

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

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

Regulation/Package Title: Package 96557 – no change rules 2012 AND
Package 96577 – language updates 2012

Rule Number(s): NO CHANGE: 4779-1-01; 1-02; 5-05; 6-01; 9-03; 10-02; 11-02; 11-03; 11-04; 11-05; 11-06; 11-07; 11-08; 11-09; 11-10; 11-11; 11-12

AMEND: 4779- 4-01; 5-01; 5-02; 5-04; 9-01; 9-02; 11-01

Date: October 16, 2012 Revised: December 5, 2012

Rule Type:

☐ New

☐ Amended

☒ 5-Year Review

☐ Rescinded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.

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117
CSIOhio@governor.ohio.gov

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.

Brief Description: No-change rules and amended rules pursuant to the Agency's 5-year rule review requirement. The scope of language included addresses educational program standards, license application requirements, license exam procedures and vendor approval, continuing education requirements, and formal hearing procedures.

The Rules listed and detailed in Package #96557, designated "no change rules 2012", are being proposed to continue without amendment, replacement or elimination. They are for the most part administrative guidelines governing how the Board conducts its business. There are no unnecessary paperwork requirements and no unreasonable adverse impacts on business: a license application (4779-6-01) requires documentation that the candidate meets basic statutory standards; the criminal record check requirements rule (4779-5-05) is modeled after language recommended by the Ohio Attorney General to implement the requirements affecting all licensing agencies; and the series includes a rule (4779-9-03) designed to provide a "diversion" option for licensees who miss their Continuing Education requirements, with allowance to keep the license status unaffected while addressing the deficiency through a measured administrative process. The 4779-11 series are rules specifically to provide a "rules of procedure" structure for any administrative hearings that may be held.

The Rules listed and detailed in Package # 96577, designated "language updates 2012", are being proposed for amendment.

- Rule 4779-4-01, proposed to amend, updates language on standards for the Board to approve certain educational programs. The changes reflect changes in the external credentialing community and clarification of existing language.
- Rule 4779-5-01 specifies approved exams for licensure; the Board is engaged in a fact finding process to determine if the amendment is appropriate. That review is not yet complete.
- Rule 4779-5-02, the amendment is proposed to allow the Board to designate additional license exam vendors, and to provide for the "timing out" after 36 months of an Approval to Sit for Exam authorization.
- Rule 4779-5-04, the amendment is proposed to eliminate redundant language that appears twice in the same rule.
- Rule 4779-9-01, the amendment is proposed to allow for the implementation of recommendations of the Human Trafficking Task Force requiring licensed professionals to engage in profession-specific training appropriate for recognizing and addressing suspected incidents of human trafficking.

- Rule 4779-9-02, the amendment updates OPPCE coursework language to include offerings addressing the subject of human trafficking recognition and response.
- Rule 4779-11-01, the amendment is a technical change correcting a citation to a section of the Ohio Revised Code.

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

[ORC 4779.08](#) -- (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?

NO. Ohio is not required to license these professions under federal law. However, please see the answer to #4 below. Given that Ohio has chosen to license these professions, federal healthcare reimbursement policy requires providers to meet state licensing requirements.

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

At the federal level, this allied healthcare sector is generally regulated under the DMEPOS (Durable Medical Equipment, Prosthetics/Orthotics & Supplies) provisions of the CMS Medicare Fee-for-Service Provider reimbursement protocols. 42 CFR part 424 Section 57 stipulates that where a state requires licensure to provide a service, a Medicare/Medicaid supplier must be in compliance with the state language.

(c) Application certification standards. The supplier must meet and must certify in its application for billing privileges that it meets and will continue to meet the following standards:

(1) Operates its business and furnishes Medicare-covered items in compliance with the following applicable laws:

(ii) *State licensure and regulatory requirements.* If a State requires licensure to furnish certain items or services, a DMEPOS supplier—

(A) Must be licensed to provide the item or service; and

(B) May contract with a licensed individual or other entity to provide the licensed services unless expressly prohibited by State law.

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The 123rd General Assembly determined in SB 238 “to establish the State Board of Orthotics, Prosthetics, and Pedorthics and provide for the licensure of Orthotists, Prosthetists, and Pedorthists ...”. The Board has sought since its inception to align the Ohio regulatory scheme with known national standards to the extent its authority will allow. The rules in the packages moving forward address the basic administrative functions of the Board in administering the chapter, and represent the Board’s understanding as to how the Ohio language can best align with the national and federal marketplace. Educational program requirements seek to defer to the national standards-setting organizations; license exam requirements defer to established practitioner exams already utilized by credentialing partners who subscribe to the recognized standards, and do not require re-administration for admission to licensure.

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?

Except for the Continuing Education language, this is not a new regulatory initiative or regulation to implement a new or different program. Most of this regulatory language guides the Board’s administrative operations. Some of the updates to language would allow the Board more flexibility in administering the license approval process. The CE language “success” will be measured by compliance determined through annual CE audits. The “License Application Procedure” language already incorporates administrative improvements made previously to eliminate the requirement that a new application be filed to “graduate” a license from Temporary to Full Practitioner status, easing both an administrative burden on the Board office and an extra application fee from the candidate’s portfolio of professional expenses.

Separate and apart from this CSI/BIA process, the Board is engaged in an internal process to better quantify and track available performance measures across its major administrative functions: license application receipt and review; renewal processing; complaint intake and investigation.

Development of the Regulation

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

In June 2012, two “OPP Rule Review” documents were uploaded to the Board’s website and an announcement was issued 06/07/2012 by email 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. Information regarding the pending review was also noted with invitations to review and respond in the Board’s newsletters issued subsequent to the June 13, 2012 and September 12, 2012 meetings. **The Director met with trade association leadership on July 12, 2012 and reviewed these rule actions as well as other agenda items of interest to the profession.**

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

Minimal feedback was received, and addressed language technicalities such as style of references to other entities. Trade association representatives had no substantive input and considered the changes non-controversial and non-adverse. One rule (exam vendor) is the subject of continuing discussion and feedback documented through the agency website.

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?

None – not relevant to this process.

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?

The enabling statutory language in the Orthotics, Prosthetics and Pedorthics Practice Act sets forth very specific requirements for licensing. Wherever possible, the Board has sought to conform the Ohio requirements to the recognized national standards through its rule promulgation authority.

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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.

None – not relevant to this process. These regulations largely govern the administrative operations of the Board. The statute requires the standards set forth in the rules.

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

A review of all of the Board's regulatory language. No other regulations govern this jurisdiction. Where possible, the Board generally seeks to assure agreement where its language intersects with other requirements, i.e., Ohio Medicaid reimbursement policies. Those cross-regulatory concerns are not addressed in this set of rules.

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.

We will incorporate the language as required or necessary into Office Policy and Procedure protocols.

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 primarily includes professional providers of Orthotic, Prosthetic and Pedorthic services – individuals licensed or certified to provide these services, and the business/facility owners who employ them.

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

The regulatory requirements include costs to meet educational standards (time, tuition and fees), but the educational requirements mirror the current status quo in the private credentialing

community. Additionally, there are licensing fees including late fees, the time and cost for an application, and the time and cost for license renewal/

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.

Criteria for educational attainment to enter the professions have been on the uptick; national credentialing standards in orthotics and prosthetics are migrating from Bachelors degree with specialized post-graduate work, to a Masters program with a specialty in the professions. These are costs that already exist in the private sector and are not replicated or enhanced by the Ohio regulatory scheme.

Northwestern University publishes cost estimates for its post-grad program at around \$45,000 including room and board:

http://chicagofinancialaid.northwestern.edu/tuition/prosthetics_orthotics.html#1213

University of Pittsburgh publishes costs for out of state tuition, Masters program in O&P at upwards of \$26,000.

<http://www.ir.pitt.edu/tuition/pghosgrad.php>

Costs for specialty education in Pedorthics, requiring a baseline of a high school education for admission and encompassing a generally 3-week, 120 hour blended protocol of classroom, online and hands-on training, tend to range from \$3000 - \$5000, depending on vendor and location.

Representative examples:

http://www.rmpi.org/index.php?submenu=Our_Courses&src=gendocs&ref=OurCourses&category=Main

<http://www.eneslow.com/inner.cfm?siteid=4&itemcategory=35819&priorId=22505>

License exam fees are set by the license exam vendor. Fee is \$250 per exam administration.

License application fees are \$125-\$150, plus costs for obtaining criminal record checks (\$65 - \$100). Time required to complete the application form and the related requirements: two to three hours.

Annual license renewal fee is \$300; time to complete the application, less than 30 minutes.

Late renewal fee is \$150.

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

Any adverse impact is driven by the specific requirements contained in the statutory language.

Renewal fees are set at a level required for the Board to meet its budgetary needs, based on number of licensees and basic costs of agency operations.

Regulatory Flexibility

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

No – compliance requirements treat all businesses the same, and all compliance requirements are driven by statutory language. Virtually all of the Board’s stakeholders exist in the small business sector.

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?

No fines or penalties required. The general orientation of the Board is to seek cooperative compliance. Included 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.