CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Board of Nursing

Regulation/Package Title: Nursing Board Five Year Rule Review: OAC Chapters 4723-8, 4723-9 and 4723-23

Rule Number(s): 4723-8-01 through 4723-8-10; 4723-9-01 through 4723-9-12; and 4723-23-01 through 4723-23-03 and 4723-23-05 through 4723-23-10; and 4723-23-12 through 4723-23-14.

Date: August 21, 2015

Rule Types: Amended, No Change and 5-Year Rule Review

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.

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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 amend, rescind, or file new or no change rules following the five-year rule review for Ohio Administrative Code (OAC) Chapters 4723-8, Advanced Practice Nurse Certification and Practice; 4723-9, Prescriptive Authority; and 4723-23, Dialysis Technicians.

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

   Ohio Revised Code (ORC) Section 4723.06
   ORC Section 4723.07
   ORC Section 4723.487 (Rule 4723-9-12, OAC)
   ORC Section 4723.50 (Chapter 4723-9, OAC)
   ORC Section 4723.79 (Chapter 4723-23, OAC)

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)?**

   The public purpose for the rule package is to provide public protection and promote safe nursing practice. The rules are being updated based on the schedule for the Board's five-year rule review. As part of that review, the Board is proposing revisions for further clarity regarding compliance and practice issues, to reflect recently enacted legislative amendments, and for technical or non-substantive reasons.

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.

Regarding licensee compliance with Rule 4723-8-05, the Board may audit, review or investigate, at any time, whether an advanced practice registered nurse (APRN) has complied with the quality assurance standards set forth in the rule.

Regarding prescriber licensee compliance with Rule 4723-9-12, the Board utilizes the Ohio Automated Rx Reporting System (OARRS) as a means to measure success and check compliance with this rule.

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.

The Board discussed the rules package at its public Board meetings in April, May and July 2015. Board meeting dates are posted on the Board website and public notice for each Board meeting is provided. In addition, agenda materials, including the proposed rule changes, are posted on the Board website.

Board staff met with staff from the Ohio State Board of Pharmacy, State Medical Board of Ohio, and Ohio State Dental Board on April 20, 2015, to review legislation (H.B. 341, 130th GA) impacting prescribing, and proposed revisions to Rule 4723-9-12. Board staff drafted proposed revisions to this Rule, and sent the revisions to the other regulatory boards for comment on April 30, 2015.

The Committee on Prescriptive Governance (CPG) convened on May 18, 2015 for a scheduled public meeting at which time Nursing Board staff reviewed the rules package with the CPG. Meetings are scheduled in advance, posted on the Board website, and open to the public.

The Board held an interested party meeting with various stakeholders on May 27, 2015. Participants included representatives of the Ohio Nurses Association (ONA) and the Ohio Association of Advanced Practice Nurses (OAAPN). Notice and invitation to the meeting was sent by e-mail on April 10, 2015 and again on May 21, 2015 to approximately 45 persons representing various stakeholders to the Board.

The Board Advisory Group on Dialysis met at the Board office on June 9, 2015 and discussed the Chapter 4723-23 rules. Meetings are scheduled in advance, posted on the Board website and 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 CPG met on May 27, 2015 at which time Nursing Board staff reviewed the rules package with the CPG. The CPG reviewed a letter dated April 10, 2015 and submitted by OAAPN and a May 12, 2015 memorandum prepared by Board staff in response to the letter (both attached). Representatives of the OAAPN asked the CPG to consider recommending an amendment to Rule 4723-9-10, OAC, to allow CTP holders to prescribe new FDA approved drugs in accordance with their standard care arrangement (SCA), rather than awaiting the CPG review. The CPG agreed by general consensus to recommend revision of Rule 4723-9-10, OAC, to allow for a CTP holder to prescribe new FDA approved drugs under a prescribing designation of "in accordance with the SCA" if the new drug is in an existing Formulary drug type or subtype with a "may prescribe" or "in accordance with the SCA" designation, until such time as the CPG reviews the drug and makes a prescribing determination.

The Board held an interested party meeting with various stakeholders on May 27, 2015. At the meeting, OAAPN requested changes to rules included in this rules package. The following is a summary of the comments from the interested party meeting and the CPG meeting that were considered by the Board at its July 2015 Board meeting. Also included are the Board's decisions regarding the rule changes:

Chapter 4723-8, Advanced Practice Nurse Certification and Practice

- 8-04: (C)(7)(a): Delete "A schedule for periodic" and insert "Biannual"
  - The Board agreed by general consensus to this revision.

- 8-04: (C)(7)(c): Delete "the" physician, insert "a" physician
  - The Board agreed by general consensus to this revision.

- 8-04: (C)(12)(b)(iv): Add "If the nurse is prescribing to minors"
  - The Board agreed by general consensus to add this language and suggested adding a cross-reference to define "minor."

- 8-04: (C)(12)(c): Delete "composed of physicians" insert "composed of at least one physician"
  - The Board agreed by general consensus to this revision.

- 8-04: (E): Delete this new proposed requirement as it is perceived to be too onerous, and should be viewed as a best practice rather than a regulatory requirement
  - The Board agreed by general consensus to keep the proposed new requirement but to remove "at least." The Board discussed that for compliance cases, the Board may need to review copies of the standard care arrangements. In addition, the requirement is a safeguard for APRNs, because if there is a

subsequent complaint, copies of the standard care arrangements will be available. The time period of six years is consistent with other retention requirements for nurses. For example six years is the length of time that nurses must retain evidence of CE.

- 8-05: (D)(1): Delete "composed of physicians" insert "composed of at least one physician"
    - The Board agreed by general consensus to this revision.

- 8-05: (D)(2): Delete the last sentence. This language is viewed as too prescriptive.
    - The Board agreed by general consensus to delete the sentence.

- 8-05: (F): The requirement that a nurse be legally responsible for verifying the credential status of each collaborating practitioner is viewed as too onerous. Both pros and cons for the nurse in conducting the verification were discussed at the meeting. For example, if the physician's credential is invalid APRN billing may be rejected by payors. On the other hand, the thought is the APRN should not be the "gatekeeper" of the physician's credential.
    - The Board agreed by general consensus to keep this language as proposed. The Board believes that the APRN is not acting as a gatekeeper, but rather it is the responsibility of APRNs to assure their collaborating physicians are properly credentialed.

Chapter 4723-9, Prescriptive Authority

- 9-04: Delete (E). The SCA review should be up to the parties, and even without the language Chapter 4723-8 quality requirements are still applicable to the SCA.
    - The Board agreed by general consensus to delete the language, as it is redundant.

- 9-05: Delete (B)(3). The rationale is that the language requiring a "supervising physician" statement applies to out-of-state applicants, and some other jurisdictions do not require APRNs to have a "supervising physician." The law (4723.482 (D), ORC) does not require documentation from a supervising physician.
    - The Board agreed by general consensus to delete the language.

- 9-08 (C)(3)(a): Add the word "business" address.
    - The Board agreed by general consensus to this revision.

- 9-10: OAAPN suggested the following changes, which staff explained could be presented to the Committee on Prescriptive Governance (CPG) at its next meeting in October 2015 for inclusion in the Board's consideration of rule proposals in 2016:
    - (B) Add requirement that the CPG meet "twice" per year instead of "once"
        - The Board agreed by general consensus not to revise the language. The CPG routinely meets 3 times a year.

- (C): Delete this paragraph
  - This paragraph lists types of drugs in the formulary and specifies that the CPG may exclude subtypes or individual drugs within those types of drugs. The Board agreed by general consensus not to delete this paragraph.

- (F): This paragraph is revised based on the recommendation made by the CPG at its May 18, 2015 meeting (as explained previously in summary of CPG input). The recommendation is made to allow prescribing of drugs approved by the FDA but not yet reviewed or approved by the Committee, if certain conditions are met.
  - The Board agreed by general consensus to this revised paragraph.

- (F)(3): OAAPN suggested that instead of requiring that the collaborating physician agree in the standard care arrangement (SCA) that drugs approved by the FDA may be prescribed prior to CPG review/approval, (F)(3) be revised to reflect "blanket" language like this: "The standard care arrangement includes a provision that the physician agrees the nurse may prescribe drugs approved by the FDA but not yet reviewed by the committee on prescriptive governance, unless later disapproved by the committee on prescriptive governance."
  - The Board agreed by general consensus to revise (F)(3) to reflect the blanket language proposed.

- (G): Delete this paragraph
  The Board agreed by general consensus not to delete this paragraph.

- 9-12(H): OAAPN expressed that (H)(1) through (H)(5) are too prescriptive and should not be in a rule. Alternatively, OAAPN requested that the last sentence in (H) be revised to state: "Consultation *may* include and result in" rather than: "Consultation *should* include and result in." The language is derived from sources including statewide policy groups established by the Governor's office, the State Pharmacy and Medical boards, and a National Association of Boards of Pharmacy (NABP) consensus document; legal consistency in applying OARRS requirements and professional standards for prescribers is viewed as necessary.

  - Subsequent to the interested party meeting in May, the State Medical Board of Ohio proposed a new rule pertaining to OARRS. The Medical Board combined (C)(1) and (C)(2) to make review of all of the items mandatory, rather than some discretionary and others mandatory. The Medical Board also removed the "red flag" terminology. The Board agreed by general consensus to retain the "red flag" language because it re-enforces the importance of reviewing OARRS.

- The Board agreed by general consensus to keep (H)(1), (2), and (3) mandatory and change (H)(4) and (5) to be optional and consistent with similar professional standards.

Chapter 4723-23, Dialysis Technicians

- 23-01(H): Definition of "home" added to clarify that a home is a patient's private residence and not a licensed facility.
  - The Board agreed by general consensus to include this definition.

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 Nursing Board utilizes observation and measurement of factual information organized for analysis and used to reason or make decisions from a variety of sources, including journal articles, studies, enforcement statistics and analysis.

The Board referred certain rules to their Advisory Groups made up of stakeholders in specific areas of nursing based on their knowledge and familiarity with data impacting particular rules. Through the Advisory Groups, the Board relied on the expertise of education providers, program administrators, nurses, dialysis technicians, employers and others based on their current practice experience and familiarity with current data in their areas of expertise.

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?

Rule 8-04:

- (E): Delete this new proposed requirement as it is perceived to be too onerous, and should be viewed as a best practice rather than a regulatory requirement
  - The Board agreed by general consensus to keep the proposed new requirement but to remove "at least." The Board discussed that for cases involving compliance issues the Board may need to review copies of the standard care arrangements. In addition, the requirement is a safeguard for APRNs, because if there is a subsequent complaint, copies of the standard care arrangements will be available. The time period of six years is consistent with other retention requirements for nurses. For example six years is the length of time that nurses must retain evidence of CE.

Rule 8-05:

- (F): The requirement that a nurse be legally responsible for verifying the credential status of each collaborating practitioner is viewed as too onerous. Both pros and cons

for the nurse in conducting the verification were discussed at the meeting. For example, if the physician's credential is invalid payers may reject the billing. On the other hand, the thought is the APRN should not be the "gatekeeper" of the physician's credential.

- The Board agreed by general consensus to keep this language as proposed. The Board believes that the APRN is not acting as a gatekeeper, but rather it is the responsibility of APRNs to assure their collaborating physicians are properly credentialed.

Rule 9-10:

- OAAPN suggested the following changes, which staff explained could be presented to the Committee on Prescriptive Governance (CPG) at its next meeting in October 2015 for inclusion in the Board's consideration of rule proposals in 2016. The CPG is a statutorily created body that is required to make recommendations to the Board related to prescribing, and statutes (Sections 4723.492, 4723.50, ORC) require that the Board promulgate rules related to prescribing that are consistent with the recommendations of the CPG. At its July 2015 meeting, the Board agreed by general consensus not to make the following rule changes suggested by OAAPN at this time, but would defer future consideration based on CPG recommendations:
    - (B) Add requirement that the CPG meet "twice" per year instead of "once"
        - The Board agreed by general consensus not to revise the language. The CPG routinely meets 3 times a year.

    - (C): Delete this paragraph
        - This paragraph lists types of drugs in the formulary and specifies that the CPG may exclude subtypes or individual drugs within those types of drugs. The Board agreed by general consensus not to delete this paragraph.

Rule 9-12(H):

- OAAPN expressed that (H)(1) through (H)(5) are too prescriptive and should not be in a rule. Alternatively, OAAPN requested that the last sentence in (H) be revised to state: "Consultation *may* include and result in" rather than: "Consultation *should* include and result in." The language is derived from sources including statewide policy groups established by the Governor's office, the State Pharmacy and Medical boards, and a National Association of Boards of Pharmacy (NABP) consensus document; legal consistency in applying OARRS requirements and professional standards for prescribers is viewed as necessary.

    - Subsequent to the interested party meeting in May, the State Medical Board of Ohio proposed a new rule pertaining to OARRS. The Medical Board combined (C)(1) and (C)(2) to make review of all of the items mandatory, rather than some discretionary and others mandatory. The Medical Board also removed the "red flag" terminology. The Board agreed by general consensus

to retain the "red flag" language because it re-enforces the importance of reviewing OARRS.

- The Board agreed by general consensus to keep (H)(1), (2), and (3) mandatory and change (H)(4) and (5) to be optional and consistent with similar professional standards.

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 considerations 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?

Because the Board initiated the rule review process due to the five-year rule review requirement, staff reviewed the rules with a focus on eliminating obsolete, unnecessary, and redundant rules and avoiding duplication. In addition, meetings with interested parties and Board Advisory Groups helped ensure that these rules do not duplicate any existing Ohio regulation.

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 these rules are applied consistently and predictably for the regulated community. The Board plans to monitor the progress with respect to the rules and report back to these groups. In addition, the Board will implement 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.

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;

Individuals licensed by ORC Chapter 4723, health care employers and entities, licensees subject to discipline and their legal counsel.

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. If licensees violate the law, they may be subject to discipline, including fines of up to $500 per violation.

Statutorily mandated OARRS checks, standards for which are set forth in rule language, under certain circumstances may require additional time to conduct the check, but the licensee may use a delegate to obtain the required information. There is no cost for signing up for OARRS access or use.

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 licensure and certification as well as fining authority is established by statute.

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

Defining professional standards of conduct with respect to APRN practice, including prescribing, and standards for dialysis practice are necessary to ensure public safety.

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.