. The Director has primary responsibility for oversight, performance, and implementation of license application and renewal processing and review, complaint processing, rules promulgation, website content creation and updating, public record fulfillment, report-writing, and all other primary agency functions.
3. Please identify the rules adopted by your department and explain how these rules are consistent with the legislative mandate of the department as expressed in the statutes that created and empowered the department?

*RC 4779.08 is the statutory section that provides the Board with its rule authority; in addition to specifying certain programmatic areas established as mandatory for the Board’s rule promulgation task. Included is the permissive language “(B) The board may adopt any other rules necessary for the administration of this chapter.” In spite of this permissive language, the Board has approached rule promulgation with an emphasis on maintaining a light regulatory touch, clarifying those aspects of the law that might be subject to misinterpretation and seeking to reduce any real or perceived regulatory conflicts. In other words, we have only supplemented statutory language where it seemed necessary for orderly administration; we have not sought to expand our regulatory scope beyond the parameters of the Practice Act.*

4. Does your department’s jurisdiction or any of its programs overlap or duplicate those of other departments? If so, what is the extent to which your department coordinates with those other departments and the extent to which the department’s programs could be consolidated with the programs of other state departments?

*As RC 4779.02 (B)(1) makes clear, there are other licensed allied healthcare professionals who may handle, fit and dispense Orthotic and Prosthetic devices within their own scopes of practice. However, to the best of our knowledge, none of those regulatory entities exhibit the depth of education, experience or training that is the hallmark of credentialed Orthotic and Prosthetic practice. Certified and licensed Orthotic, Prosthetic and Pedorthic practitioners bring to their hands-on consumer care role a unique fund of knowledge and skill sets including design and fabrication of devices customized to maximize the rehabilitation and independent mobility potential of patients, and how subtle or significant changes to those devices interact with the wearer’s physical abilities, disabilities, and motivation. Where we encounter a conflict or complaint involving an individual licensed by another agency, we generally “refer and defer,” and offer technical assistance about appropriate O&P practice to the other agency.*

*We believe the proposed consolidation with the OT-PT-AT Board could provide an appropriate basis for maintenance of professional licensure for this allied healthcare sector in terms of operational efficiencies and lowering of costs, both to the state and our applicants and licensees. If given the opportunity, we would suggest some further tweaking of the language to improve both the transition and administrative efficiencies once completed, and so would respectfully offer our subject matter expertise and request notification of any such opportunity for constructive engagement.*

5. Is your department necessary to protect the health, safety, or welfare of the public? If so, how?

6. What is the amount of regulation exercised by your department compared to such regulation, if any, in other states?
Our answer to questions 5 & 6 hit on the same points so we are offering to provide the response as if they are one question.

The profession and the Board believe licensure of these hands-on consumer care professionals is in the interest of the state of Ohio healthcare environment and the interests of Ohio consumers who require and deserve access to individually-appropriate custom fabricated and custom fitted Orthotic, Prosthetic, and Pedorthic devices.

Licensure is far from universal across states, but Ohio can be considered on the leading edge of the movement toward licensure as a standard for these professions. Only about a half-dozen states provided for licensure when Ohio’s law passed. By 2006, eleven (11) states had licensing provisions. In 2017, seventeen (17) states address O&P licensure or certification in their statutory structures.

As we have testified previously, the legislature could assist the Board and the professions it regulates by closing some gaps in licensure requirements through provisions for the licensure or registration of Orthotic Fitters and Diabetic Therapeutic Shoe Fitters. These are direct-service providers who are recognized nationally but for which the Board does not presently have an appropriate basis to require inclusion within its statutory scope.
7. Describe the general costs and impact of your department’s activities on Ohio’s businesses and individuals.

The Practice Act and thus the Board does not address licensure, certification or accreditation of business entities/facilities where its licensees practice their trade. The Board recognizes and regrets that its fees for licensure are among the highest if not the highest for individual licenses in the scope of allied healthcare professional licensing. Those costs are driven from the fact that the constituent licensed population, highly specialized as it is, is small and thus the per capita costs assessed through license application and renewal fees is disproportionately high. We are constrained in this regard by the state of Ohio’s budgetary philosophy that a licensing agency should support its expenses against the 4K9 fund by the revenue it generates through its licensing operations. Our current fee rule and schedule is posted to the Board’s website:

<table>
<thead>
<tr>
<th>Service Description</th>
<th>Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial License Application – All Types – Full</td>
<td>$150</td>
</tr>
<tr>
<td>Initial License Application – All Types – TEMP</td>
<td>$150</td>
</tr>
<tr>
<td>Annual License Renewal – All Types – Full</td>
<td>$400</td>
</tr>
<tr>
<td>One-time License Renewal – All Types – TEMP</td>
<td>$400</td>
</tr>
<tr>
<td>Late Fee – License Renewal</td>
<td>$200</td>
</tr>
<tr>
<td>Late Fee – OPPCE</td>
<td>$100</td>
</tr>
<tr>
<td>License Upgrade – TEMP&gt;Full</td>
<td>$100</td>
</tr>
<tr>
<td>License Consolidate – LO or LP &gt; LPO</td>
<td>$100</td>
</tr>
<tr>
<td>License Issuance</td>
<td>$100</td>
</tr>
<tr>
<td>New OPPCE Activity Review</td>
<td>$50</td>
</tr>
<tr>
<td>Certified license verification OR Replace wall certificate</td>
<td>$25</td>
</tr>
<tr>
<td>Fine, per violation</td>
<td>$250</td>
</tr>
</tbody>
</table>

8. Identify and explain your customer service standards and what methods you use to monitor or improve customer service at your agency.

Our customer service standards are posted prominently on our website. We work in very close contact with our licensed constituency and strive to have an inclusive and transparent complaint processing methodology that keeps both licensees and consumers fully informed about professional practice standards and the authority and limitations of agency responsibility.
9. Please provide an assessment of the authority of your department regarding fees, inspections, enforcement, and penalties.

**Fees:** As indicated above, fees are high for the sector, but that fact is driven by the small size of the constituent licensed population and Ohio’s budgetary philosophy. In spite of a 33% increase in renewal fees enacted by the Board in FY15, costs keep rising and our revenue-expense numbers are out of balanced, weighted to the expense side.

**Inspections:** The Board has no statutory authority to conduct inspections per se as we do not regulate practice sites. A standard of care complaint generally results in a review (“inspection”, perhaps) of a practitioner’s patient records.

**Enforcement:** Our enforcement activities tend to focus on practice standards of care, continuing education requirements (CE accounting is tied to license renewal requirements), and complaints of unlicensed practice. Significant gaps in our ability to address unlicensed practice flow from the lack of authority to license or register Orthotic Fitters and Diabetic Therapeutic Shoe Fitters, combined with inaction from the federal government in completing its regulatory framework of requirements for Orthotic and Prosthetic services. The recent Supreme Court decision in the North Carolina Dental Examiners case has created additional legal uncertainty to the mix.

**Penalties:** The Board has authority to enact fines for non-compliance but has only recently included such provisions in its fee schedule and does not rely on fine or penalty fees to meet its budgetary responsibilities.

10. Has your department’s operation been impeded or enhanced by existing statutes and procedures and by budgetary, resource, and personnel practices? If so, which sections?

   The general answer is no, but we would suggest that the above-noted expansion of licensing/registration authority would be of assistance in providing a more fair “level playing field” regulatory environment in which the agency could operate more efficiently and effectively.

11. Has your department recommended statutory changes to the general assembly that would benefit the public as opposed to the persons regulated by the department? If so, have those policies been adopted and implemented?

   Please reference our answers to questions #5, 6 and 10 above.

12. Has your department required or requested any persons it regulates to report to it the impact of department rules and decisions on the public as they affect service costs and service delivery?

   We do not believe we have the regulatory authority to require such a report. We have sought to exercise extraordinary due diligence in compliance with the stakeholder outreach, publication and notice requirements attendant to rule promulgation, including changes to the fee rule.
13. Describe how your department encouraged public participation in its rule-making and decision-making?

a. Prominent placement of “Rules Pending Review” information on the agency website.
b. More than the minimal requirements of notification by email blasts and invitations to the stakeholder community to provide pro-active and well as re-active information for the Board’s consideration.
c. Maintenance of close communications with professional association personnel and attendance at professional association meetings.

14. What is the process for formal public complaints that are filed with the department? And how are they resolved?

Complaints, although few, may come to the Board’s attention by referral from another regulatory entity, telephone intake followed by a written complaint, a complaint filed on a form provided by website link or by mail in response to a telephone intake, or since early in FY17, a complaint may be lodged through the module offered on the new eLicense platform. Information about filing a complaint and the extent and limitation of the Board’s authority are displayed prominently on the “Consumers” tab of the Board’s website. Complaints are initially reviewed for subject matter jurisdiction; they are reviewed or investigated by seeking additional information and documentation from complainants and, where indicated, notification to a licensee with a request for documentation and response; and review by a board member expert as to standard of care or appropriate practice parameters. If any Board action is indicated after review, we seek resolution through either informal but documented-to-the-file cooperative compliance communications; where formal action is indicated, we seek resolution through Consent Agreement wherever possible.

15. Does federal law require that Ohio perform some or all of the tasks of your agency? If so, what functions are required and how are they met?

Yes and no. Federal law does not require the state to license these professions, but does require some deference to state requirements where licensure is in effect. The agency is required to report formal adverse actions to the National Practitioner Data Bank (NPDB).

16. Please describe in detail how any state regulation or rule, of your department, exceeds or differs from any similar federal requirements with a similar impact.

N/A
17. Please identify the department's practices and methods to comply with public records requests; any methods to make your records more generally available or online; the number of public records disputes during the last 2 years and the top 3 record types that are requested by the public.

*We keep a public record log and generally evidence a response time of 48 -72 hours, but most record requests are for lists of licensees. When requests require interpretation and/or any significant data protection/redaction for compliance with privacy standards and public records law, we confer closely with assigned counsel at the Attorney General of Ohio, Health and Human Services Section.*