

# CSI - Ohio

The Common Sense Initiative

## Business Impact Analysis

Agency Name: State Medical Board of Ohio

Regulation/Package Title: Physician Assistant Rules

Rule Number(s): 4730-1-01, 4730-1-02, 4730-1-03, 4730-1-04, 4730-1-06,

4730-1-07, 4730-2-01, 4730-2-02, 4730-2-03, 4730-2-07, 4730-2-08, 4730-2-09,

01, and 4730-3-02

Date: August 2, 2017

**Rule Type:**

☒ New

☐ 5-Year Review

☒ Amended

☒ Rescinded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.*

Amendment and recession of the rules applicable to physician assistants are proposed to implement the significant changes to physician assistant licensing and practice enacted in SB 110, effective October 15, 2015. Certain rules, such as 4730-1-07, are also amended to

reflect new rules for physicians and physician assistants concerning prescriptive practices for controlled substances, including, but not limited to, opioid analgesics. Rule 4730-1-06 is also amended to incorporate the requirement of HB 290 of the 131<sup>st</sup> General Assembly, which enacted Section 4745.04, Ohio Revised Code, which allows up to one-third of continuing medical education to be obtained via the provision of free medical care to the indigent and uninsured. The rules in this package as are follows:

**4730-1-01: Definitions:** Due to being significantly changed to reflect the statutory amendments, the current rule is proposed to be rescinded and a new rule adopted.

**4730-1-02: Physician assistant practice:** To be rescinded

**4730-1-03: Duties of a supervising physician:** To be rescinded

**4730-1-04: Supervision:** To be rescinded

**4730-1-06: Licensure as a physician assistant:** Due to being significantly changed to reflect the statutory amendments, the current rule is proposed to be rescinded and a new rule adopted.

**4730-1-07: Miscellaneous provisions:** Amended to reflect statutory changes in terminology and to reflect additional rules in Chapter 4731 of the Administrative Code that are applicable to physician assistants. Due to more than fifty percent of the rule being changed the current rule will be rescinded and a new rule 4730-1-07 adopted.

**4730-2-01: Definitions (applicable to prescribing):** Amended to reflect statutory changes in terminology.

**4730-2-02: Educational requirements for prescriptive authority:** To be rescinded

**4730-2-03: Application for a provisional certificate to prescribe:** To be rescinded

**4730-2-07: Standards for prescribing:** Amended to reflect changes in statutory terminology

**4730-2-08: Standards for personally furnishing drugs and therapeutic devices:** To be rescinded

**4730-2-09: Standards for personally furnishing samples of drugs and therapeutic devices:** To be rescinded

**4730-2-10: Standards and procedures for review of the "Ohio Automated RX Reporting System":** Amended to reflect statutory changes. Due to more than fifty percent of the language being changed the current rule will be rescinded and a new rule 4731-2-10 will be adopted.

**4730-3-01: Definitions (related to criminal records checks):** Amended to reflect current statutory terminology

**4730-3-02: Criminal records checks:** Amended to reflect current statutory terminology

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

The following provisions of the Ohio Revised Code authorize the Medical Board to adopt the subject rules: 4730.07, 4730.14, 4730.39, 4730.53, and 4745.04.

**3. Does the regulation implement a federal requirement?**

The rules in this package do not implement a federal requirement.

**4. 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.*

No, none of the rules in this package are proposed to obtain or maintain approval for activity relative to a federal law or program.

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

Not applicable.

**6. 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 rules in this package notify physician assistants, physicians, administrators, and the public of the requirements for physician assistant licensure and practice. The provisions of Chapter 4730, Ohio Revised Code, which is the Physician Assistant Practice Act, were significantly amended by SB 110 of the 131<sup>st</sup> General Assembly. In addition, the Medical Board seeks to delete provisions of rules that parrot statutory language and rescind rules that in whole merely mimic the language of a statute. Rule 4730-1-07 is amended to clarify that all rules in Chapter 4731-11, Ohio Administrative Code, are also applicable to physician assistants, which is consistent with the State of Ohio policy concerning the prescribing of opioid analgesics. Finally, the rules implement HB 290 of the 131<sup>st</sup> General Assembly, which enacted Section 4745.04, Ohio Revised Code, which allows up to one-third of continuing medical education to be obtained via the provision of free medical care to the indigent and uninsured.

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

The success of the rules will be measured by having rules written in plain language, licensee compliance with the rules, and minimal questions from licensees, medical practices, and medical facilities regarding the provisions of the rules.

**Development of the Regulation**

**8. 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.*

As is required by Section 4730.06, Ohio Revised Code, the Medical Board worked with the Physician Assistant Policy Committee (“PAPC”) in reviewing the rules and arriving at the proposed language. The review for this package of rules started in October 2015 and continued periodically until this filing.

The proposed rules were also sent for initial comment to all physician assistants for whom the Medical Board has an email address, the Ohio Association of Physician Assistants (“OAPA”), medical professional associations such as the Ohio State Medical Association, attorneys who regularly represent Medical Board licensee before the Medical Board, professional organizations such as the Ohio Hospital Association, and all individuals and organizations who have requested notice of the Medical Board’s rule activities. Not all rules were sent to interested parties at the same time. The groupings of rules were sent on March 11, 2016, April 15, 2016, May 13, 2016, and June 20, 2017. Any comments received were then shared with the PAPC for further discussion.

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

There were no comments from interested parties. PAPC members agreed with the approach of rescinding all rules that merely mimic statutory language. PAPC members also carefully reviewed the rule language to ensure that the terminology was amended to reflect the statutorily amended terminology. Rule 4730-1-06 reflects the PAPC recommendation for the addition of several sources for continuing medical education. Rule 4730-2-02 was originally proposed to be amended, but will be rescinded at the recommendation of PAPC. The rule was originally enacted to facilitate the issuance of “provisional certificates to prescribe” based upon the educational experience of the applicant who had a master’s degree that was in a concentration other than physician assistant studies. However, in 2016 PAPC recommended that the rule be rescinded and all applications for a “valid prescriber number” where the applicant does has a master’s degree that is not in physician assistant studies be reviewed on a case-by-case basis to determine whether the master’s degree curriculum provided appropriate and sufficient pharmacology coursework.

The Ohio Association of Physician Assistants also provided input that the continuing medical education language of proposed Rule 4730-1-06 should not be substantially changed other than the addition of more sources for obtaining continuing education. The suggestion was accepted.

**10. 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?**

Scientific data was not used to develop the rule or the measurable outcomes of the rules. The current rules in Chapter 4730 of the Administrative Code were reviewed with three goals: (1) The rules must reflect the provisions of Chapter 4730 of the Revised Code, effective October 15, 2015; (2) Only provisions that are required to implement the Revised Code should be included in rule; and (3) The requirements of the rules should be clear.

**11. 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 4731-1-05, the rule setting forth the requirements for quality assurance activities by the supervising physician, was, at the recommendation of the PAPC, originally proposed with more frequent review of the physician assistant's practice, to include a larger number of patient records. However, based upon input received from interested parties, including the Ohio Association of Physician Assistants, the rule was put on "hold" for review in the future.

**12. 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 rules are performance based. They set required outcomes without specifying the details of how to reach an outcome.

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

The Medical Board is the only agency that regulates the practice of physician assistants and the physicians who supervise them. Therefore, the rules do not duplicate existing Ohio rules.

**14. 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.**

Information concerning the rules will be circulated to all the interested parties listed in question 7, above, and to all physician assistants for whom the Medical Board has an email address; notice of the rules will be published in the Medical Board's enews, which is sent to all licensees via email; and the rules will be made available on the Medical Board's website. The rules will be adhered to by the Medical Board's employees. Questions concerning the rules will be fielded by Medical Board staff. If appropriate, guidance documents, such as FAQs, will be created.

**Adverse Impact to Business**

**15. 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 is made up of physician assistants, physicians, and medical practices and medical facilities, such as hospitals, that avail themselves of physician assistant services.

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

Most of the adverse impact caused by the rules originates from the requirements of the Revised Code. For example, the requirements for physician supervision, which

can be seen as imposing a cost for compliance, are actually contained the provisions of Sections 4730.02, 4730.19, 4730.20, 4730.21, and 4730.22, Ohio Revised Code. Likewise, the adverse impact arising from complying with Rule 4731-2-10 requiring that a physician assistant check the prescription monitoring program maintained by the Board of Pharmacy when prescribing a controlled substance, which can be seen as imposing a cost for compliance, stems from Section 4730.53, Ohio Revised Code. In addition, the requirement in Rule 4730-2-07 that a physician assistant obtain Drug Enforcement Administration registration in order to prescribe a controlled substance is found in Section 4730.41, Ohio Revised Code. The requirement that a physician assistant complete continuing medical education, which requires payment of registration fees, is found in Section 4730.14, Ohio Revised Code. Finally, the requirement that a licensure applicant submit to a fingerprint procedure for a criminal records check, which incurs a vendor fee and fees from the applicable federal and state agencies, originates with Section 4730.101, Ohio Revised Code.

The requirement of Rule 4730-2-07 setting criteria for prescribing in a prescriber-patient relationship may be seen as imposing a cost of compliance for physician assistant practice.

Complying with the requirements of Rule 4730-2-10 creates an adverse impact in that Paragraph (B) sets the minimal standards of care for considering whether a controlled substance is appropriate to prescribe for a patient. The rule also sets parameters for practice by requiring a check of the prescription monitoring program when certain “red flags” are seen. Although there is no fee to register with the prescription monitoring program, it is also often argued that having to check the program takes the time of the prescriber.

Rule 4730-1-07 causes an adverse impact in that it requires that a physician assistant’s practice comply with rules on prescribing, universal precautions, and sexual misconduct that are found in Chapter 4731, Ohio Administrative Code. These rules are applicable to the supervising physician as well.

Failure to comply with the background check requirement will cause the application to be denied or possibly abandoned for failure to supply all required information for a complete application.

Finally, failure to comply with the rules may lead to administrative discipline of the supervising physician’s and/or physician assistant’s license to practice, which may include a civil penalty of up to twenty thousand dollars.

**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.***

Most of the adverse impact caused by the subject rules arises by setting parameters for physician assistant practice that cannot be quantified. The rules impact on the time and activity required to practice within the minimal standards of care should be nil as the criteria in the rules are basic to good medical practice. However, a physician assistant who has not subscribed to the basic tenets of good medical practice might see the standards as restrictive and time consuming. If so, the financial impact depends upon the compensation of the physician assistant and the amount of extra time and effort required to comply with the rules. Signing up for the prescription monitoring program requires the completion of paperwork and perhaps the time and expense of a notary public, but no application fee. Checking the prescription monitoring program takes some time, but it can be handled by a delegate and there is no fee. The cost of physician supervision depends upon the compensation paid to the physician and physician assistant and the amount and kind of interaction between them.

The cost of complying with Rule 4730-3-02, however, is quantifiable. According to the information on the Attorney General’s website (<http://www.ohioattorneygeneral.gov/Business/Services-for-Business/WebCheck/Webcheck-Community-Listing>), the cost ranges from \$58 to \$67.00.

The cost of continuing medical education (“CME”) varies depending upon the courses chosen by the physician assistant from a wide variety of courses offered by numerous approved sponsors. A CME course may be offered free by an employer or require a registration fee. Courses listed on the webpage of the National Commission on Certification of Physician Assistants include courses ranging from \$44 to \$350. See <https://www.nccpa.net/finding-sa-and-pi-cme>. Other courses may have a significantly higher registration fee, and may require travel and lodging for participation. However, Rule 4731-1-06 also incorporates a means by which the physician assistant may obtain up to one-third of the required CME by providing free care to the indigent and uninsured.

The failure to comply with the application procedures set forth in Rule 4730-1-06 may lead to denial of the application.

Finally, the administrative discipline for violation of a rule could range from a reprimand to permanent revocation. In addition, an administrative penalty of up to \$20,000 could be levied.

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

As stated above, most of the adverse impact caused by the rules originates from the requirements of the Revised Code or are within the accepted basic standards of good medical practice. Patients need to be able to trust that physician assistants will provide care

that is within the minimal standards of care and complies with the requirements of the Ohio Revised Code.

### **Regulatory Flexibility**

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

No exception or alternative means of compliance is available based upon the size of the business. The dangers caused by medical practice that fails to comply with accepted standards of medical practice or state or federal law does not diminish with the size of a medical practice.

**18. 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 require a reporting of paperwork to the Medical Board. Moreover, the requirements of the rule are too basic to safe medical practice to waive fines and penalties for first-time offenders.

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

The Medical Board routinely answers questions concerning Medical Board statutes and rule requirements. Where appropriate, guidance documents, such as FAQs, are published.