



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 4723-8, 4723-9, 4723-23.

Rule Number(s): 4723-8-01, 4723-8-02, 4723-8-03, 4723-8-04, 4723-8-05, 4723-8-06,
4723-8-08, 4723-8-10, 4723-8-11, 4723-9-01, 4723-9-02, 4723-9-03, 4723-9-08, 4723-9-09,
4723-9-10, 4723-9-11, 4723-9-12, 4723-9-13, 4723-9-14 (New), 4723-23-01, 4723-23-02,
4723-23-03, 4723-23-05, 4723-23-06, 4723-23-07, 4723-23-08, 4723-23-09, 4723-23-10,
4723-23-12, 4723-23-13, 4723-23-14.

Date of Submission for CSI Review: August 24, 2020

Public Comment Period End Date: September 8, 2020

Rule Type/Number of Rules:

New/ 1 rules

No Change/ 6 rules (FYR? Yes)

Amended/ 24 rules (FYR? Yes)

Rescinded/ 0 rules (FYR?)

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

CSIPublicComments@governor.ohio.gov

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.

The Board proposes to amend or file no change rules following the five-year review for Ohio Administrative Code Chapters 4723-8, Advanced Practice Registered Nurse Certification and Practice, Chapter 4723-9: Prescriptive Authority, and Chapter 4723-23: Dialysis Technicians. The Board is proposing one new rule in Chapter 4723-9.

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

CSIPublicComments@governor.ohio.gov

Chapter 8 Advanced Practice Registered Nurse Certification and Practice

All of the following amendments were recommended by the Advisory Committee on Advanced Practice Registered Nursing (APRN Committee)¹ (meeting July 6, 2020) and Board of Nursing (meetings May 20-21, 2020 and July 22-23, 2020):

- Rule 8-01: Paragraphs (I) and (F) are revised to reflect changes made by HB 197, 133rd GA, including cross references to new statutes that delineate CRNA scope of practice; a definition is revised as some CRNA functions do not require that supervision be by “immediate presence” (see 4723.43 (B)(1), ORC).
- Rule 8-02: Paragraph A is revised to reflect changes made by HB 197, 133rd GA. Paragraph C is revised to add language clarifying CRNA authority to issue medication orders within facility settings as modified by HB 197.
- Rule 8-03: Paragraphs A and B are revised to reflect changes made by HB 197.
- Rule 8-04: Language is revised to reflect changes made by HB 111, 132nd GA (ORC 4723.431, ORC). Additional revisions are made to eliminate provisions, as recommended by the Ohio Association of Advanced Practice Nurses (OAAPN), viewed as burdensome and/or unnecessary: Paragraph (D)(7)(a), remove requirements for two-year standard care arrangement (SCA) review, (D)(7)(d), remove required chart review unless the APRN is engaged in direct patient care, (D)(10), delete obsolete language regarding arrangements for reimbursement under the Medicaid assistance program, (D)(11)(b), delete statements regarding FDA approved or pending approval parameters which are unnecessary with an exclusionary formulary, (D)(11)(c), delete requirements for periodic prescription review as other mechanisms monitor inappropriate prescribing (e.g., OAARS). OAAPN also requested revisions to Paragraphs (A)(2) and (D)(4)(a) to better reflect current practices. *Note that references to paragraph (D) herein refer to the language as proposed; paragraph (D) is currently paragraph (C).*

¹ The APRN Committee is established by ORC 4723.493, and is composed of: Four advanced practice registered nurses, each actively engaged in the practice of advanced practice registered nursing in a clinical setting in this state, at least one of whom is actively engaged in providing primary care, at least one of whom is actively engaged in practice as a certified registered nurse anesthetist, and at least one of whom is actively engaged in practice as a certified nurse-midwife; (2) Two advanced practice registered nurses, each serving as a faculty member of an approved program of nursing education that prepares students for licensure as advanced practice registered nurses; (3) A member of the board of nursing who is an advanced practice registered nurse; (4) A representative of an entity employing ten or more advanced practice registered nurses actively engaged in practice in this state.

- Rule 8-05: Paragraph (D)(1) (renumbered C) is revised because this rule provides standards for standard care arrangements, and the “supervising” language and “dentist” language relates to CRNAs, who do not have standard care arrangements. Additionally, OAAPN recommended deletion of the following requirements: in paragraph (D)(1) (renumbered C), periodic review of prescribing patterns; in paragraph (B), review of the SCA every two years; and paragraph (F), APRN verification of the collaborating physician’s license status every two years.
- Rule 8-06: Updates are made to reflect the current name of a form and to cross reference Rule 4723-1-03.
- Rule 8-08: Language in paragraph (C) is removed as recommended by the APRN Committee, consistent with changes made previously for LPN/RN renewal (see Rule 4723-7-09).
- Rule 8-11(B)(4): Revised to refer to current version of referenced form. The APRN Committee also recommended changing paragraph (B)(1) to refer to “specialty” instead of “practice” as a more accurate term.

Chapter 9: Prescriptive Authority

- In Rule 9-01: Paragraph (B) is removed at the request of OAAPN, as obsolete with the adoption of an exclusionary formulary. Rule 9-01(E)(1)(a): Update name of board of regents to “the Ohio department of higher education” (renumbered D).
- Rule 9-02: In paragraph (A)(2)(d)(i), a cross reference is added for clarity to the definitions in Rule 4723-9-10 regarding “acute/sub-acute/chronic pain.” In paragraph (A)(2)(d)(ii), the “governor’s cabinet opiate action team” is replaced with “recoveryOhio initiative”. See EO 2019-08D, creating the RecoveryOhio Advisory Council and subsequent Initiative. At the request of OAAPN, language was removed from paragraph (A)(2)(d)(iii) as it was viewed as unnecessarily specific. In paragraph (A)(4), language is removed at the request of OAAPN as unnecessary.
- Rule 9-08: Globally, language is modified consistent with Section 4723.42, ORC and the eLicense system: “An advanced practice registered nurse with a current, valid license designated as”, to reflect the licensing credential subtypes (designations). Paragraph (A)(1) is revised to reference the Formulary set forth in Rule 4723-9-10

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

CSIPublicComments@governor.ohio.gov

(rather than online). Other changes are made to update cross references to Pharmacy Board rules.

- Rule 9-10(A)(13), and (I)(3), (K)(7): When this rule was revised last year, the definition of “terminal condition” was revised to mirror the Medical Board’s definition applicable to prescribing for acute/sub-acute/chronic pain above MED levels (see (I)((3) and (K)(7)). However, in reviewing Section 4723.481, ORC (APRN limits on prescribing schedule IIs), the definition of “terminal condition” is “as defined in Section 2133.01, ORC”. This is different than the Medical Board’s definition. To conform to the statute, (A)(13) is revised to mirror the statutory definition: “as defined in 2133.01, ORC”, and paragraphs (I) and (K), which apply to exceptions authorizing the APRN to exceed MED levels, are revised to refer to “terminal condition” matching the Medical Board language that is in the current version of (A)(13).
- Rule 9-10: Globally, language is modified consistent with Section 4723.42, ORC and the eLicense system: “An advanced practice registered nurse with a current, valid license designated as”, to reflect the licensing credential subtypes (designations).
- Rule 9-10(K)(6)(a)(iv) and (b): The APRN Committee recommended adding language to clarify, and add flexibility to cover patient populations, that APRNs with certification in hematology, or coursework in hematology leading to certification in oncology, may prescribe above the 120 MED if needed, and to reference physicians certified in oncology or hematology.
- Rule 9-10(M): The APRN Committee recommended adding a cross reference to the statutory definition of “abortion”. This term is defined in ORC 2919.11: “As used in the Revised Code, "abortion" means the purposeful termination of a human pregnancy by any person, including the pregnant woman herself, with an intention other than to produce a live birth or to remove a dead fetus or embryo. Abortion is the practice of medicine or surgery for the purposes of section 4731.41 of the Revised Code.”
- Rule 9-11(A)(2): Revised to refer to the “recoveryOhio initiative”.
- Rule 9-12(A)(5): Update cross reference to rule 4729:8-2-01. Paragraph (H) is revised at the request of OAAPN as a less burdensome alternative.
- Rule 9-13: Globally, language is modified consistent with Section 4723.42, ORC and the eLicense system: “An advanced practice registered nurse with a current, valid license designated as”, to reflect the licensing credential subtypes (designations).

- New Rule 4723-9-14: This rule is proposed according to ORC 4723.51, which requires that the Nursing Board adopt rules that establish standards and procedures to be followed by advanced practice registered nurses in the use of all drugs approved by the FDA for use in medication-assisted treatment (MAT), including controlled substances in Schedules III, IV, or V. The required rules must also address detoxification (withdrawal management) with statutorily required components (relapse prevention, diversion control, patient assessment, individual treatment planning, counseling and recovery support), which is the subject of proposed Rule 4723-9-14.
 - ORC Section 4723.51 requires the Nursing Board to adopt withdrawal management rule language consistent with language adopted by the State Medical Board. Nursing Board and Medical Board staff worked collaboratively with stakeholders and medical experts to develop common language, beginning in December 2017. In order to achieve public consensus and consistency, the Medical Board moved forward with its withdrawal management rules first. On May 20, 2020, the Medical Board’s draft withdrawal management rule language for physicians and physician assistants (Rules 4130-4-01, 4730-4-02, 4731-33-01, and 4731-33-02) was approved by CSI.
 - Nursing Board proposed Rule 4723-9-14 consistently reflects the provisions set forth in the Medical Board rules, as modified for advanced practice registered nurse practice (the primary modifications are that advanced practice registered nurses are not “supervised” as are physician assistants but “collaborate” under standard care arrangements with physicians; and definitions are included within Rule 4723-9-14 rather than in a separate rule).
 - Rule 4723-9-14 provides treatment and detoxification parameters for prescribers who wish to treat opiate addiction via office-based treatment with controlled substances in schedule III, IV, or V (“OBOT”) that have been specifically approved by the U.S. Food and Drug Administration (hereinafter “FDA”) or by a non-controlled substance. At this time, the only approved controlled substances are buprenorphine products, including the drug with the brand name of Suboxone. The only FDA approved non-controlled substance for treating opioid addiction is Naltrexone, which is sold under the brand name Vivitrol, among others. The need for regulation is urgent, as there are reports that some prescribers are setting up “pill mills” for specifically approved buprenorphine products, similar to the “pill mills” where prescription opiates such as OxyContin and Vicodin were prescribed for other than legitimate medical purposes (see e.g.,: <https://www.nytimes.com/2013/11/17/health/in-demand-in-clinics-and-on-the-street-bupe-can-be-savior-or-menace.html?searchResultPosition=2>). Recognizing the constellation of factors related to opiate addiction, treatment, and illegal activity, the rule attempts to strike a proper balance between access to opiate addiction treatment and diversion of specifically approved buprenorphine products by setting forth the requirements for treating opiate addiction in a non-institutional setting so that

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

CSIPublicComments@governor.ohio.gov

the treatment and detoxification can be performed in a safe manner for the patient and reduce the risk of unlawful behavior of patients, practitioners, and others.

- The APRN Committee initially reviewed the Medical Board withdrawal management rule language at its March 2, 2020 meeting; the Committee on Prescriptive Governance² reviewed the Medical Board withdrawal management rules at its March 17, 2020 meeting. The Nursing Board reviewed the Medical Board draft rule withdrawal management rule language at its May 20-21, 2020 meeting. No changes were recommended at these meetings. The Advisory Committee reviewed proposed Rule 4723-9-14 at its July 6, 2020 meeting and did not have any recommended variations, and the language was approved by the Nursing Board at its July 22-23, 2020 meeting.

Chapter 23: Dialysis Technicians

Global changes throughout the Chapter include removing references to “OCDT” and “Ohio Certified Dialysis Technician”, as these terms are not in Ohio law and are not used within the current Ohio eLicense system or on license applications; the current terminology is “Dialysis Technician” or “DT”; or “Dialysis Technician Intern” or “DTI.” Other global changes are to refer to on-line licensing which has replaced a paper application process. The Advisory Group on Dialysis³ reviewed and agreed with the proposed changes at its May 18, 2020 meeting, and the Board approved the changes at its July 22-23, 2020 meeting.

² The CPG is established by ORC 4723.49, and is composed of: (1) Two advanced practice registered nurses, one of whom is nominated by an Ohio advanced practice registered nurse specialty association and one of whom is nominated by the Ohio association of advanced practice registered nurses or its successor organization; (2) A member of the board of nursing who is an advanced practice registered nurse and represents the public; (3) Two physicians, each actively engaged in practice with a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner, one of whom is nominated by the Ohio state medical association or its successor organization and one of whom is nominated by the Ohio academy of family physicians or its successor organization; (4) A member of the state medical board who is a physician and represents the public; (5) A pharmacist actively engaged in practice in this state as a clinical pharmacist. The CPG is the subject of pending legislation that would sunset the Committee.

³ This Advisory Group is established by ORC 4723.79 and is composed of: (1) Four dialysis technicians; (2) A registered nurse who regularly performs dialysis and cares for patients who receive dialysis; (3) A physician, recommended by the state medical board, who specializes in nephrology or an advanced practice registered nurse recommended by the board of nursing who specializes in nephrology; (4) An administrator of a dialysis center; (5) A dialysis patient; (6) A representative of the Ohio hospital association; (7) A representative from the end-stage renal disease network, as defined in 42 C.F.R. 405.2102.

- Rule 23-01 Global change to remove references to “Ohio Certified Dialysis Technician” and replace with “Dialysis Technician” or “DT”. Update reference to reflect on-line application. Paragraph (E) is clarified to indicate that faculty-interactive theoretical instruction may be on-line.
- Rule 23-02(A)(1): Updated to include current name of form and cross reference Rule 4723-1-03.
- Rule 23-05: Revised to update form names, cross reference to Rule 4723-1-03, and conform to current licensing processes, reflected in previous rule changes for RN/LPN renewal, reactivation and reinstatement.
- Rule 23-06: Revised to update form names, cross reference to Rule 4723-1-03, and conform to current licensing processes, reflected in previous rule changes for RN/LPN renewal, reactivation and reinstatement.
- Rule 23-07(A)(1), (C)(1): Revised to update form names and cross reference to Rule 4723-1-03. In paragraph (H)(2), language is revised at the request of the Advisory Group on Dialysis to say “at least” 45 days.
- Rule 23-08: Paragraph (F) is revised to reference both vacancy and new appointment notification consistent with nursing education program rules.
- Rule 23-09: Make global change to remove “Ohio Certified Dialysis Technician” consistent with Ohio law and current eLicense system.
- Rule 23-10: The word “candidate” is added for clarification.
- Rule 23-13: Make global change to remove “Ohio Certified Dialysis Technician” consistent with Ohio law and current eLicense system.

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

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

CSIPublicComments@governor.ohio.gov

ORC 4723.01, 4723.24, 4723.41, 4723.42, 4723.43, 4723.431, 4723.46, 4723.47, 4745.04, 3313.539, 3707.511, 3707.521 (OAC Chapter 4723-8)

ORC 4723.48, 4723.481, 4723.482, 4723.484, 4723.486, 4723.487, 4723.488, 4723.49, 4723.50, 4723.51, 4723.491, 4723.492, 3719.062 (OAC Chapter 4723-9)

ORC 4723.71 - .79, 4723.08 (OAC Chapter 4723-23)

- 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

- 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 requires the Board of Nursing to adopt rules governing the practice of nursing, including standards and procedures for licensure, criteria and standards for evaluating the qualifications for advanced practice registered nurses, criteria for standard care arrangements required by ORC 4723.431, quality assurance standards for advanced practice registered nurses, minimum standards for continuing education, and other rules necessary to enforce ORC Chapter 4723.

ORC Section 4723.06 requires the Board to approve under ORC Section 4723.46 national certifying organizations for advanced practice registered nurse examinations.

ORC Section 4723.47 authorizes the Board to adopt rules regarding review of patient information available through OARRS.

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

CSIPublicComments@governor.ohio.gov

ORC Section 4723.50 requires the Board to adopt rules necessary to implement the provisions of Chapter 4723. pertaining to the authority of advanced practice registered nurses designated as clinical nurse specialists, certified nurse midwives, and certified nurse practitioners to prescribe drugs and therapeutic devices, including but not limited to courses of instruction and criteria for standard care arrangements described in ORC 4723.431.

ORC Section 4723.51 requires the Board to adopt rules establishing standards and procedures for advanced practice registered nurses in the use of drugs for medication- assisted treatment including detoxification (withdrawal management), relapse prevention, patient assessment, individual treatment planning, counseling, diversion control and other topics considered best practices.

ORC Section 4723.79 requires the Board to adopt rules to administer and enforce Sections 4723.71-.79, ORC, regarding dialysis technician and dialysis technician intern testing organizations, examinations, continuing education, licensing, medication administration standards and other topics.

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

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.

Two statutorily appointed bodies composed of members of the public reviewed rules in this package: The Advisory Committee on Advanced Practice Registered Nursing (meetings March 2, 2020, July 6, 2020) and the Advisory Group on Dialysis (meeting May 18, 2020). In

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

CSIPublicComments@governor.ohio.gov

addition, the Committee on Prescriptive Governance had an opportunity to recommend revisions to prescribing rules (meeting March 17, 2020).

On June 1, 2020, the Board posted notification on its website, with links to proposed rule language, and emailed this information to interested parties requesting feedback or comments by June 30. Interested parties 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, state entities (e.g, State Medical Board, Pharmacy Board), and other stakeholders.

Regarding proposed Rule 4723-9-14, as discussed in Item 2., above, Rule 4723-9-14 substantively mirrors the Medical Board withdrawal management rules. The initial draft of the rules was completed with significant input from the Ohio Department of Mental Health and Addiction Services (ODMHAS). The Medical Board physician assistant rules (Chapter 4730-4) were then discussed with the members of the Physician Assistant Policy Committee (“PAPC”), which is composed of three physician assistants, a M.D., a D.O., and a physician member of the Medical Board, at a public meeting held on June 10, 2019. The physician rules (Chapter 4731-33) were discussed by the Medical Board’s Policy Committee at a public meeting on July 10, 2019. The Advisory Committee on Advanced Practice Registered Nursing reviewed the Medical Board withdrawal management rule language at its March 2, 2020 meeting; the Committee on Prescriptive Governance reviewed the Medical Board withdrawal management rules at its March 17, 2020 meeting. The Nursing Board reviewed the Medical Board draft rule withdrawal management rule language at its May 20-21, 2020 meeting. No changes were recommended at these meetings. The APRN Committee reviewed proposed Rule 4723-9-14 at its July 6, 2020 meeting and did not have any recommended variations, with the understanding that the rule language needed to be consistent with the Medical Board’s rule language; and the language was approved by the Nursing Board at its July 22-23, 2020 meeting.

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

On June 1, 2020, interested parties were encouraged to provide feedback on the rules with a requested June 30, 2020 deadline. On June 30 and July 2, the Ohio Association of Advanced Practice Nurses (OAAPN) submitted comments on Chapter 4723-8 and 4723-9. No other comments were received. The comments from OAAPN were reviewed by the Advisory

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

CSIPublicComments@governor.ohio.gov

Committee on Advanced Practice Registered Nursing (July 6, 2020). The Committee made recommendations to the Board based on OAAPN's comments, as indicated in Item 2. above.

Rule 4723-9-14 was developed collaboratively with the State Medical Board and ODMHAS (see Item 9, above). The Medical Board received comments concerning the definitions of "withdrawal management" by US WorldMeds, the Cleveland Clinic and the Northeast Ohio Hospital Opioid Consortium. The comments were incorporated into the proposed definition. The Medical Board also received comments concerning the definition of "ambulatory detoxification" from the Cleveland Clinic and US WorldMeds. The comments were incorporated into the definition and clarified the definition's use by practitioners providing detoxification in the listed settings. The Medical Board received comments from Innovative Health Solutions that the rules should reflect that there are nonpharmacological treatment options for opioid withdrawal and language was added to address this. The Nursing Board received comments from OAAPN on July 2, 2020, asking for changes in the Nursing Board language that, if made, would substantively modify the rule from the Medical Board withdrawal management rule language. These changes were not made in order to maintain consistency between the rules as required by ORC 4723.51.

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?

Regarding Rule 4723-9-14, the rule was developed based upon the following published protocols:

- "TIP 45, Detoxification and Substance Abuse Treatment," published by the Substance Abuse and Mental Health Services Administration: <https://store.samhsa.gov/system/files/sma15-4131.pdf>
- "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/Executive-Summary/SMA18-5063EXSUMM>
- "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>

The rule also benefited from the input of the medical director and other staff of the Ohio Department of Mental Health and Addition Services. ODMHAS certifies community behavioral health agencies that provide behavioral health services and is the lead Ohio agency for addiction services information.

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

CSIPublicComments@governor.ohio.gov

Regarding the five-year review rules, 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 Committee on Advanced Practice Registered Nursing (see footnote 1), the Advisory Group on Continuing Education, the Advisory Group on Dialysis, Advisory Group on Nursing Education, and the Committee on Prescriptive Governance (see footnote 2). 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?

Regarding Rule 4723-9-14, see response to Item 10, above. Regarding the five-year review rules in this package, no alternatives were considered because minimum licensing, education and practice standards are the essential foundation for competent nursing and dialysis care, patient safety, and public protection, and these standards are consistent with prevailing nursing and dialysis practice and evidence-based nursing research.

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 proposed rules set out the required activities but do not specify the 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 Nursing Board is the only agency authorized to regulate the practice, including the prescribing practice, of advanced practice registered nurses, and the practice of dialysis technician interns / dialysis technicians.

Regarding the withdrawal management rule, 4723-9-14, the Nursing Board worked closely with the State Medical Board and ODMHAS so that the rule does not conflict with those agencies' recommendations concerning medication assisted treatment and detoxification.

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

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

CSIPublicComments@governor.ohio.gov

Nursing Board's website, and information concerning the rules with links to the rules will be e-mailed to attorneys, licensees, nursing and dialysis practice associations, associations, health care system representatives and other regulatory agencies, and will also be distributed 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;

- Individuals applying to obtain licenses as advanced practice registered nurses, dialysis technician interns, and dialysis technicians;
- Dialysis technician training programs;
- Individuals licensed/certified by ORC Chapter 4723.;
- Regarding Rule 4723-9-14, the impacted business community is composed of advanced practice registered nurses who provide office based withdrawal management for alcohol or opioid addiction.

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

Rules in 4723-8-01 to 8-11 establish a licensure process for advanced practice registered nursing, including fees and required application information for initial licensure and renewal. The rules establish continuing education requirements which may require expenditures to complete coursework. The rules also establish minimum standards of practice for APRNs, and grounds for disciplinary action if standards are not met. Sanctions for violation of Chapter 4723., ORC or Chapter 4723-8, OAC may include fines, license restrictions, suspension or revocation.

Rule 4723-8-06 requires application information for approval as a national certifying organization.

Rules in 4723-9-01 to 9-13 establish a establish minimum standards of safe prescribing practice for APRNs designated as certified nurse midwives, certified nurse practitioners, and clinical nurse specialists, and grounds for disciplinary action if standards are not met. Sanctions for violation of Chapter 4723., ORC or Chapter 4723-9, OAC may include fines, license restrictions, suspension or revocation. Rule 4723-9-11 requires coursework in Ohio laws governing drugs and prescriptive authority, as required by law, which may require an

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

CSIPublicComments@governor.ohio.gov

expenditure to complete. For out of state APRN applicants who have not taken coursework in advanced pharmacology, this coursework is required by law, as set forth in Rule 4723-9-03, which may require an expenditure to complete.

Rules in 4723-23-01 to 23-14 establish an approval process for dialysis technician training programs, and a certification process for dialysis technician interns and dialysis technicians, including fees and required application information for training program approval and reapproval, and technician certification and renewal of certification. The rules establish continuing education requirements which may require expenditures to complete coursework. The rules also establish minimum standards of practice for dialysis technicians and interns, and grounds for disciplinary action if standards are not met. Sanctions for violation of Chapter 4723., ORC or Chapter 4723-23, OAC may include fines, certification restrictions, suspension or revocation.

Regarding proposed Rule 4723-9-14, the advanced practice registered nurse who chooses to provide medication-assisted treatment and withdrawal management for addiction will incur the cost of the time needed to perform the required assessment, formulation of an appropriate treatment plan for each patient, and documentation of compliance with the activities required by the rule. However, the required activities should not add significantly to the practice costs of an APRN who practices within the minimal standards of care. The U.S. Drug Enforcement Administration (DEA) requires, pursuant to 21 USC § 823(g)(2), that an APRN who intends to prescribe certain controlled substance medications for the purposes of maintenance and detoxification of opiate addiction receive a waiver from special registration requirements (waiver). There is no fee associated with applying for the waiver. An APRN who intends to prescribe specifically approved buprenorphine products, which are a schedule III, IV, or V controlled substance, must have a current DEA certificate of registration (also known as a DEA number). Individuals who violate Rule 4723-9-14 may be subject to disciplinary action according to ORC 4723.28(B), including a fine of up to \$500.00 per violation.

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 4723.08, ORC, establishes fee payments for advanced practice registered nurse, dialysis technician, and dialysis technician intern licensing and licensing renewal, and dialysis technician training program approval and reapproval.

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

CSIPublicComments@governor.ohio.gov

The fees are \$35 (dialysis technician intern and dialysis technician, Rule 4723-23-02, -03, and -05); and \$150 and \$135 (APRN license and renewal, ORC 4723.08); and \$300 (dialysis technician training program approval/reapproval, Rule 4723-23-07).

APRNs and dialysis technicians who violate minimum standards of care set forth in Chapter 4723-8, 4723-9, or 4723-23, OAC, may incur disciplinary sanctions, which may include fines, continuing education, or restriction, suspension or revocation of the license or certificate. There may be associated costs for licensees or 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 Chapters 4723-8, -09, and -23, OAC, have established minimum standards of safe nursing and dialysis practice for many years with the potential for disciplinary action based on violations.

There is a cost inherent in engaging in the business of being a Board approved dialysis technician training program (Chapter 4723-23), or in operating an independent practice as an APRN (Chapters 4723-8 and 4723-9). The costs are variable and determined by individual business operations.

Regarding Rule 4723-9-14, see Item 16.b., above.

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

The minimum standards of safe practice for advanced practice registered nurses, set forth in Chapter 4723-8, including for prescribing, set forth in 4723-9; and for the provision of safe dialysis care set forth in Chapter 4723-23, are essential for public protection, and are designed to reduce health care errors, harm to patients and substandard practice. The information sought in forms required for licensing and certification, and for training program approval, are needed to ensure that applicants meet minimum statutory qualifications, and that application standards are applied in a fair and legally consistent manner.

Regarding proposed new Rule 4723-9-14, Ohio is experiencing an epidemic of opiate abuse and overdose deaths. Specifically approved buprenorphine products have been used successfully for the maintenance treatment for opioid dependence as part of a treatment plan that includes counseling and psychosocial support. However, specifically approved buprenorphine products are themselves opioids that are subject to abuse. Concerns have been brought forward by law enforcement, treatment providers, and governmental agencies that office-based maintenance treatment with specifically approved buprenorphine products may be contributing to the opiate

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

CSIPublicComments@governor.ohio.gov

problem in Ohio. In compliance with Section 4723.51, protection of the public, in general, and persons with opiate addiction, in particular, necessitates that the Nursing Board regulate the office based maintenance treatment and detoxification of persons with addiction in a safe manner, yet at the same time providing greater access to that treatment in Ohio.

Regulatory Flexibility

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

Existing 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. Similarly, regarding new Rule 4723-9-14, treatment of patients with opioids is a complex matter which impacts the health and safety of patients. The public safety requirements relevant to these rules require consistency in their application to all licensees and are not amenable to exemptions or alternative means of compliance for small businesses.

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?

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 (see footnotes 1-3), 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. Nursing Board staff members provide answers to APRN practice and prescribing questions, via a designated email address and by telephone. The Board provides educational materials as needed through FAQs posted on its website, and through a quarterly newsletter (*Momentum*). All relevant forms and information for APRNs, dialysis technicians and training programs are also available on the Board's website.

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

CSIPublicComments@governor.ohio.gov