

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: State Board of Orthotics, Prosthetics, and Pedorthics (OPP)

Regulation/Package Title: 5-year rule review 2015 -2016 (FY16)

Rule Number(s):

TO AMEND: 4779-2-03 Board records; 3-01 Definition of Terms;

3-02 Device/scope of practice definitions; 5-02 Admission to exam;

5-03 License application procedure; 7-01 license certificate and ID card

10-01 Ethics/Professional Conduct

RESCIND/PROMULGATE NEW: 5-01 The Exams

NO CHANGE: 2-01 Board organization; 2-02 Personnel;

4-02 Certificate program requirements

Date: 12/28/2015

Rule Type:

☒ New

☒ 5-Year Review

☒ Amended

☒ Rescinded

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

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Regulatory Intent

1. Please briefly describe the draft regulation in plain language.

Please include the key provisions of the regulation as well as any proposed amendments.

A number of the rules for AMENDMENT in this package are being updated to prepare the Board's regulatory language within its authority to be capable to address the innovations and opportunities that a new eLicensing platform developed by DAS/IT Services in cooperation with the licensing Boards and Commissions consortium offers both agencies and their constituent licensees.

A prime example is **4779-2-03 Board records**, which is written to maintain current documentation requirements but also allows for the adoption of "best practices" protocols with system on-boarding, thus : "meets any documentation standards established as best practices for administration of the eLicense database system maintained for the board by the department of administrative service division of information technology. ... "

Similarly, **4779-3-01 Definition of Terms** in addition to housekeeping updates includes a reference to online license lookup as the preferred system of license verification, and the elimination of wallet ID cards

4779-3-02 – Device-related and Scope of Practice Definitions -- AMEND

In addition to a change in the definition of "accommodative" to address confusion created by differential use of the term brought to the Board's attention by one of its constituent licensees, the language of the rule is being updated to recognize the development and innovation of 3D printing as it is being experienced in this health care device fabricating sector. "The use of CAD/CAM software or digital software packages and hardware to generate a negative model (3D printing) can be used for direct fabrication of intermediate stages of the device up to and including the final or definitive device itself."

Finally in this rule, we are seeking to more closely align the definition of orthotic devices dispensed-as-is with no customization with the federal standard. Thus,

~~"(G) "Minimal fitting" as used in section 4779.01 of the Revised Code and rule 4779-3-02 of the Administrative Code means a the prefabricated device which is fit for size by use of not more than two simple body size measurements; which is sized as small, medium, large, extra large, 2xl, 3xl; which is fastened or fit to the body or body part by use of elastic or self fastening straps, buttons or strips; which is not molded by the consumer care provider to fit the consumer; and which is not provided by the manufacturer with items or component parts which are intended or designed to be~~

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custom molded, heat moldable or custom fitted is classified as an off the shelf (OTS) device by the U.S. department of health and human services center for medicare/medicaid services.”

4779-5-01 The examinations - RESCIND/PROMULGATE NEW, and

4779-5-02 Admission to exam - AMEND

This language is being updated to serve two primary purposes: (a) to expand the scope of practitioners in Pedorthics to allow entrance to those who have passed the “BOC” pedorthic certification exam, as the Board has determined there is general consensus that the educational and testing standards governing the BOC administration for Pedorthics is functionally equivalent to the ABC regimen; (b) to establish a limit to serial issuance of Temporary licenses, which the Board understands as a credential meant to be held for a short period of time while other licensing requirements are completed. While the statute is not specific, the Board suggests that a candidate who is unable to pass the exam should not be allowed to continue to engage in practice indefinitely without close supervision.

4779-5-03 License application procedure - AMEND

These are minor housekeeping changes to keep language consistent with other changes being made in related rules; to anticipate changes that will be put in place with the onboarding of the new eLicense platform; and to clarify that the limited reciprocity licensing track prescribed by Section 4779.17 of the Revised Code provides a waiver of the Ohio-licensed supervision requirement.

4779-7-01 License certificate and ID card - AMEND

These changes are all focused on the enhancements available in the new eLicense platform and to clarify that the Board has discontinued issuance of annual license renewal wallet ID cards. License renewal cards are only reliably accurate as to status on the day they are printed; real time online license verification is available through the eLicense Center license lookup function.

4779-10-01 Ethical and Professional Conduct - AMEND

Language is being added to clarify that cooperation with a Board investigation is a matter of professional conduct subject to enforcement action.

(M) A license holder, or an applicant for licensure, shall provide a written response within a reasonable period of time not to exceed thirty days to any written inquiry regarding compliance with law or rule received from the board. A licensee or an applicant for licensure may not withhold or refuse to provide copies of any records requested by the board or its representative.

Two of the **NO CHANGE** rules in this package deal specifically and only with administrative operations of the Board and have no adverse impact on licensees or their employers (**4779-2-01 Board Organization** and **4779-2-02 Personnel**). The third no-change rule, 4779-4-02 Certificate Program Requirements, clarifies and facilitates employers' and applicants' understanding as to how the Board interprets statutory language that has become somewhat outdated since its passage 15 years ago.

2. Please list the Ohio statute authorizing the Agency to adopt this regulation.

The Board's rulemaking authority is provided by RC 4779.08 which states at Division (A):
The state board of orthotics, prosthetics, and pedorthics shall adopt rules in accordance with Chapter 119. of the Revised Code to carry out the purposes of this chapter ...

3. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program? *If yes, please briefly explain the source and substance of the federal requirement.*

NO.

4. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

The rules referenced in this action are focused on internal administrative issues for implementation of Chapter 4779 as a professional practice act for the regulated professions in the state of Ohio and in the case of 4779-3-02 seeks to align Ohio language with federal requirements to limit confusion, regulatory conflict, and inefficient enforcement activity.

5. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?

Chapter 4779, Ohio Revised Code, establishes the Board for the general purpose of protecting the public who are consumers of these specialized, customized medical devices. The statute as implemented through the rules seeks to establish minimum standards of education, training and care for the allied healthcare professionals who deliver the services.

[ORC Section 4779.08](#) requires (“shall adopt rules”) the Board to develop and implement rule language to carry out the chapter’s purposes, including all the subjects covered in this rule review.

6. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?

These rules do not implement, modify or expand any programmatic initiative or benefit and thus the proposed changes will not result in any quantifiable outcome-oriented data.

Development of the Regulation

7. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.

If applicable, please include the date and medium by which the stakeholders were initially contacted.

We began posting information on the website and soliciting feedback from stakeholders in June 2015, and have updated the website information at least twice while in process. Most recent comprehensive review was updated in December, as attached to this report. Announcements are issued to **licensees, employers and other stakeholders as maintained on the Board's Stakeholders Distribution List, which includes representatives of Ohio and National professional trade associations and credentialing partners.** The documents listed all the rules pending review with short descriptions, and included a "Stakeholder response form" to assist in providing feedback relevant to the rule review process and the particular requirements of ORC 107.52.

8. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?

➤ *Specific outreach on 4779-3-02 was solicited, received and suggestions were considered and incorporated as deemed appropriate.*

9. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

N/A

10. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?

From an administrative perspective, this is basic language largely governing the administrative operations of the Board. Most of the package represents an effort to update administrative process descriptions and understandings to allow a more complete realization of the operational efficiencies offered by the upcoming onboarding to a new eLicense platform.

11. Did the Agency specifically consider a performance-based regulation? Please explain.
Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.

Not applicable to these rules.

12. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

Information publication, stakeholder notification, review by OAG/HHS.

13. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

These rules govern standard administrative processes and describe requirements that are applied consistently in relation to all of the agency's stakeholders.

Adverse Impact to Business

14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

a. Identify the scope of the impacted business community;

The impacted business community is identified as applicants for licensure, current constituent licensees, and their employers.

b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and

The rules addressing exam requirements allow for additional licensing opportunities for persons credentialed in the podiatric profession but who followed a pathway not previously recognized in Ohio. While this may result in an increase in license fee requirements for an employer's personnel, it simultaneously decreases enforcement/compliance conflicts and allows for more independent practice free from otherwise burdensome supervision requirements.

c. Quantify the expected adverse impact from the regulation.

The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a “representative business.” Please include the source for your information/estimated impact.

Answer same as for (b) above.

15. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

The regulated community sought state licensure when the O&P leadership in the state advocated passage of the Practice Act in the 123rd General Assembly. These regulations do not impose any significant additional reporting or process requirements not already factored into the cost of doing business in this sector.

Regulatory Flexibility

16. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

No. Chapter 4779 does not provide for licensing/regulation of the business entity itself per se; it only provides for licensing of individual practitioners. No distinction is or can be fairly drawn between individual practitioners based on the relative size of the business in which they are employed.

17. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

The agency considers licensees’ requests for relief from late payment or late filing penalties on a case by case basis, and as reflected in the Board’s minutes, such requests are often granted on a one-time basis for good cause shown. In addition, the general orientation of the Board is to seek cooperative compliance. Other rule language establishes a mechanism to minimize the incidence of first-time paperwork violation and to provide for an informal remediation protocol. See [OAC 4779-9-03 OPPCE accrual deficiency and remediation](#).

18. What resources are available to assist small businesses with compliance of the regulation?

Board office staff offer assistance as needed upon contact and request.

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