CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Board of Nursing

Regulation/Package Title: APN Prescribing of Schedule II Controlled Substances

Rule Number(s): 4723-8-01 through 4723-8-05 and 4723-8-10 and 4723-9-01, 4723-9-02, 4723-9-07, and 4723-9-10 through 4723-9-13

Date: 7/30/12

Rule Type:

- ☐ New
- ☐ 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.

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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.

Senate Bill 83 of the 129th General Assembly (SB 83) requires the Board of Nursing to adopt rules as necessary to implement the bill's provisions pertaining to the authority of an Advanced Practice Nurse (APN) who holds a certificate to Prescribe (CTP) to prescribe schedule II controlled substances. The rules must conform to the recommendations submitted by the Committee on Prescriptive Governance (CPG). The bill requires the Board's rules to include criteria for the components of APN standard care arrangements, with physicians and podiatrists, that address prescribing schedule II controlled substances. Also included in the Chapter 8 and 9 rule changes are technical changes occurring in those chapters. The proposed revisions are amendments except for new Rule 4723-9-13 that is specific to the content of schedule II continuing education.

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

Ohio Revised Code (ORC) Section 4723.07 is the statutory authority for Ohio Administrative Code (OAC) rules 4723-8-01 through 4723-8-05 and 4723-8-10 and ORC Section 4723.50 is the statutory authority for OAC rules 4723-9-01, 4723-9-02, 4723-9-07 and 4723-9-10 through 4723-9-13.

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 for OAC rules 4723-8-01 through 4723-8-05 and 4723-8-10 and 4723-9-01, 4723-9-02, 4723-9-07 and 4723-9-10 through 4723-9-13.

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

Not applicable to OAC rules 4723-8-01 through 4723-8-05 and 4723-8-10 and 4723-9-01, 4723-9-02, 4723-9-07 and 4723-9-10 through 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 purpose of these rules is to ensure proper education and training related to the expanded authority of APNs to prescribe schedule II controlled substances, and to provide for proper safeguards and parameters to protect the public.

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

Success will be measured by having the rules written in plain language for clarity, by identifying instruction specific to schedule II controlled substances within the course of study in advanced pharmacology required for applicants in order to obtain a certificate to prescribe (CTP) and by requiring APN authorized prescribers licensed by the Board to complete continuing education requirements for renewal of their CTPs during the 2013 renewal period. Ultimate success is measured in patient safety through proper prescribing.

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 Committee on Prescriptive Governance (CPG) was involved in developing and reviewing language for these rules. The CPG, established by statute, is a multi-disciplinary group consisting of APNs, pharmacists, and physicians. In recognition of the importance of the rules and the expedited timelines that would result for timely implementation, the Board asked the CPG to begin this process even before SB 83 was formally passed by the legislature. The CPG first met to discuss these issues on February 13, 2012, March 19, 2012, and met again to review rule language on May 14, 2012.

On April 19, 2012, staff met with the Ohio Council of Deans and Directors of Baccalaureate and Higher Degree Nursing Programs and provided an overview of the rules being considered based on SB 83.

On May 7, 2012, the Board provided interested parties, including the Ohio Nurses Association, the Ohio Association of Advanced Practice Nurses, the Council for Ohio Health Care Advocacy, and representatives of Ohio healthcare systems and education programs, with draft rule language, and requested comments. On June 27, 2012, the Board held an interested party meeting to review the proposed rules. Representatives from the Ohio Association of Advanced Practice Nurses, the Ohio Nurses Association, and the Council for Ohio Health Care Advocacy reviewed and commented on the rules.

Another group of stakeholders involved in the development of the rules was the Board's Advisory Group on Continuing Education. The Advisory Group is composed of continuing education approvers, four continuing education providers, and one member actively involved with a national accreditation system for nursing continuing education. The Advisory Group reviewed the continuing education rules on June 15, 2012.

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

Chapter 4723-8 Advanced Practice Nurse Certification and Practice

Rule 4723-8-04 currently specifies the requirements for standard care arrangements (SCA) and includes provisions that apply to the CTP holder's authority to prescribe in paragraph (C)(12). The rule also lists additional quality assurance provisions specific to the prescribing component of practice. The CPG recommended:

1. Add a requirement that CTP holders comply with Rule 4723-9-12, OAC, related to accessing the Ohio Automated Rx Reporting System (OARRS);
2. Add a requirement for the SCA to address the CTP holder's prescribing of schedule II medications;
3. Amend the semi-annual review of prescriptions written to specifically include the review of schedule II controlled substances.

Rule 4723-8-04(C)(12)(c): The CPG recommended, and the Board agreed at the May and July meetings, to require a review, at least semiannually, of "a representative sample" of all schedule II prescriptions written.

Rule 4723-8-04(C)(12)(d): A comment was received that the word "indicia" in the first draft of the rule be changed as the general public may not understand this word. The Board revised the language and deleted the word indicia.

Chapter 4723-9 Prescriptive Authority

For Rule 4723-9-01(F), regarding the course of study in advanced pharmacology required for CTP applicants, the Advisory Group on Continuing Education recommended that "planned classroom and clinical study" be deleted, since the Group had recommended that Rule 9-02(A)(5) be revised to allow for independent study. However, the law itself requires that the course of study in advanced pharmacology required for the CTP "shall consist of planned classroom and clinical instruction," thus, this change was not made. See Section 4723.482(B)(2), ORC. For this reason, the independent study language that was added in the last draft of Rule 4723-9-02 was removed in the draft presented for the July Board meeting.

Rule 4723-9-01(F)(2) was revised as recommended by the Advisory Group and consistent with OAC Chapter 4723-14.

Rule 4723-9-02 currently contains the components of the 45 contact hour course of study that is to be completed by CTP candidates prior to entering a certificate to prescribe externship. This rule will be amended to include instruction specific to schedule II controlled substances included

in the bill. The CPG agreed that the minimum number of contact hours for the course should not increase. Instead, the specific instruction will be integrated into the existing hours.

Rule 4723-9-02(A)(2): SB 83 amends Section 4723.482, ORC, to mandate that new CTP applicants obtain at least six hours of instruction specific to schedule II controlled substances. With this new requirement, CTP applicants must obtain a minimum of 45 hours in advanced pharmacology, including:

- 36 hours in pharmacokinetic principles and clinical application, and principles of use of drugs and therapeutic devices in the prevention of illness and maintenance of health (4723-9-02(A)(2)(a));
- 6 hours in fiscal/ethical implications that apply to prescribing, and state and federal laws that apply to the authority to prescribe (note that the law requires this content, but Rule 4723-9-02 establishes the 6 hour minimum) (Rule 4723-9-02(A)(2)(b));
- 6 hours in schedule II controlled substances (Rule 4723-9-02 (A)(2)(c)).

Because the total number of hours would equal 48 (rather than 45), at the May and July meetings, the Board approved the following language:

"(d) Up to three hours of instruction specific to schedule II controlled substances as set forth in paragraphs (A)(2)(c)(iii) and (A)(2)(c)(iv) of this rule may be credited toward satisfying the six hours of instruction required by paragraphs (A)(2)(b)(i) and (A)(2)(b)(ii) of this rule."

This will allow the Board to accept overlap between the content in schedule II substances that relates to fiscal/ethical considerations and state/federal laws, up to three hours.

Language is added in Rule 4723-9-02(A)(2)(c)(iii) (the 6-hour course in schedule II controlled substances required by SB 83), regarding the use of stimulant therapies. Although this language is not contained in SB 83, input was received during the June 27, 2012 meeting with interested parties that the focus on pain medications may overshadow needed education in other categories of schedule II medications, for example, medications used in the treatment of ADHD. The same language appears in Rule 4723-9-13. The Board agreed to this addition at the July 2012 Board meeting.

Rule 4723-9-07(A)(2): The CPG and the Board, at the May meeting, agreed to add language that the 12 hours of CE required for CTP renewal include "instruction specific to controlled substances" without specifying any minimum number of hours in schedule II drugs.

Rule 4723-9-12: The CPG recommended referencing Rule 4723-9-12, OARRS, within the SCA Rule 4723-8-04.

Rule 4723-9-13: The CPG recommended establishing new Rule 4723-9-13 specifying the content of the schedule II instruction required for CTP renewal, and that the instruction will be approved through the Board's continuing education processes. The Board also added language regarding the use of stimulant therapies. Although this language is not contained in SB 83, input was received during the June 27, 2012 meeting with interested parties that the focus on pain medications may overshadow needed education in other categories of schedule II medications, for example, medications used in the treatment of ADHD. The same language appears in Rule 4723-9-02. The Board agreed to this addition at the July 2012 Board meeting.

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 educational content, important from a practice and public protection viewpoint, was driven by scientific data.

Rule 4723-9-13 specifies the continuing education required by SB 83. In addition, the Nursing Board recommended that additional provisions be included and the CPG agreed. These additions are scientifically based on research and established treatment standards and best practices. The additions are consistent with the statutory guidance and assist licensees and Board approved providers in providing a sharper focus to the required continuing education.

- (B)(1)(a): Add language regarding contraindications, including risk, evaluation and mitigation strategies for the use of opiates in the treatment of chronic pain for non-terminal conditions, and the need for periodic assessment and documentation of the patient's functional status;
- (B)(1)(b): Add a reference to the FDA;
- (B)(1)(c): Add a reference to the use of stimulant therapies;
- (B)(1)(e): Add references to rules adopted by the State Medical Board and Pharmacy Board;
- (B)(1)(f): Add language regarding "addiction" and the use of OARRS.

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 Advisory Group on Continuing Education met on June 15, 2012 and recommended that Rule 4723-9-02 be revised so that the pharmacology course content referenced in (A)(2)(b) and (c) be separated into new paragraphs so that these content areas would not need to be "specific to the nursing specialty." These changes were not made because ORC Section 4723.482(B)(4) requires

that in order to qualify as a course of study in advanced pharmacology, "the content of the course of study shall be specific to the applicant's nursing specialty."

The Advisory Group on Continuing Education questioned whether, to the extent some of the pharmacology course of study is required to include education in Ohio-specific guidelines and recommendations for pain management therapies, and "state laws" in prescribing schedule II controlled substances (Rule 4723-9-02(A)(2)(c)(ii) and (c)(iv)), the Board should require that if this educational content is satisfied by an (A)(5)(b) continuing education program approved by an OBN provider unit, that unit should be headquartered in Ohio. This would have placed a burden on applicants and continuing education providers, so the provision was not included in the rules.

As discussed above, the Advisory Group had also recommended that (A)(5) be revised to allow for independent study. However, the law itself requires that the course of study in advanced pharmacology required for the CTP "shall consist of planned classroom and clinical instruction," thus, this change was not made. See Section 4723.482(B)(2), ORC. The independent study language that was added in the last draft of Rule 4723-9-02 was removed in the draft presented at the July Board meeting.

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 required outcome of these rules is strict compliance with the standards and rules governing the prescribing and utilization of schedule II controlled substances. Schedule II controlled substances are categorized as drugs with a high potential for abuse. SB 83 established the parameters for education of CTP applicants and CTP holders affected by the bill and directed the Board to promulgate rules after seeking guidance and review of the CPG that is comprised of various stakeholders from a variety of related professions. This mandated process and required outcome resulted in no direction to consider performance-based regulation, except for Rule 4723-9-07(A)(2) in which the CPG and the Board, at the May 2012 meeting, agreed to add language that the 12 hours of CE required for CTP renewal include "instruction specific to controlled substances" without specifying any minimum number of hours in schedule II drugs.

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

Meetings with the CPG, interested parties, and the Board's Advisory Group on Continuing Education 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 the CPG, interested parties, and the Board's Advisory Group on Continuing Education will help ensure that these rules are applied consistently and predictably for the regulated community because leaders in the affected community will meet periodically during the implementation period of the rules and beyond. The Board plans to monitor the progress with respect to the rules and report back to these groups. In addition, the Board will continue to utilize its website and other social media to update affected applicants and licensees, approved continuing education providers, 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;

The impacted business community may include post-licensure education programs and providers of continuing education coursework who develop their curriculum and/or continuing education programs according to legal requirements.

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

Pursuant to the mandates of SB 83, the adverse impact of the rules may relate to APNs and CTP applicants who need to obtain the six hours of required education in schedule II controlled substances. However, APNs are already required to obtain 24 hours of continuing education each two-year renewal period so costs are already incurred based on the current requirements.

For education programs and approved Board providers of continuing education, the Board rules will assist educators by clearly identifying the educational content related to schedule II controlled substances that is required by SB 83, which may lessen the cost of developing the program content.

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.

It is expected that the requirements will create competition amongst approved providers of continuing education and this will mediate costs. Because APNs are already required to obtain continuing education for each two-year renewal period, the adverse impact is not expected to be quantifiable. In addition, many institutions and employers provide continuing education directly

for their APN employees and the institutions would absorb these costs as part of the operational costs of their existing education departments and personnel.

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

SB 83 mandated that the course in advanced pharmacology required for CTP applicants include instruction specific to schedule II controlled substances, and further, for APNs who currently hold CTPs, that continuing education specific to schedule II controlled substances be obtained prior to the 2013 CTP renewal deadline. For post-licensure education programs, and continuing education providers, the schedule II course content is intended to safeguard the public by educating prescribing APNs on standards and rules related to prescribing schedule II controlled substances. The Board's proposed rules follow the legislative mandate and are consistent with the Governor's direction to timely, and if possible proactively, address problematic issues with the prescribing of schedule II controlled substances.

Regulatory Flexibility

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

SB 83 mandated that all CTP applicants and APN authorized prescribers obtain the required education or continuing education. The rules are consistent with the legislative mandate, so there are no exemptions.

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?

The rules do not impose fines or penalties. Waivers of fines and penalties for paperwork violations and first time offenders may be considered consistent with ORC section 119.14 and ORC 4723.061 which does not require the Board of Nursing to act on minor violations of the Nurse Practice Act or the rules adopted under it, if the violations are committed by applicants or individuals licensed under this chapter and the Board determines that the public is adequately protected by issuing a notice or warning to the alleged offender.

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 to respond to any questions or concerns about the implementation of the rules with respect to the course content in advanced pharmacology required for CTP certification, continuing education requirements for CTP holders, and rules related to APN prescribing practice. The Board's Advisory Group that includes continuing education approvers and providers and licensees may also assist small businesses provide the required educational content. The Board also continues to use its website,

newsletter and social media to regularly update the public and licensees, including small businesses, to changes in requirements and provide frequently asked questions.