



Common Sense Initiative

Mike DeWine, Governor
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Business Impact Analysis

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

Rule Contact Name and Contact Information:

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

2019 Technical Changes

Rule Number(s): 4723-1-03, 4723-5-04, 4723-5-10, 4723-5-11, 4723-5-21, 4723-6-01, 4723-6-02, 4723-6-03, 4723-7-05, 4723-7-06, 4723-8-08, 4723-9-10, 4723-9-13, 4723-20-01, 4723-20-03, 4723-20-07.

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/___ (FYR?)

Amended/ 16 rules (FYR? No)

Rescinded/___ rules (FYR?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.

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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.

The Board proposes to amend Rules 4723-1-03, 4723-5-04, 4723-5-10, 4723-5-11, 4723-5-21, 4723-6-01, 4723-6-02, 4723-6-03, 4723-7-05, 4723-7-06, 4723-8-08, 4723-9-10, 4723-9-13, 4723-20-01, 4723-20-03, and 4723-20-07, in order to make technical corrections (delete obsolete or redundant language), respond to legislative changes, and/or to comply with law requiring consistency between Nursing Board and Medical Board prescribing rules.

Amendments:

- Rule 4723-1-03: Update form references for forms/applications located on the Board's website.
- Rule 5-04(B)(4): Delete this paragraph as it covers the same information as (B)(3), and is inconsistent with Section 4723.07(B)(7), ORC, which says "may" withdraw approval, not "shall."

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- Rule 5-10(A)(5)(b) and 5-11(A)(5)(b): As recommended by the Advisory Group on Nursing Education, Rule 5-10(A)(5)(b) and 5-11(A)(5)(b): Remove the requirement that preceptors have at “at least two years” experience in nursing practice.
- Rule 4723-5-21(E)(2): Amend this language consistent with removal of the two-year experience requirement for preceptors in Rules 4723-5-10, 5-11.
- Rules 4723-6-01, 6-02, and 6-03: Amendments are proposed for these rules to remove references to “chemical dependency” and replace with “substance use disorder”, consistent with HB 119, 132nd GA.
- Rules 4723-7-05(E)(1) and 7-06(F)(1): The Board is recommending the process for issuance of a temporary permit to RN/LPN endorsement applicants be changed to lessen the burden on applicants and expedite issuing permits by eliminating the documentation of completion of a nursing education program requirement. The rationale is that: (a) The law, Section 4723.09(D), ORC, does not require this documentation for temporary permits; (b) Frequently the education program information is not readily available through NURSYS, which staff relies upon to confirm licensure in another state, and this delays the temporary permit process; (c) Endorsement applicants are required to provide evidence of licensure in another NCSBN jurisdiction, which would require completion of a NCSBN-member approved education program; (d) To obtain a full license, documentation of completion of an education program is required.
- Rule 4723-8-08(B): The language for RNs allows for those newly licensed on or after July 1 to have a license renewal date in the next odd-numbered year (see 4723-7-09(J)); this language is proposed for APRNs rather than the renewal fee waiver. In addition, since the law was changed to establish an APRN license (H.B. 216, 131st GA), the license renewal is separate from the RN license renewal application, so language is obsolete and is deleted to reflect this.
- Rule 4723-9-10: JCARR provided guidance in October 2018 indicating that the rule be revised to include the exclusionary formulary for prescribing in the body of the rule itself, rather than referring to a formulary that is posted online. The definition of “terminal condition” is revised consistent with State Medical Board Rule 4731-11-01, filed by the Medical Board in March 2019 with CSI, in response to public feedback. Additionally, oncologists and hematologists were added by the Medical Board in Rule 4731-11-14 (filed with CSI in March 2019) as prescribers who may exceed the 120 MED; consistently, APRNs with national certification in oncology or hematology would also be able to exceed

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the 120 MED for established patients. Lastly, language regarding pain management, hospice and palliative care is not new but reorganized for clarity.

- 4723-9-13: Changes are proposed to reflect changes in Rule 4723-9-10, i.e., the formulary is included in rule rather than online. Other changes include adding Certified Nurse Midwives as prescribers who can potentially engage in medication-assisted treatment. Effective October 24, 2018, the “Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act” (H.R. 6), was signed into law amending 21 U.S.C. § 823 to expanding the definition of “qualified other practitioners” for purposes of buprenorphine prescribing for MAT. The addition of CNMs is supported by ACNM and OAAPN. Changes are proposed to 4723-9-13(A)(7), (A)(9), (C)(2), (C)(3) - (5), (C)(6), (C)(9), (C)(10), so that the Rule is consistent with the Medical Board rules for MAT (see 4731-33-01, 4731-33-03, 4731-33-04), effective April 30, 2019. H.B. 49 (132nd GA), Section 4723.51(C), ORC, requires that the Nursing Board rules for MAT and the Medical Board rules be mutually consistent.
- Rules 4723-20-01, 20-03, and 20-07: No changes are proposed to the rule bodies. The three rules were reviewed in five-year review in 2018 and submitted as “no change” rules. LSC advised the Board on October 22, 2018, that even if the rules had no changes, in order to update a paragraph reference in the statutory authority (which is not part of the rule itself but is included in filing materials), the rules would need to be re-filed. Rather than do this, the Board opted to make the correction this year. The statutory reference is “4723.07(K)” due to a law change (not “L”). The Board would submit as “4723.07” and eliminate the subparagraph completely.

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 4723.35 (Rule 4723-6-01, 4723-6-02, 4723-6-03)
ORC 4723.09 (Rule 4723-7-05, 4723-7-06)
ORC 4723.24, 4723.42, 4723.47 (Rule 4723-8-08)
ORC 4723.50, 3719.062, 4723.481, 4723.49, 4723.491, 4723.492, 4723.486, 4723.487, 4723.488 (Rule 4723-9-10)
ORC 4723.50, 4723.51 (Rule 4723-9-13)

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?

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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.

- 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 4723.06 requires the Board of Nursing to issue and renew nursing licenses, define minimum education standards for nursing programs, survey, inspect and grant approval to nursing programs based on standards established in rules adopted by the Board, establish a program for substance use disorder in accordance with ORC Section 4723.35, and make an annual edition of the exclusionary formulary established in rules available to the public.

ORC Section 4723.07 requires the Board of Nursing to adopt rules governing the practice of nursing, including standards and procedures for licensure, criteria for evaluating the credentials endorsement applicants, minimum standards for approval of nursing education programs, universal and standard precautions to be used by licensees/certificate holders, and other rules necessary to enforce ORC Chapter 4723.

ORC Sections 4723.481 through 4723.51 establish a statutory scheme for Board regulation of APRN (CNP, CNS, CNM) prescriptive authority, including restrictions on what drugs may and may not be prescribed to Ohio patients. Rules 4723-9-10 and 4723-9-13 implement the policy of the State of Ohio to establish standards for prescribing controlled substances, including opioid analgesics, and minimum standards and procedures for the provision of medication-assisted treatment.

- 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?**

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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

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, ODMHAS, 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, and corrections to Rule 4723-9-10 and 4723-

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9-13 consistent with changes implemented by the State Medical Board for prescribing opioid analgesics and engaging in medication-assisted treatment.

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?

Rule 4723-9-10: Scientific data and data from OARRS was used in the original development of the rule. The Board did not utilize additional scientific data for these limited amendments.

Rule 4723-9-13: The initial draft of rule language as filed last year was completed with significant input from the Ohio Department of Mental Health and Addiction Services (ODMHAS) and the State Medical Board. H.B. 49 (132nd GA), Section 4723.51(C), ORC, requires that the Nursing Board rules for MAT and the Medical Board rules be mutually consistent. The current proposed amendments are drafted consistently with medication-assisted treatment filed by the State Medical Board for MAT (see 4731-33-01, 4731-33-03, 4731-33-04), effective April 30, 2019, which were reviewed by the Medical Board's Physician Assistant Policy Committee and Policy Committee with input provided by practitioners and interested parties, such as the Ohio State Medical Association. In addition, effective October 24, 2018, the "Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act" (H.R. 6), was signed into law amending 21 U.S.C. § 823 to expanding the definition of "qualified other practitioners" for purposes of buprenorphine prescribing for MAT. For scientific research/articles related to the development of prescribing parameters for MAT, see, e.g., <https://www.samhsa.gov/medication-assisted-treatment>; "TIP 63, Treatment Improvement Protocol, Medications for Opioid Use Disorder for Healthcare and Addiction Professionals, Policymakers, Patients and Families," published by the Substance Abuse and Mental Health Services Administration: <https://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use-Disorder-Full-Document-Including-Executive-Summary-and-Parts-1-5-/SMA18-5063FULLDOC>; "The ASAM National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use," published by the American Society of Addiction Medicine: <https://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf>.

No specific scientific data was used to develop the remaining 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 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

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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 and prescribing 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 amendments to prescribing rules for APRNs, reflected in Rule 4723-9-10 and 4723-9-13, are consistent with prescribing rules adopted by the State Medical Board.

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 due to the necessity of establishing clear, consistent processes and standards to achieve public protection.

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

The Nursing Board is the only agency authorized to regulate the prescribing practices of advanced practice registered nurse CNPs, CNSs, and CNMs. The Nursing Board worked closely the State Medical Board, and with ODMHAS so that the rules do not conflict with ODMHAS's recommendations concerning medication-assisted treatment for opioid addiction. Other amendments in the package are specifically intended to eliminate obsolete, unnecessary, or redundant language, or conform with legislative changes. 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 for nursing education programs (Chapter 4723-5, OAC), the alternative to discipline/substance use disorder program (Chapter 4723-6, OAC), and nurse licensure (Chapter 4723-7, OAC).

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

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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*).

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;

The scope of the impact business community would be Advanced Practice Registered Nurses licensed by the Nursing Board who are authorized to prescribe controlled substances, including opioids. Others impacted, although not adversely by the amendments, would include applicants for nurse licensing by endorsement and nursing education programs.

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

Regarding Rules 4723-5-10, 5-11, and 5-21, the amendment to eliminate the two-year requirement for preceptors will reduce the burden on nursing education programs in securing preceptors. The amendments to Rules 4723-7-05 and 7-06 will reduce the time period for processing endorsement applications, thereby reducing the burden of compliance for out of state nurse applicants. Regarding Rule 4723-9-10, the amendments would lessen the adverse impact by allowing APRNs nationally certified in hematology and oncology to prescribe higher doses to their cancer patients, when necessary to relieve pain. In addition, the amendments would eliminate the requirement for a second opinion to determine that a patient has a terminal condition. Regarding Rule 4723-9-13, the amendments would expand the pool of APRNs authorized to engage in MAT by including CNMs.

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.

Advanced practice registered nurses who prescribe controlled substances in violation of Rules 4723-9-10 or 4723-9-13 may incur disciplinary sanctions according to Section 4723.28, ORC, which may include fines, continuing education, or restriction, suspension or revocation of the

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license. There may be associated costs for APRNs 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 Rule 4723-9-10 and historical rules have established prescribing standards for many years with the potential for disciplinary action based on violations.

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

The State has a compelling interest in promoting safe prescribing of controlled substances, including for the treatment of pain, and treatment of substance use disorder/alcoholism through the use of medication assistance, while avoiding risk of harm to patients. Allowing some additional options for cancer patients and patients with terminal conditions, and expanding the pool of MAT prescribers to include CNMs, is consistent with this interest.

Regulatory Flexibility

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

Rules 4723-9-10 and 9-13, designed for public protection and safe patient care, must be consistently applied, so the regulations do not provide exemptions or alternative means of compliance.

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 violations of prescribing standards, 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.

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

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update the public and licensees, including small businesses, to changes in requirements and to provide frequently asked questions.

The Board has a dedicated Prescribing Resources website page (including, e.g., the Exclusionary Formulary, APRN Prescribing Process Flowchart, OARRS registration information, interactive Opioid Mapping Tool) and a dedicated APRN email staffed by nursing specialists.