

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Board of Nursing

Regulation/Package Title: Five Year Rule Review: OAC Chapters 4, 6, 18 and 20

Rule Number(s): 4723-4-01, 4723-4-03, 4723-4-04, 4723-4-05, 4723-4-06, 4723-4-07,
4723-4-08, 4723-4-09; 4723-6-01, 4723-6-02, 4723-6-03, 4723-6-04, 4723-6-05, 4723-6-06;
4723-18-01, 4723-18-02, 4723-18-03, 4723-18-04, 4723-18-05, 4723-18-06, 4723-18-07,
4723-18-08, 4723-18-09, 4723-18-10; 4723-20-01, 4723-20-02, 4723-20-03, 4723-20-04,
4723-20-05, 4723-20-06, 4723-20-07.

Date: September 7, 2018

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 Rescinded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.

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, or file no change rules following the five-year review for Ohio Administrative Code (OAC) Chapters 4723-4, Standards of Practice Relative to RN or LPN; 4723-6, Alternative Program for Chemical Dependency/Substance Use Disorder Monitoring; 4723-18, Practice Intervention and Improvement Program (PIIP); and 4723-20, Prevention of Disease Transmission.

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

Ohio Revised Code (ORC) Section 4723.07
ORC 4723.35 (OAC Chapter 4723-6)
ORC 4723.282 (OAC Chapter 4723-18)
ORC 4723.07(K) (OAC Chapter 4723-20)

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 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 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 updated consistent with the schedule for the Board's five-year rule review. Executive Order 2011-01K, "Establishing the Common Sense Initiative" requires agencies to draft rules in plain English. Since 2005, and on a continuing basis, the Board conducts a "plain English" review of its rules and amends or rescinds rule language that is obsolete, unnecessary, ineffective, contradictory or redundant. HB 216, 131st GA, effective April 6, 2017, eliminated the "certificate of authority" and "certificate to prescribe" for Advanced Practice Registered Nurses (APRNs), and references to these certifications are deleted as obsolete. HB 49 (132nd GA) implemented ORC 4723.51(B), which requires that the Board of Nursing adopt rules establishing standards and procedures to be followed by APRNs in the use of drugs approved by the FDA for use in medication-assisted treatment. Consistent with this, amendments are made in Rule 4723-6-02 paragraph (B)(1), and Rule 4723-6-03(B)(3), to add an exception for medication-assisted

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treatment. Globally, cross-references are revised to provide currently correct citations or names for laws, rules, forms/applications, or entity names.

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 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 11, 2018 meeting, and provided to the Committee on Prescriptive Governance for its July 23, 2018 meeting. These meetings are scheduled by email and are open to the public with meeting materials posted on the Board's website. On June 1, 2018, the Board posted notification on its website of a June 26, 2018 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 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), state entities (e.g, State Medical Board, Pharmacy Board), and other stakeholders.

8. 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.

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?

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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 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.

Chapter 4723-4, OAC, Standards of Practice Relative to RN or LPN: These rules are based on the body of nursing research and literature. The Board also convenes Board Committees on Practice to solicit information from experts in both the private and public sectors on new procedures and practice. This information is taken into consideration for rules and Interpretive Guideline development.

Chapter 4723-6, OAC, Alternative Program for Chemical Dependency/Substance Use Disorder Monitoring: The Board conducted an in-depth review of the Board's regulatory requirements with recommendations adopted by the National Council of State Boards of Nursing, "*Substance Use Disorder in Nursing, a Resource Manual & Guidelines for Alternative and Disciplinary Monitoring Programs (2011)*." The National Council recommendations were established based on best practices for diversion programs identified in literature, research studies, and by state boards of nursing across the country.

Chapter 4723-18, OAC, Practice Intervention and Improvement Program: These rules are based on various types of practice remediation programs for health care professionals. The National Council of State Boards of Nursing uses the Board rules as a regulatory model for other nursing boards. The Board collects information on nursing practice breakdown and reports the data to a national database that collects practice breakdown data from boards of nursing across the country in order to identify the root causes of nursing practice breakdown examining both system issues and the nurse's involvement.

Chapter 4723-20, OAC, Prevention of Disease Transmission: These rules are consistent with federal Centers for Disease Control and Prevention guidelines for infection control and disease transmission prevention, and State Medical Board rules for universal precautions, disinfection and sterilization.

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?

Chapters 4723-6 and 4723-18, OAC, govern programs that are legislatively established "regulatory alternatives" to public discipline. Over the last two years, the Board reviewed both the chemical

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dependency and practice deficiency programs, and re-affirmed its commitment to provide both alternative programs. The Board is committed to offer these programs so nurses can be retained in the workforce if they successfully resolve substance use disorders and remediate practice deficiency issues.

No alternatives for Chapter 4723-4, OAC, were considered because minimum nursing 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.

No alternatives for Chapter 4723-20, OAC, were considered because these infection control procedures are consistent with federal guidelines and prevailing practices throughout the health care system.

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.

Chapters 4723-4 and 4723-20, OAC, reflect minimum standards of safe nursing care. The proposed rules set out the required activities but do not specify a means of performing the required activities. The Board did not propose performance-based regulations in these rules due to considerations of setting established processes and standards to achieve public protection.

Chapters 4723-6 and 4723-18, OAC, govern alternative to public discipline programs that require standardized rules to clearly set forth eligibility criteria that must be met and maintained for continued participation and successful completion. The outcome for participants who are able to successfully complete the programs will be reflected in a continued ability to practice with unrestricted licenses and no disciplinary action. The Board audits and reports on the number of participants in both programs who successfully complete the programs.

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

Because the Board initiated the rule review process due to the five-year rule review requirement, 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 nursing practice (Chapter 4723-4, 4723-20), and to establish the alternative to discipline programs reflected in Chapters 4723-6 and 4723-18.

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 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 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*).

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. and nursing employers.

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

Violations of Chapter 4723-4, OAC, Standards of Practice Relative to RN or LPN, may result in disciplinary sanctions, which may include fines, continuing education, or restriction, suspension or revocation of the nurse’s license; or referral to the alternative program for practice, dependent on the facts and circumstances of the violation. There may be associated costs for licensees to comply with the terms and conditions of the sanction and demonstrate compliance and the ability to provide safe nursing care. These are not new costs as Chapter 4723-4, OAC, has established minimum standards of safe nursing care for many years with the potential for disciplinary action based on violations.

To participate in the Alternative Program for Chemical Dependency/Substance Use Disorder Monitoring, as set forth in Chapter 4723-6, OAC, licensees will incur the costs of drug/alcohol screening, drug or alcohol evaluations, treatment and recovery programs. Employers may incur minimal costs associated with workplace monitoring and reporting as part of the licensee’s employment. Licensee costs associated with the Alternative Program are established by providers who are not regulated by or affiliated with the Board. Costs associated with the program are not new but have existed since the diversion program was established by the legislature in 1995.

To participate in the Practice Intervention and Improvement Program, as set forth in Chapter 4723-18, OAC, licensees may incur costs for remedial education, or if the employer provides it, there would not be a cost. The employer may incur the cost of offering remedial education and practice monitoring although usually the employer offers remediation and monitoring as part of the nurse's employment. Licensee costs associated with the program are established by providers who are not regulated by or affiliated with the Board. Costs associated with the program are not new but have existed since the program was established by the legislature in 2001.

Chapter 4723-20, OAC, Prevention of Disease Transmission, may have costs associated with equipment needed to prevent the transmission of disease and prevent infection, such as hand sanitizer, soap, gloves, disinfectants, etc., but these are not new costs. Employers have incurred these expenses for many years as part of their operational costs.

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.

Chapter 4723-4, OAC, Standards of Practice: Violations of this chapter may result in disciplinary sanctions, which may include fines, required continuing education, or the license being restricted, placed on probation, suspended or revoked dependent on the violation. Disciplinary sanction fines are established in Section 4723.28, ORC, at not more than \$500 per violation; and continuing education may be free, or may have a cost, generally ranging between \$10-\$200, depending on the continuing education the licensee chooses to access. For example, one company offers unlimited continuing education for \$44.95 a year. Most CE can be obtained on-line or "on-demand."

Chapter 4723-6, OAC, Alternative Program for Chemical Dependency/Substance Use Disorder Monitoring: In order to participate in this diversion program, licensees will incur the costs of drug and/or alcohol screening, drug and/or alcohol evaluations, and treatment and recovery programs. Insurance may offset part of the costs. Drug screening generally costs between \$41 (per screen drug screen) and \$82 (for a combined drug and alcohol screen), and approximately 12-15 random screens per year are required. Evaluations may range from \$400-600. Employer costs would be the time associated with workplace monitoring and reporting to the Board about work performance and compliance with the program requirements.

Chapter 4723-18, OAC, Practice Intervention and Improvement Program: Licensees may incur costs for remedial education, if the employer does not offer the education. The employer may incur the cost of offering remedial education and practice monitoring although most often the employer offers remediation and monitoring as part of the nurse's employment.

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Chapter 4723-20, OAC, Prevention of Disease Transmission: The cost of hand sanitizer, soap, gloves, disinfectants, etc., depends on the type and size of the institution or company. Employers have incurred these types of expenses for many years as part of their operational costs.

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

The standard of care rules in Chapter 4723-4, OAC, are essential for public protection and safe nursing practice and are designed to reduce health care errors, harm to patients, substandard practice, theft, patient abuse, and fraud.

The alternative programs for certain licensees with substance use disorders or practice deficiencies in Chapters 4723-6 and 4723-18, OAC, respectively, are legislatively mandated and are designed to provide a diversion-based model enabling nurses to return to practice after demonstrating the ability to provide safe nursing care. This decreases the costs associated with employee turnover; costs of nursing education programs to educate additional nurses; and orientation costs of the employer for new employees.

The rules establishing prevention of disease transmission in Chapter 4723-20, OAC, are legislatively mandated, and are designed to prevent disease transmission and prevent infection, which saves significant costs associated with health care worker illnesses, patient harm, employer liability, and public health epidemics.

Regulatory Flexibility

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

The rules, designed for public protection and safe nursing care, must be consistently applied, so the regulations do not provide exemptions or alternative means of compliance.

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 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.

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

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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 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 alternative to discipline programs (Chapters 4723-6 and 4723-18) have dedicated staff, email contacts, and materials available on the Board's website to assist licensees and their legal representatives.