

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Board of Nursing

Regulation/Package Title: Opioid Prescribing Rules for Sub-acute & Chronic Pain; Dialysis Technician Certification; Youth Concussion Assessment and Clearance

Rule Number(s): 4723-1-03; 4723-8-11; 4723-9-10; 4723-9-12; 4723-23-03; 4723-23-10

Date: June 14, 2018

Rule Types: Amended

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

- 4723-9-10 and 4723-9-12: The rules establish the formulary/standards of prescribing for APRNs designated as CNPs, CNMs, or CNSs, and the standards and procedures for review of the drug database established and maintained by the state board of pharmacy (OARRS), respectively. The proposed amendments are to establish

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- parameters for opioid analgesic prescriptions for the treatment of sub-acute and chronic pain. Section 4723.481, ORC, requires that APRNs prescribe in a manner that does not exceed the authority of the collaborating physician or podiatrist, including requirements for chronic pain prescribing. Rule 4723-9-10 would be amended to mirror/cross-reference the new sub-acute/chronic pain prescribing parameters proposed in Medical Board Rule 4731-11-14. The language would require prescribers to first explore non-medication treatment options, create “safety checkpoints” for patient assessment depending on the potency of the medication (i.e., the level of Morphine Equivalent Daily Dose or MED), and consult with a pain management specialist at extremely potent dosage levels associated with overdose. Rule 4723-9-12(D) is updated to reflect the OARRS report check triggered by opioid analgesic prescribing. The sub-acute/chronic pain language does not apply to hospice care patients, terminal conditions including terminal cancer, or inpatient prescriptions.
- 4723-23-03 and 4723-23-10: Amended to reduce the training time for dialysis technician (DT) certification from 12 months to 6 months, and update related DT testing organization and application form references in those rules and Rule 4723-1-03.
 - 4723-8-11: The rule establishes medical procedures for youth concussion assessment and clearance to return to sports by CNSs and CNPs. The amendment is to update the reference to the most current guideline for youth concussion assessment and clearance, the Consensus Statement on Concussion in Sports – the 5th International Conference on Concussion in Sport held in Berlin, October 2016, which replaces the previous 2012 Zurich Guidelines.

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

Ohio Revised Code (ORC) Section 4723.07
ORC Sections 3719.062, 4723.50 (rule 4723-9-10)
ORC Sections 4723.50, 4723.487 (rule 4723-9-12)
ORC Sections 3313.539, 3707.511, 3707.521 (rule 4723-8-11)
ORC Section 4723.79 (rule 4723-23-03)
ORC Section 4723.74, 4723.79 (rule 4723-23-10)

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 applied to all the rules in this package.

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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 rule 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)?

As to all of the proposals in this package, the rule language is intended to actively safeguard the health of the public through the effective regulation of nursing practice.

- 4723-9-10, 4723-9-12: Section 3719.062 (SB 319, 131st GA), ORC, authorizes health care licensing boards to adopt rules limiting the amount of opioid analgesics that may be prescribed. Section 4723.50, ORC, requires the Nursing Board to adopt rules to implement drug prescribing standards for APRNs. Ohio is experiencing an opioid epidemic that negatively impacts public health resulting in profound consequences to Ohio's economy and way of life. The Governor has directed that the state's professional licensing boards take action by rule to help affect change and improve health outcomes. The public purpose for the rule package is to reduce the frequency and amount of opioids prescribed for sub-acute and chronic pain, while establishing parameters for prescribing a dosage levels associated with increased risk of dependency and/or fatality. The rules as proposed preserve the ability for providers to prescribe at 50, 80, and 120 MED levels as specified in the rule when clinically appropriate and with proper documentation. The rule language consistently cross-references State Medical Board proposed Rule 4731-11-4 to ensure consistency in patient care and in accordance with Section 4723.481, ORC, which requires that APRNs prescribe in a manner that does not exceed the authority of the collaborating physician or podiatrist, including requirements for chronic pain prescribing. Section 4723.487, ORC, authorizes the Nursing Board adopt rules for prescribing APRN standards/procedures regarding review of patient information in OARRS, in compliance with Section 4729.80, ORC.
- 4723-23-03, 4723-23-10, and 4723-1-03: Section 4723.79, ORC, requires the Nursing Board to adopt rules to administer and enforce Section 4723.71 to 4723.79, ORC. The proposed revision to dialysis technician certification Rules 4723-23-03 and 4723-23-10 is intended to lessen the dialysis training time period from 12 months to 6 months; this time reduction has been determined by the Board to sufficiently ensure that the public is protected with providers who have the competency to provide safe dialysis care. Amendments to Rule 4723-1-03 are for clarity of public reference to ensure that form titles/dates are accurate, consistent with Executive Order 2011-01K.
- 4723-8-11: The rule is required by Section 3707.521, ORC. The rule is required to implement the recommendations of the Ohio Department of Health Committee,

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which was charged in HB 487 (130th GA), with developing guidelines related to youth sports concussions. Section 3707.521, ORC, required the Nursing Board to adopt rules establishing standards that are “equal to or stronger than” the guidelines developed by the Committee. For ease of reference, the Ohio Youth Sports Concussion & Head Injury Return-to-Play Guidelines Committee Final Guidelines Report, pp 7-8, Committee Recommended Guidelines, and p.17, Medical Clearance to Return to Play After Suspected Concussion form are attached. The amendment is to update the reference from previous Consensus Statement (2012 Zurich) to the most current Consensus Statement, the “Consensus Statement on Concussion in Sports – the 5th International Conference on Concussion in Sport held in Berlin, October 2016” (2016 Consensus Statement), which replaces the 2012 Zurich statement. A copy of the 2016 Consensus Statement is also attached for reference.

6. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?

Outcomes reflecting the impact of the limits on opioid prescribing resulting in benefits for public safety will be measured by OARRS data, and public health and law enforcement related statistics. Success will also be achieved and measured by having clear rules written in plain language resulting in licensee compliance with the rules and avoiding unintended consequences.

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.

Governor Kasich and the Governor’s Cabinet Opiate Action Team (GCOAT) were instrumental in reviewing state and federal standards and OARRS trends that indicated now is the right time to move forward in collaboration with government and public stakeholders to establish certain standards for opioid use in the treatment of chronic and sub-acute pain. Directors and staff from the Boards of Nursing, Medicine, Dental and Pharmacy, and from the Ohio Department of Mental Health and Addiction Services, have all met to discuss the need for consistent standards of practice reflective of a common goal to reduce the frequency and amount of opioids prescribed for chronic and sub-acute pain, while preserving the ability for providers to prescribe at 50, 80, and 120 limits specified in the rule when clinically appropriate and with proper documentation of consultation, pain management agreements and/or provision of naloxone prescriptions as indicated.

The prescribing parameter concepts set forth in the chronic pain rule are already familiar to APRN prescribers and other stakeholders. Ohio Section 4723.481, ORC, requires that

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APRNs prescribe in a manner that does not exceed the authority of the collaborating physician or podiatrist, including requirements for chronic pain prescribing. See Medical Board Section 4731.052, ORC; Chapter 4731-21, OAC (these rules date back to 1998). In addition, *Ohio Guidelines for Prescribing Opioids for the Treatment of Chronic, Non-Terminal Pain 80 mg of Morphine Equivalent Daily Dose (MED) “Trigger Point”* have been in place since October 2013.

The Nursing Board discussed the rules package at its public Board meeting in April 2018 and sent a draft rule approved by the Board to various interested parties for initial comment prior to filing with the CSI. The Board also posted the draft rule and call for comments on the Board’s website and distributed information through e-news and social media. Board meeting dates, rule information and agendas are posted on the Board’s website and interested parties are sent notice by e-mail prior to Board and Committee meetings. The Board held an interested party meeting on May 14, 2018 in conjunction with review of the rule language by the Advisory Committee on Advanced Practice Nursing (APRN Committee). The APRN Committee was established in 2017 by HB 216 (131st GA) to “advise the board regarding the practice and regulation of advanced practice registered nurses and may make recommendations to the committee on prescriptive governance. The committee may also recommend to the board that an individual with expertise in an advanced practice registered nursing specialty be appointed under division (B) of this section as an additional member of the committee.” Section 4723.493, ORC. The interested party meeting reflected a broad base of public members, including representatives from the Ohio Association of Advanced Practice Nurses (OAAPN), the Ohio Nurses Association (ONA), health care systems and higher education programs. At the May 14 meeting the APRN Committee recommended approval of the rule amendments with minor changes; the Committee reviewed and approved of the current version of all of the rules in this package, including the chronic and sub-acute pain rules, the youth concussion rule, and the dialysis rules, at its public meeting on June 11, 2018.

The Committee on Prescriptive Governance (CPG) reviewed and approved of a substantively similar version of the chronic and sub-acute pain prescribing parameter language at its March 2018 meeting. CPG meetings are open to the public.

The Advisory Group on Dialysis, a body established by Section 4723.71, ORC, composed of members including dialysis industry representatives, an Ohio Hospital Association representative, individual providers, and a dialysis care patient, met in March 2018 and recommended the Board amend its rules (4723-23-03, 4723-23-10) to reduce the training time for dialysis technician (DT) certification from 12 months to 6 months, and update related DT testing organization and application form references in those rules and Rule 4723-1-03. This change was reviewed by members of the public at the May 14 interested party’s meeting and approved by the Board its May meeting.

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

On May 14, the Advisory Committee on Advanced Practice Registered Nursing met in conjunction with an interested party meeting to review proposed revisions to Rules 4723-9-10 and 4723-9-12. The Committee agreed to the language as proposed with two changes:

- 1) The draft language was revised to reflect the Committee's recommendation to change the word "nurse" to "advanced practice registered nurse" where possible, with the understanding that the rule does not apply to CRNAs.
- 2) Paragraph (M)(7), page 11, is changed to delete "hospice patient or" and instead states "in a hospice care program".

Regarding all of the rules in this package, representatives from the Ohio Association of Advanced Practice Nurses (OAAPN), other associations, providers, educators and health care system representatives attended the May 14 interested party meeting and did not provide any additional comments or objections to the rule proposals, nor did any other member of the public.

On June 11, the APRN Committee met and again reviewed Rules 4723-9-10, 4723-9-12, and 4723-8-11, and had no additional suggested revisions.

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?

The Board relied on scientific data, state and national guidelines, the expertise of members of the Governor's GCOAT task force, which includes medical professionals, professional associations, education providers, employers, and APRNs, based on their current practice experience and familiarity with current data from their areas of expertise. The *Ohio Guidelines for Prescribing Opioids for the Treatment of Chronic, Non-Terminal Pain 80 mg of Morphine Equivalent Daily Dose (MED) "Trigger Point"*, in place since October 2013, and OARRS data were relied upon as foundational sources for the rules in this package, including the actions that prescribers must take at the 50, 80 and 120 MED dosage "trigger points." The Ohio State Board of Pharmacy contributed research correlating these "trigger points" with adverse patient outcomes based on OARRS data, and national data correlating adverse patient outcomes with dosage levels. See, e.g., *CDC Guideline for Prescribing Opioids for Chronic Pain*, discussing 50 MED level). In addition, the sub-acute pain rules reflect an effort to address the issue of opioid prescribing in the "sub-acute" phase, i.e., six weeks, but less than twelve weeks, to hopefully prevent a chronic opioid use problem later.

Regarding Rules 4723-23-03, 4723-23-10, the Advisory Group on Dialysis, a body established by Section 4723.71, ORC, composed of members including dialysis industry representatives, an Ohio Hospital Association representative, individual providers, and a dialysis care patient, met in March 2018 and recommended the Board amend its rules to reduce the training time for dialysis

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technician (DT) certification from 12 months to 6 months, and update related DT testing organization and application form references in those rules and Rule 4723-1-03. The change from 12 months to 6 months was recently implemented by The Board of Nephrology Examiners Nursing Technology (BONENT), a non-profit organization promoting excellence in the quality of care of nephrology patients in the United States and many countries around the world.

Regarding Rule 4723-8-11, the updated reference to the most current Consensus Statement ensures that providers are directed to the most current scientific data and conclusions regarding procedures to diagnosis youth concussion and clear the player to return to sport, i.e., the “Consensus Statement on Concussion in Sports – the 5th International Conference on Concussion in Sport held in Berlin, October 2016” (2016 Consensus Statement), which replaces the 2012 Zurich statement. A copy of the 2016 Consensus Statement is attached for reference.

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?

The Board assisted the Governor and the GCOAT in Ohio’s collaborative efforts to curb use of opioids unless medically necessary. Ohio has authored several written guidelines in its efforts to assist prescribing licensees, the public and other stakeholders change practice patterns that result in increased risk of opioid abuse. In light of the continuing opioid epidemic and public protection concerns and to further consistency in prescribing practices and the common direction of the other licensing boards in this focused effort, the Board did not consider further regulatory alternatives in this rule package.

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 Board did not propose performance-based regulations in this rule package due to the necessity of setting established processes and standards to achieve its public protection mandate.

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

Regarding the chronic/sub-acute rule proposed prescribing language, these measures are being taken in concert with the Governor, stakeholder Cabinet Agencies, other professional licensing boards and other stakeholders, including licensees with expertise in their professional specialties. SB 319 (131ST GA) granted specific authority for the professional licensing Boards to promulgate rules targeting this issue. Staff reviewed all of the rules in the package with a secondary focus on eliminating obsolete, unnecessary, and redundant rules, correcting typographical errors and avoiding duplication.

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.

Collaborative meetings with the Governor, stakeholder Cabinet Agencies, other professional licensing boards and other stakeholders, including licensees with expertise in their professional specialties help ensure that these rules are applied consistently and predictably for the regulated community. The Board and other parties to these collaborative rules plan to monitor the progress with respect to the rules and report back to various groups. In addition, the Board will implement the new rules to help ensure compliance with the regulations, while using its website, newsletter, and social media to update and inform licensees, continuing education providers, nursing education and training programs, other stakeholders, and the public in general. Licensees and applicants must also complete continuing education on Ohio law and rules and advanced pharmacology as a required part of their licensure application and also to renew their licensure.

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;

Those impacted may include the public, their employers, and individuals licensed by ORC Chapter 4723, education and training programs and other health care providers, employers and entities such as insurers.

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

Individuals are required to have a license and meet various conditions for licensure to obtain and renew their licenses. Licensees are required to meet minimal standards of care and if not are subject to possible discipline. Advanced practice registered nurses are required to complete advanced pharmacology coursework as part of their initial licensure and through continuing education that is required as part of the renewal process on a biennial basis. Regarding the changes to the dialysis technician certification rules, there is no adverse impact in reducing the time for training from 12 months to 6 months; nor is there any adverse impact in updating the youth concussion rule to reflect the updated version of the Consensus Statement.

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.

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There is no anticipated adverse impact cost attached to these rules because establishing consistent standards in rule should result in better health outcomes. Better treatment results in cost savings to patients, their employers, their insurers and benefits should be achieved across the board for stakeholders to the new rules.

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

Ohio is suffering from an opioid epidemic. The regulatory intent justifies any impact on business in these rules because these rules are critical to setting consistent standards in the use of opioids for the treatment of chronic/sub-acute pain.

Regulatory Flexibility

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

Public safety requirements relative to the rules reviewed in this package require consistency in their application to all licensees and are not amenable to exemptions or alternative means of compliance for small businesses.

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 Sections 119.14 and 4723.061, ORC, 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 notice or warning to the alleged offender adequately protects the public.

18. 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. The Board APRN Committee, and other advisory groups also may respond to questions from small businesses. 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. The Board has developed a prescribing flowchart posted on its website to assist APRN prescribers in decision-making, which will include the new rule language. It is anticipated that the State Medical Board will adopt FAQs as needed to assist providers with respect to its proposed chronic/sub-acute pain rule upon which the Nursing Board rule is based; the Nursing Board would post this information on its website and distribute to APRN prescribers.

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