**ACTION: Final** 

DATE: 12/18/2017 8:26 AM

# CSI - Ohio

## The Common Sense Initiative

## **Business Impact Analysis**

Agency Name: <u>Ohio Board of Nursing</u>

Regulation/Package Title: <u>Technical Revisions: OAC Chapters 4723-2, 4723-7, 4723-8, 4723-9</u> and 4723-23.

Rule Number(s): 4723-2-03; 4723-7-09; 4723-8-01 through 4723-8-05 and 4723-8-07 through

4723-8-10; 4723-9-01 through 4723-9-12; 4723-23-01 and 4723-23-08.

Date: September 15, 2017

Rule Types: <u>Amended, Rescind and New</u>

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.

#### **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.

The Board proposes to amend individual rules within Ohio Administrative Code (OAC) Chapters 4723-2, Licensing for Active Duty Military and Veterans; 4723-7, Examination and Licensure; 4723-8, Advanced Practice Registered Nurse Certification and Practice; 4723-9, Prescriptive Authority; and 4723-23, Dialysis Technicians.

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

Ohio Revised Code (ORC) Section 4723.07 ORC Section 5903.10 (OAC Rule 4723-2-03) ORC Sections 4723.487 and 4723.50 (OAC Rule 4723-9-10) ORC Section 3719.062 (OAC Rule 4723-9-10) ORC Section 4723.79 (OAC Rule 4723-23-08)

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.* 

The answer is no to both questions as applied to all the rules in this package.

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

The question is not applicable to this rule package.

# 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)?

The public purpose for the rule package is to actively safeguard the health of the public through the effective regulation of nursing education and practice. The rules are being revised consistent with the need for update or to provide further clarity, including for technical or non-substantive reasons. Recently enacted legislative amendments also required changes be made to the rules.

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

Success will be measured by having clear rules written in plain language, by licensee compliance with the rules, and minimal questions from licensees and the public regarding the requirements of the rules.

### **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.

The Board discussed the rules package at its public Board meetings in April, May, July and September 2017. Board meeting dates and agendas are posted on the Board's website and interested parties are sent notice by e-mail prior to the meeting.

The Board held an interested party's meeting with multiple stakeholders on June 19, 2017. Participants and invitees included representatives of the Ohio Nurses Association (ONA), the Ohio Association of Advanced Practice Nurses (OAAPN), Council for Ohio Health Care Advocacy (COCHA), the Licensed Practical Nurse Association of Ohio (LPNAO), the Ohio Council of Deans and Directors of Baccalaureate and Higher Degree Nursing Programs (OCDD), the Ohio Organization of Practical Nurse Educators (OOPNE), and the Ohio Council for Associate Degree Nursing Education Administrators (OCADNEA). Notice and invitation to the meeting was sent by e-mail on June 2, 2017 to approximately 40 persons representing various stakeholders to the Board.

The Committee on Prescriptive Governance (CPG) met in May 2017 and reviewed the proposed rules in OAC Chapter 4723-9. CPG meetings are scheduled by e-mail and are open to the public.

The Advisory Committee on Advanced Practice Registered Nursing (ACAPRN) met in June 2017 and reviewed the proposed rules in OAC Chapter 4723-9 and other rules in this package. The ACAPRN meetings are scheduled by e-mail and are open to the public.

The Board's Advisory Group on Dialysis met in March 2017 and made recommendations regarding teaching methods in dialysis training programs. The proposed amendments are consistent with recent changes to nursing education program rules. The Advisory Group on Dialysis meeting is scheduled by e-mail and open to the public.

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

Kim Parks, attorney from Bricker and Eckler was the only person who attended the interested party meeting for this rule package. She only had a few informational questions and had no objections to any rules.

The Board's Advisory Group on Dialysis met in March 2017 and made recommendations regarding teaching methods in dialysis training programs. The proposed amendments are consistent with recent changes to nursing education program rules. At the May 2017 Board meeting, the Board approved the Advisory Group on Dialysis recommendations for Rule 4723-23-01(D) by revising the 100 clock hours of instruction to allow for "faculty-

interactive" theoretical instruction and removing "classroom setting." Rule 4723-23-08(A)(1) will be amended to refer to "theoretical" instruction instead of "classroom."

At the July 2017 Board meeting, the Board reviewed written comments dated June 30, 2017, from a representative of OAAPN regarding language changes to OAC Rule 4723-9-10. Similar comments were previously reviewed at the June 2017 interested party meeting. Consistent with discussion at the ACAPRN meeting in July 2017, the Board accepted the recommended changes.

At the July 2017 Board meeting, the Board agreed, if possible, to make additional changes to Rule 4723-9-10, which was to be final filed on August 21, 2017, related to prescribing opioid analgesics for acute pain, in order to address OAAPN's requested changes, not related to acute pain prescribing:

- (F)(6)(a): delete the word "thorough" and add "relevant."
- (F)(6)(d): delete "ruling out the existence of any recognized contraindications."
- (F)(6)(f): delete the word "Properly."

In addition, OAAPN presented suggested language changes to and questions involving several rules in this package. The Board made changes following discussion at the July 2017 Board meeting, including revising Rule 4723-8-03(A)(1)-(4) to limit the use of initials to those set forth in ORC Section 4723.03(E), and in paragraphs (A) and (B) of Rule 4723-9-10 references to "physician consultation" and "physician initiation" were eliminated as this language was from the previous drug formulary, which was changed in HB 216 to an exclusionary formulary.

The Board chose not to remove the requirement in Rule 4723-8-05(F) requiring APRNs to verify the license status of their collaborating physicians. This request was entertained two years ago and the Board had extended the time frame from annual verification to every two years. In addition, the Board did not change language in 4723-8-10(A) that refers to an APRN's "area of practice" to "specialty." The Board noted that the term "specialty" would be inconsistent and/or subject to misunderstanding and confusion in terminology in light of the APRN national Consensus Model on which national certification and subsequent practice is based. The Common Sense Initiative has as one of its goals to avoid confusing language.

The Board was made aware in September 2017 that the Medical Board's recent rules on acute pain prescribing were construed to permit physician assistants (PAs) to exceed the 30 MED limits set forth in rule, consistent with the narrow exception authorized for their supervising physicians (see OAC Rule 4731-11-13). After meeting with representatives of the Pharmacy and Medical Boards, the Administration and other interested parties, the Board at its September 13, 2017 Board meeting reviewed and authorized amended language to Rule 4723-9-10 to implement a similar narrow exception for APRNs who collaborate with the

treating physician. By amending the Rule in similar fashion, the Rule avoids an adverse business impact and allows the APRN provision of care to be consistent with PA practice in similar settings in collaboration with the treating physicians who retain singular accountability for prescriptions under this exception.

# 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?

Through the Advisory Groups, the Board relied on the expertise of licensees, education providers, and program administrators based on their current practice experience and familiarity with current data from their areas of expertise, and others such as the CPG, ACAPRN, and the Governor's Cabinet Opiate Action Team (related to changes recommended in OAC Chapter 4723-9 and specifically Rule 4723-9-10).

# 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 Board did not consider other regulatory alternatives in this rule package based on its duty to carry out its public protection mission, and in part because certain rule revisions require updating or amendment related to statutory requirements or for technical or non-substantive reasons.

### 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.

The Board did not propose performance-based regulations in this rule package due to considerations of setting established processes and standards to achieve its public protection mandate.

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

Staff reviewed the rules with a focus on eliminating obsolete, unnecessary, and redundant rules, correcting typographical errors and avoiding duplication. In addition, meetings with interested parties, Board Advisory Groups, and ACAPRN helped ensure that these rules do not duplicate any existing Ohio regulation.

# 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.

Meetings with interested parties, Board Advisory Groups, and ACAPRN help ensure that these rules are applied consistently and predictably for the regulated community. The Board

plans to monitor the progress with respect to the rules and report back to these groups. In addition, the Board will implement the regulations while using its website, newsletter, and social media to update and inform licensees, continuing education providers, nursing education and training programs, other stakeholders, and the public in general. Licensees must also complete at least one hour of continuing education on Ohio law and rules as a required part of their licensure renewal application.

### **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;

Individuals licensed by ORC Chapter 4723, dialysis training programs, education and training programs, and certificate holders subject to the rules and possible discipline for non-compliance.

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

Individuals are required to have a license and meet various conditions for licensure to obtain and renew their licenses. The ability to earn continuing education for certain volunteer activities could possibly have some minimal cost effect on continuing education providers.

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.

There is no anticipated adverse impact cost attached to these rules.

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

The regulatory intent justifies any impact on business in these rules because these rules are critical to setting consistent standards to further the Board's mission of public safety.

#### **Regulatory Flexibility**

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

Public safety requirements relative to the rules reviewed in this package require consistency in their application to all licensees and are not amenable to exemptions or alternative means of compliance for small businesses.

# 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?

Waivers of fines and penalties for paperwork violations and first time offenders may be considered consistent with Sections 119.14 and 4723.061, ORC, which do not require the Board to act on minor violations of the Nurse Practice Act or the rules adopted under it, if applicants or individuals licensed under Chapter 4723 of the Revised Code commit violations and following review the Board determines that issuing a notice or warning to the alleged offender adequately protects the public.

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

The Board employs staff dedicated to assist the public and small businesses by responding to any questions or concerns about the implementation of the rules. The Board Advisory Groups and ACAPRN also may respond to questions from small businesses. The Board continues to use its website, newsletter and social media to regularly update the public and licensees, including small businesses, to changes in requirements and to provide frequently asked questions.