CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Board of Nursing

Regulation/Package Title: Nursing Board Opioid Prescribing Rules for Acute Pain

Rule Number(s): 4723-9-09 (rescind); 4723-9-10 (rescind); and 4723-9-10 (new)

Date: May 10, 2017

Rule Types: New and Rescind

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

1. **Please briefly describe the draft regulation in plain language.**
   Please include the key provisions of the regulation as well as any proposed amendments.

   The Board proposes to rescind rules 4723-9-09 and 4723-9-10 and adopt a new rule 4723-9-10 that limits initial opioid analgesic prescriptions for the treatment of acute pain to 5 days for minors and 7 days for adults. The new rule also includes a 30MED average daily dose

limit over those periods. The rule prohibits using extended-release and long-acting opioids for treating acute pain. The rule provides for the possibility to exceed opiate dose day limits for treating pain under specified circumstances when determined to be clinically necessary and with proper documentation. The rule does not apply to hospice care situations, cancer treatment, palliative care, terminal conditions, inpatient prescriptions or treatment within an opioid detoxification or maintenance program. The new rule will also retain applicable standards and formulary language from both rules with updated language reflecting recent statutory changes to the format of the Advanced Practice Registered Nurse (APRN) drug formulary.

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

   Ohio Revised Code (ORC) Section 4723.07
   ORC Section 4723.50 (OAC Chapter 4723-9)
   ORC Section 3719.062

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.

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)?**

   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 acute pain, while preserving the ability for providers to prescribe beyond limits specified in the rule when clinically appropriate and with proper documentation.

   The new rule is intended to actively safeguard the health of the public through the effective regulation of nursing education and practice. The rules are also being updated consistent with the recent legislation, including changes to APRN practice in HB 216, 131st GA, and drug and prescribing language in SB 319, 131st GA, both of which became effective April 6, 2017.

Recently enacted legislation necessitates changes to certain aspects of rules 4723-9-09 and 4723-9-10, consistent with new statutory language and in order to implement changes to the APRN prescribing formulary.

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 his 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 acute pain. Directors and staff from the Boards of Nursing, Medicine, Dental and Pharmacy 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 acute pain, while preserving the ability for providers to prescribe beyond limits specified in the rule when clinically appropriate and with proper documentation.

   The Nursing Board discussed the rules package at its public Board meeting in April 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 Committee on Prescriptive Governance will meet at the Board office on May 15, 2017 and review the proposed rules in this package. CPG meetings are open to the public.

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

The Nursing Board has received written support of the new rule from the Ohio Nurses Association (ONA).

The Ohio Association of Advanced Practice Nurses (OAAPN) wrote the Board on April 27, 2017 with comments. They did not object to the standards being proposed for acute pain prescribing. Concerns were more technical and changes were made accordingly as summarized below:

- 4723-9-10(F)(2): Typographical error corrected.
- 4723-9-10(F)(8): Paragraph removed that required the prescription to be "in accordance with the nurse's scope of practice," as this was redundant of 4723-9-10(F)(1).
- 4723-9-10(G)(2): Language now reads as "A physician initially prescribed" instead of "*The nurse's collaborating* physician initially prescribed," consistent with HB 216.
- 4723-9-10(M)(1): Paragraph removed that required the prescription to be "in accordance with the nurse's scope of practice," as this was redundant of 4723-9-10(F)(1).

Note that after Rule 4723-9-10 revisions related to acute pain prescribing are effective (August 31, 2017 is target effective date), additional changes to the rule recommended by the Board, with input from the CPG and APRN Advisory Group, may be proposed subject to a second November rules hearing. It is anticipated that a memo will be prepared for the July 2017 Board meeting discussing any additional changes as part of the Board's annual rule review package. Due to the need to promulgate these rules as expeditiously as possible in light of public safety concerns and to coordinate these rules with like agencies, the Board will develop technical changes following further review in 2017 following review and consideration by the CPG and APRN Advisory Committee.

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 licensees with relevant experience, their professional associations, education providers, employers, and nurses, based on their current practice experience and familiarity with current data from their areas of expertise. The GCOAT guidelines and OARRS data were relied upon as foundational sources for the rules in this package, including the day dose limits and the corresponding 30 MED limits. OARRS data suggests that the state could see an estimated reduction of 109 million opiate doses once the new rules are in effect.

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?**

    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 granted specific authority for the professional licensing Boards to promulgate rules targeting this issue. Staff reviewed the rules 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 rule 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.

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.

There is no anticipated adverse impact cost attached to these rules because by 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 rule.

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 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 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.