

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Board of Nursing

Regulation/Package Title: 2018 Technical Changes; and Medication-Assisted Treatment

Rule Number(s): 4723-5-08, 4723-7-04, 4723-7-05, 4723-7-06 4723-7-10; 4723-9-13.

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☐ Rescinded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.

Amended

- 4723-5-08(J): Technical correction changing “not less than seven business days” to “not more than seven business days.”

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- Rules 4723-7-04, 7-05, 7-06: Make changes to update language related to foreign-educated endorsement applicants and delete obsolete language:
 - 7-04(B)(3) and (F)(1): Delete requirement, as foreign-educated endorsement applicants have already been licensed by exam in another NCSBN member jurisdiction that presumably determined that individual's educational preparation was substantially similar.
 - 7-05 (A)(1)(b), 7-06(A)(1)(b): Delete as there are no programs that are not NCSBN member jurisdiction programs, except foreign programs discussed in Rule 7-04.
- Rule 4723-7-10(B): Update to remove obsolete reference to "certificate of authority" as the Board no longer issues certificates of authority.

New:

- Rule 4723-9-13: HB 49 (132nd GA) implemented ORC 4723.51(B), which requires that the Board of Nursing shall 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. The statute states that the rules "shall address detoxification, relapse prevention, patient assessment, individual planning, counseling and recovery supports, diversion control, and other topics." The content of this rule addresses these topic areas with the exception of detoxification, which the Board intends to propose in a subsequent rule. ORC 4723.51(C) requires that the rules adopted by the Board of Nursing for medication-assisted treatment shall be consistent with rules adopted by the State Medical Board for physicians and physician assistants. The State Medical Board submitted its rules to CSI on August 3, 2018, and proposed rule 4723-9-13 is consistent with those rules. As is stated in the Medical Board's CSI BIA, the need for regulation is urgent, as there are reports that 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.,* July 2018 Data Brief, U.S. Department of Health and Human Services Office of Inspector General detailing "extreme use and prescribing" of opioids in the State of Ohio (<https://oig.hhs.gov/oei/reports/oei-05-18-00010.pdf>). Recognizing the factors related to opiate addiction, treatment, and illegal activity, the rule is intended to strike a necessary balance between access to opiate addiction treatment and diversion of buprenorphine products by setting forth the requirements for treating opiate addiction in a non-institutional setting so that treatment can be performed in a safe manner for the patient and reduce the risk of unlawful behavior of patients, practitioners, and others.

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

Ohio Revised Code (ORC) Section 4723.07

ORC Sections 4723.51, 4723.50 (Rule 4723-9-13)

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- 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.

None of the rules in the package implement a federal requirement.

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

ORC 4723.51 requires the Board of Nursing to adopt Rule 4723-9-13.

- 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. Rule 4723-9-13 is proposed to implement the policy of the State of Ohio to set minimum standards and procedures for the provision of medication-assisted treatment. The policy reflects concerns that some medication-assisted treatment programs have provided such treatment outside the minimal standards of safe care. Rules 4723-5-08, and 4723-7-04, 7-05, 7-06, and 7-10, are being amended to correct language and delete obsolete language, and in doing so, provide further clarity. Executive Order 2011-01K, “Establishing the Common Sense Initiative” (EO), 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.

- 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.

- Rule 4723-9-13: The initial draft of rule language was completed with significant input from the Ohio Department of Mental Health and Addiction Services (ODMHAS) and the State Medical Board. The rule is drafted consistently with medication-assisted treatment rules proposed by the State Medical Board, which were reviewed by the

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Medical Board's Physician Assistant Policy Committee (February 12, 2018) and Policy Committee (February 14, 2018); and by interested parties, such as the Ohio State Medical Association. The rule concepts were discussed with the Board of Nursing's Committee on Prescriptive Governance (March 5, 2018), a Committee composed of physicians, advanced practice registered nurses (APRNs) and a pharmacist; and discussed with the Advisory Committee on Advanced Practice Registered Nursing (APRN Committee) at multiple meetings (January 29, 2018; May 14, 2018; June 11, 2018). The APRN Committee, established by HB 216 (131st GA), is composed of APRNs including those recommended by organizations such as the Ohio Association of Advanced Practice Nurses (OAAPN). An interested party meeting was held on May 14, 2018 for review of the medication-assisted treatment rule and was attended by licensees and representatives of health care systems, nursing associations (OAAPN, ONA), and the State Medical Board.

- In addition to Rule 4723-9-13, the other rules in this package were reviewed by the APRN Committee at its June 11, 2018 meeting; in early June 2018, the Board posted on its website and emailed the Ohio Nurses Association, other nursing associations and other stakeholders copies of the proposed rules for purposes of an interested party meeting scheduled on June 26, 2018.
- The amendment to Rule 4723-5-08 was recommended by the Advisory Group on Nursing Education, a body composed of nursing education program faculty, to correctly convey the original intent of the language.

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

Rule 4723-9-13 represents a collaborative effort on the part of the State Medical Board with significant input from the Ohio Department of Mental Health and Addiction Services (ODMHAS). Because the Nursing Board's medication-assisted treatment rule is required to be consistent with the State Medical Board rules, input from stakeholders in the medical community significantly impacted the draft rule:

- Thirty-three comments were received following the February 2018 circulation of the first draft of the Medical Board rules. *See State Medical Board BIA, August 3, 2018 BIA attached spreadsheet;*
- The Medical Board rules were then revised and sent for comment by all persons who had commented initially. Four additional comments were received. *See State Medical Board BIA (August 3, 2018), attached spreadsheet.* Incorporation of comments and the rationale for changes made to the Medical Board rules, which directly impacted the final draft of Nursing Board Rule 4723-9-13, are outlined in the State Medical Board's BIA (August 3, 2018), Item 8.

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- The APRN Committee and interested parties, representing nursing associations and health care systems, provided comments at the May 14, 2018 interested party meeting that were incorporated into the final draft of Rule 4723-9-13:
 - Language was added including 8 hours of biennial continuing education in substance abuse and addiction for APRNs providing medication-assisted treatment (paragraph (B)(2));
 - Language was added to clarify that the APRN may perform or “confirm the completion of” patient assessment steps listed in paragraph (C);
 - Globally, the word “nurse” was replaced with Advanced Practice Registered Nurse in all instances;
 - In paragraph (C)(5), original language requiring “collaboration” was revised to “refer and work jointly”;
 - The definition of “qualified behavioral healthcare provider” was expanded to include APRNs licensed as a CNS or CNP holding national certification in psychiatric mental health, or CNSs who were “grandfathered” and not required to obtain national certification, but whose specialty is psychiatric mental health; and to include APRNs who hold certification as a certified addictions registered nurse-advanced practice issued by the Addictions Nursing Certification Board (paragraphs (A)(9)(d), (f));
 - Wording was added to require the provision of buprenorphine products in compliance with the FDA approved REMS (paragraph (C)(9)). According to the FDA, “[a] Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. REMS are designed to reinforce medication use behaviors and actions that support the safe use of that medication. While all medications have labeling that informs health care stakeholders about medication risks, only a few medications require a REMS.” <https://www.fda.gov/Drugs/DrugSafety/REMS/default.htm>.
 - Language setting specific dosage periods for buprenorphine during the induction phase was replaced with language requiring the dosing not exceed the recommendation in the FDA labeling, except for medically indicated circumstances as documented in the medical record (paragraph (C)(9)(d);
 - Language setting specific dosage levels for naltrexone for treatment of opioid use disorder was replaced with language requiring the dosing to comply with FDA labeling (paragraph (C)(10)).

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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Rule 4723-9-13 is based on the State Medical Board's proposed rules for medication-assisted treatment, which are based on two published protocols.

- "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-Documents-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>

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

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?

See response to #8, above.

11. Did the Agency specifically consider a performance-based regulation? Please explain.
Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.

The proposed rules set out the required activities but do not specify a means of performing the required activities.

12. 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 certified nurse practitioners and clinical nurse specialists. 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.

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 help ensure that rules are applied consistently and predictably for the regulated community. The Board plans to monitor progress

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with respect to new Rule 4723-9-13, and report back to these groups. 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;

Nursing students, individuals licensed by ORC Chapter 4723., nursing education programs, and APRN CNPs and CNSs who provide medication-assisted treatment.

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

Rule 4723-9-08: The amendment to paragraph (J) of the rule will not have an adverse impact.

Rules 4723-7-04, 7-05, 7-06, 7-10: The amendments will have no adverse impacts on applicants for nursing licenses.

Rule 4723-9-13: The adverse impact is the cost of continuing education (CE) related to substance abuse and addiction. While APRNs are already required to complete CE (ORC 4723.24), the rule requires APRN CNPs or CNSs who wish to provide medication-assisted treatment to obtain 8 hours in CE related to substance abuse and addiction. However, the content in substance use and addiction may be counted toward those currently required hours.

The APRN CNP or CNS who chooses to provide medication-assisted treatment for opioid addiction will also 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 minimum standards of safe 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. In order to obtain

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the waiver, the APRN must complete 24 hours of initial training in the topic areas outlined in 21 USC 823(g)(2)(G)(iv); this can be satisfied by completing both the 8-hour waiver course required for treatment of opioid use disorder that physicians take, plus an additional 16-hour course offered free of cost by the Substance Abuse and Mental Health Services Administration (SAMHSA). The 8-hour course is also offered free of charge through SAMHSA by Providers of Clinical Support System (<https://pcssnow.org>).

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).

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.

The cost of CE in substance abuse and addiction is variable according to the provider.

There is no fee associated with applying for the 21 USC Section 832(g)(2) waiver.

In order to obtain the waiver, the APRN must complete 24 hours of initial training in the topic areas outlined in 21 USC 823(g)(2)(G)(iv); this can be satisfied by completing both the 8-hour waiver course required for treatment of opioid use disorder that physicians take, plus an additional 16-hour course offered free of cost by the Substance Abuse and Mental Health Services Administration (SAMHSA). The 8-hour course is also offered free of charge through SAMHSA by Providers of Clinical Support System (<https://pcssnow.org>).

The fee associated with the DEA registration is \$731.00 for the initial application and for every three-year renewal cycle.

Individuals who receive formal disciplinary action for violating the Rule 4723-9-13 may be subject to civil penalties set forth in ORC Section 4723.28.

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

Ohio is experiencing an epidemic of opiate abuse and overdose deaths. Specifically approved buprenorphine products have been successfully used 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 buprenorphine products may

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be contributing to the opiate problem in Ohio. The Board of Nursing is required to adopt rules in compliance with ORC 4723.51 in order to protect the general public, and specifically, persons with opiate addiction, by regulating the office-based treatment of opioid addicted patients in a safe manner, yet at the same time providing greater access to treatment for those patients.

Regulatory Flexibility

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

Rule 4723-9-13: Treatment of patients with opioids is a complex matter which impacts the health and safety of patients. The public safety requirements relevant to this rule require consistency in its application to all prescribers and are not amenable to exemptions or alternative means of compliance for small business.

The proposed amendments to other rules in the package similarly require consistency in their application to all license applicant processes and nursing education programs, and are not amenable to exemptions or alternative means of compliance for small business.

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?

Rule 4723-9-13: Waivers of fines and penalties for paperwork violations and first time offenders may be considered consistent with ORC 119.14 and ORC 4723.061, which do not require the Board to act on minor violations of the Nurse Practice Act or rules adopted under it, if applicants or individuals licensed under Chapter 4723., ORC commit violations and following review the Board determines that issuing a notice or warning to the alleged offender adequately protects the public.

There are no fines or penalties associated with the other rules in this package.

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

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*). License applicants receive detailed information with license applications. Nursing education programs are aided by staff members through a dedicated email address and by telephone. In addition, the Board hosts at least two Nursing Education Workshops each year, to update nursing education program administrators and faculty on rules related to nursing education program applications.