



Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

Carrie Kuruc, Director

Business Impact Analysis

Agency, Board, or Commission Name: Ohio Board of Nursing

Rule Contact Name and Contact Information:

Holly Fischer, Chief Legal Counsel, hfischer@nursing.ohio.gov

Regulation/Package Title (a general description of the rules' substantive content):

Five Year Rule Review: OAC Chapters 4723-2, 4723-16, 4723-17, 4723-25, and 4723-26

Rule Number(s): 4723-2-01, 4723-2-02, 4723-2-03, 4723-2-04, 4723-16-01, 4723-16-02, 4723-16-03, 4723-16-04, 4723-16-05, 4723-16-06, 4723-16-07, 4723-16-08, 4723-16-09, 4723-16-10, 4723-16-12, 4723-16-13, 4723-17-01, 4723-17-03, 4723-17-05, 4723-17-06, 4723-17-07, 4723-25-01, 4723-25-02, 4723-25-03, 4723-25-04, 4723-25-05, 4723-25-06, 4723-25-07, 4723-25-08, 4723-25-09, 4723-25-10, 4723-25-11, 4723-25-12, 4723-25-13, 4723-25-14, 4723-25-15, 4723-25-16, 4723-25-17, 4723-25-18, 4723-26-01, 4723-26-02, 4723-26-04, 4723-26-05, 4723-26-06, 4723-26-07, 4723-26-08, 4723-26-09, 4723-26-10, 4723-26-11, 4723-26-12, 4723-26-13, 4723-26-14.

Date of Submission for CSI Review: September 4, 2019

Public Comment Period End Date: September 18, 2019

Rule Type/Number of Rules:

New/ ___ rules

No Change/ 33 rules (FYR? Yes)

Amended/ 19 rules (FYR? Yes)

Rescinded/ ___ rules (FYR? ___)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Reason for Submission

1. R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.

Which adverse impact(s) to businesses has the agency determined the rule(s) create?

The rule(s):

- a. Requires a license, permit, or any other prior authorization to engage in or operate a line of business.
- b. Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.
- c. Requires specific expenditures or the report of information as a condition of compliance.
- d. Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.

Regulatory Intent

2. Please briefly describe the draft regulation in plain language.
Please include the key provisions of the regulation as well as any proposed amendments.

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

CSIPublicComments@governor.ohio.gov

The Board proposes to amend, or file no change rules following the five-year review for Ohio Administrative Code (OAC) Chapters 4723-2, Licensing for Active Duty Military and Veterans, Chapter 4723-16, Hearings, Chapter 4723-17, Intravenous Therapy Courses for Licensed Practical Nurses, Chapter 4723-25, Nurse Education Grant Program, and Chapter 4723-26, Community Health Workers.

Chapter 2 Licensing for Active Duty Military and Veterans

- Rule 2-01 (A)(3)(f), (g): Delete cross reference in (f) to Rule 4723-8-01, not necessary; delete (g), obsolete.
- Rule 2-03 (C): Delete cross reference to Rule 4723-8-01, not necessary.

Chapter 16: Hearings

- Rule 16-07(B)(2): Update reference from “chemical dependency” to “substance use disorder” consistent with HB 119 (132nd GA).
- Rule 16-08(A): Change “thirty” to “forty-five.”

Chapter 17: Intravenous Therapy Courses for Licensed Practical Nurses

- Rule 17-01(C): Change “client” to “patient” consistent with changes made throughout Chapter 4723, OAC over the past five years.
- Rule 17-01(G): Update cross reference (should be: paragraph (N) of Rule 4723-14-01).
- Rules 4723-17-01, 17-03: Changes are proposed to add a reference to “physician assistant” consistent with SB 110 (131st GA) which added physician assistants to the providers that may direct LPN practice.
- Rule 17-03(C)(3): Update cross reference (should be: Section 3721.01, ORC).
- Rule 17-06: In the header language, delete the reference to 4723.18(A)(4)(a), ORC, as that language was removed by HB 216 (131st GA) and the correct reference should be Section 4723.19, ORC. In (A), delete the 40 hour minimum for the continuing education course, as determined by the Board at the April meeting, and as recommended by the Advisory Group on Continuing Education. At the end of the Rule, add as Statutory Authority Section 4723.19, ORC.
- 17-07(A)(5): Update name of form.
- 17-07(C): For endorsement applicants, delete the last sentence regarding the Board requiring completion of continuing education in IV therapy.

Chapter 25: Nurse Education Grant Program

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

CSIPublicComments@governor.ohio.gov

- Rule 25-02(H)(2): Replace “Ohio board of regents” with “chancellor of higher education” to reflect current statutory terminology.
- Rule 25-02(L): Update cross reference to Rule 4723-5-01(CC) (not X).
- Rule 25-06(C): Update name of form.
- Rule 25-07: Replace “Ohio board of regents” with “chancellor of higher education” to reflect current statutory terminology.
- Rule 25-09(A): Update name of form.
- Rule 25-15(A): Update names of forms.
- Rule 25-15 (B): Add clarifying language.

Chapter 26: Community Health Workers

- Rule 26-02, 26-05, 26-14: Update name of form.
- Rule 26-04: Update name of form, make changes consistent with renewal process for other licensees.
- Rule 26-12: Replace “Ohio board of regents” with “chancellor of higher education” to reflect current statutory terminology

3. Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.

Ohio Revised Code (ORC) Section 4723.06, 4723.07
 ORC 5903.01, 5903.04, 5903.10, 5903.12, 4723.24, 4723.651, 4723.77, 4723.69, 4723.79
 (OAC Chapter 4723-2)
 ORC 4723.28 (OAC Chapter 4723-16)
 ORC 4723.01(F), 4723.18, 4723.181 (OAC Chapter 4723-17)
 ORC 4723.063 (OAC Chapter 4723-25)
 ORC 4723.81 to 4723.88 (OAC Chapter 4723-26)

**4. 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 to all the rules in this package.

5. 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 package

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

CSIPublicComments@governor.ohio.gov

6. 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.

ORC Section 4723.07 authorizes the Board of Nursing to adopt rules governing the practice of nursing, including standards and procedures for licensure, minimum standards for nursing education programs, continuing education, and other rules necessary to enforce ORC Chapter 4723.

ORC Sections 5903.01, 5903.04, 5903.10, 5903.12 authorize license agencies including the Board of Nursing to implement rules to consider military and veteran status, and military/veteran spouse status, in requirements for education, licensing, renewal, and continuing education.

ORC Sections 4723.18 and 4723.181 authorize the Board of Nursing to adopt rules to implement minimum standards for intravenous therapy performed by licensed practical nurses including education, licensure, and continuing education.

ORC Section 4723.063 authorizes the Board of Nursing to establish and administer the Nurse Education Grant Program (NEGP).

ORC Sections 4723.81 to 4723.88 authorizes the Board of Nursing to develop and implement a program for the certification of community health workers.

7. 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.

8. Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?

If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

No.

Development of the Regulation

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

CSIPublicComments@governor.ohio.gov

9. 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 and July. Board meeting dates and agendas are posted on the Board's website and interested parties are sent notice by e-mail prior to each Board meeting.

The rules package was reviewed by the Board Committee on Advanced Practice Registered Nursing at its June 17, 2019 meeting, and provided to the Committee on Prescriptive Governance for its May 21, 2019 meeting; an overview of the proposals was presented at the Advisory Group on Continuing Education at its July 26, 2019 meeting. All of these meetings are scheduled by email and are open to the public with meeting materials posted on the Board's website. On June 3, 2019, the Board posted notification on its website of a June 17, 2019 interested party meeting soliciting feedback/comments, and invited interested parties to attend by email, with copies of all of rules/proposed changes in the package. Interested parties invited included law firms/attorneys who have represented licensees in administrative hearings before the Board of Nursing; the Ohio Nurses Association (ONA), the Ohio Association of Advanced Practice Nurses (OAAPN), the Licensed Practical Nursing Association of Ohio, the Ohio Council of Deans and Directors of Baccalaureate and Higher Degree Nursing Programs (OCDD), the Ohio Organization of Practical Nurse Educators (OOPNE), the Ohio Council for Associate Degree Nursing Education Administrators (OCADNEA), the Council for Ohio Health Care Advocacy (COCHA), other associations, health care system representatives (e.g., OhioHealth, DaVita Kidney Care), state entities (e.g, State Medical Board, Pharmacy Board), and other stakeholders.

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

The Board did not receive any proposed changes or comments regarding the rules in this package. This may be attributable to the majority of the proposed changes being technical corrections/changes to remove obsolete language.

11. 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?

No specific scientific data was used to develop the rules listed in this package. The Board utilizes the expertise of practitioners and specialists appointed to advisory groups and committees in the development of administrative rules, including: The Advisory Group on Advanced Practice Registered Nursing (a statutory committee composed of APRNs with

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

CSIPublicComments@governor.ohio.gov

practices in, for example, primary care, anesthesiology, nursing education), Advisory Group on Continuing Education, Advisory Group on Dialysis, Advisory Group on Nursing Education, and the Committee on Prescriptive Governance (a statutory committee composed of physicians, advanced practice registered nurses and a pharmacist). The Board also convenes Practice Committees on focused issues that invite data and research for review and recommendation, from specialists in both the private and public sectors.

12. 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?

No alternatives were considered because minimum licensing, education and practice standards are the essential foundation for competent nursing care, patient safety, and public protection, and these standards are consistent with prevailing nursing practice and evidence-based nursing research. The Board of Nursing reviewed administrative hearing rules adopted by other state agencies that conduct ORC Chapter 119., hearings (e.g., State Medical Board) and found that differences to be insubstantial.

13. 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 consider performance-based regulations for the rule package. It is the Board's responsibility to ensure that education, licensing and continuing education requirements are consistently applied, and to set forth clear, established processes and standards to achieve public protection. Similarly, rules related to administrative hearings, and NEGP grant eligibility, application and disbursement require consistent application to all parties. The proposed rules set out the required activities but do not specify a means of performing the required activities.

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

The Board initiated the rule review process due to the five-year rule review requirement, and in doing so, staff reviewed the rules with a focus on eliminating obsolete, unnecessary, and redundant rules and avoiding duplication. In addition, communicating proposed changes with interested parties and Board advisory groups/committees helped ensure that these rules do not duplicate existing Ohio regulation. Finally, the Nursing Board is the only agency authorized to establish minimum standards of safe practice for licensed practical nurse intravenous therapy (Chapter 4723-17) and certified community health workers (4723-26), and to establish and maintain the Nurse Education Grant Program (Chapters 4723-25).

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

CSIPublicComments@governor.ohio.gov

15. 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 and Board advisory groups/committees help ensure that rules are applied consistently and predictably for the regulated community. The rules will be posted on the Nursing Board’s website, information concerning the rules will be included in information material e-mailed to attorneys, licensees and nursing practice associations, and notices will be sent to associations, individuals, health care system representatives and groups via social media. Nursing Board staff members provide answers to practice questions, including prescribing, via a designated email address and by telephone. The Board will provide educational materials as needed through FAQs and a quarterly newsletter (*Momentum*). Hearing examiners that conduct administrative hearings for the agency receive copies of OAC Chapter 4723-16 and rule revision updates, and are evaluated on their ability to fairly and impartially apply hearing rules to all parties.

Adverse Impact to Business

16. 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 applying to be certified community health workers and businesses conducting community health worker training programs;
- Individuals licensed/certified by ORC Chapter 4723.;
- Continuing education providers;
- Nurse Education Grant Program applicants and grantees.

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

Rule 4723-2-03 and 2-04 requires that information be provided in order to qualify for fee waivers and extension of time to obtain continuing education.

Rules 4723-16-01 to 16-13 establish time frames related to and/or information required in filings in administrative hearing cases conducted pursuant to Chapter 119., ORC.

Rule 4723-17-05 requires that information be provided in an application to conduct continuing education courses in intravenous therapy for licensed practical nurses.

Rule 17-06 establishes a minimum curriculum for intravenous therapy courses for licensed practical nurses, which may require expenditures for materials, supplies and personnel to conduct the curriculum.

Rule 17-07 requires information be provided to document completion of an approved course in intravenous therapy.

Rules 4723-25-01 to 25-18 require information be provided in order to apply for Nurse Education Grant Program funds and disbursement of funds.

Rules in 4723-26-01 to 26-14 establish an approval process for training programs and certification process for certified community health workers, including certification and renewal of certification fees. Individuals may work as community health workers without certification, however, certification may provide career/salary benefits.

Rules in 4723-26-01 to 26-14 establish a minimum standards of practice for certified community health workers, and grounds for disciplinary action if standards are not met. Sanctions for violation of Chapter 4723., ORC or Chapter 4723-26, OAC may include fines, certification restrictions, suspension or revocation.

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.

ORC Section 4723.83, ORC, requires a fee payment for community health worker certification, and ORC Section 4723.87 requires a fee payment for community health worker training program applications. The fees are \$35 (Rule 4723-26-02) and \$300 (Rule 4723-26-14) respectively.

Certified community health workers who violate standards of care set forth in Chapter 4723-26, OAC, may incur disciplinary sanctions, which may include fines, continuing education, or restriction, suspension or revocation of the certificate. There may be associated costs for certificate holders to comply with the terms and conditions of the sanction and demonstrate compliance and the ability to provide care. These are not new costs as Chapter 4723-26, OAC, has established minimum standards of safe community health worker practice for many years with the potential for disciplinary action based on violations.

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

CSIPublicComments@governor.ohio.gov

There is a cost inherent in engaging in the business of being a Board approved continuing education program or an accredited continuing education provider for intravenous therapy (Chapter 4723-17), or in operating a community health worker training program (Chapter 4723-16). The costs are variable and determined by the extent of education provided. There is no fee associated with the intravenous therapy approved education provider status.

To apply for NEGP grant money under OAC Chapter 4723-25, completion of application materials consistent with eligibility is required.

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

The minimum curriculum and standard of care rules in Chapter 4723-17, OAC and Chapter 4723-26 are essential for public protection and safe practice, and are designed to reduce health care errors, harm to patients, substandard practice, theft, patient abuse, and fraud. The information sought in forms required for application processes for the NEGP is needed to ensure that grant funds are awarded and disbursed in a legal and consistent manner.

Regulatory Flexibility

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

The rules, designed for public protection and safe patient care, must be consistently applied, so the regulations do not provide exemptions or alternative means of compliance. The rules related to NEGP eligibility and grant disbursement need to apply equally to all applicants and be consistently implemented. Rules related to administrative hearings need to be applied in a fair and consistent manner to all parties.

19. 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?

Regarding Chapter 4723-26, waivers of fines and penalties for paperwork violations and first time offenders may be considered consistent with ORC Sections 119.14 and 4723.061 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 warning to the alleged offender adequately protects the public.

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

CSIPublicComments@governor.ohio.gov

20. 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. Board advisory groups and committees, composed of continuing education approvers, providers, educators, practitioners, and licensees also may respond to questions from small businesses. The Board provides Interpretive Guidelines related to specific practice standards in order to assist the practitioner and employer. 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.

Nursing Board staff members provide answers to intravenous therapy and community health worker practice questions, via a designated email address and by telephone. The Board will provide educational materials as needed through FAQs and a quarterly newsletter (*Momentum*). The NEGP (Chapter 4723-25) has a dedicated webpage with materials available to assist grant applicants/grantees, as well has dedicated Board staff. All relevant forms and information for community health worker training programs and certification, military/veteran license fee and continuing education waivers are also available on the Board's website.