



Business Impact Analysis

Agency Name: State Medical Board of Ohio

Regulation/Package Title: Physician Assitant Rules - 2013

Rule Number(s): NO CHANGE: 4730-1-01, 4730-1-02, , 4730-1-04, 4730-1-05, 4730-2-01, 4730-2-02, 4730-2-04, 4730-2-07, 4730-2-08, and 4730-2-09.

AMENDED: 4730-1-03, 4730-1-06, 4730-1-07, 4730-1-08, 4730-2-03, 4730-2-05, 4730-2-06, 4730-3-01, and 4730-3-02

NEW: 4730-2-10.

RESCINDED: Appendix A to Rule 4730-2-06

Date: November 6, 2013; Revised Febraury 26, 2014

Rule Type:

- | | |
|------------------------------------|--|
| <input type="checkbox"/> New X | <input type="checkbox"/> 5-Year Review X |
| <input type="checkbox"/> Amended X | <input type="checkbox"/> Rescinded X |

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.

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Please include the key provisions of the regulation as well as any proposed amendments.

The rules implement Chapter 4730, Ohio Revised Code, for the regulation of physician assistant practice. Rules 4730-1-01, 4730-1-02, 4730-1-04, and 4730-1-05, which set standards for licensure application, physician assistant practice, and physician supervision, and Rules 4730-2-01, 4730-2-02, 4730-2-04, and 4730-2-07 through 4730-2-09, which regulate physician assistant prescribing, are proposed to be continued with no amendment. The following rules are proposed to be amended:

Rule 4730-1-03 (Duties of a supervising physician) is amended by adding paragraph (F) to reflect the language of Section 4730.04(C), Ohio Revised Code, enacted by Am. Sub. H.B. 284 of the 129th General Assembly, effective March 22, 2013.

Rule 4730-1-06 (Certificate to practice as a physician assistant) contains only a technical amendment by the addition of the Medical Board's internet address at which the prescribed application may be found.

Rule 4730-1-07 (Miscellaneous provisions) applies various rules in Chapter 4731 of the Administrative Code to physician assistants as though fully set out in Chapter 4730 of the Administrative Code. Rule 4730-1-07 is proposed to be amended by incorporating by reference rules in Chapter 4731-11 that regulate the prescribing of controlled substances.

Rule 4730-1-08 (Special services plan) contains only a technical amendment by the addition of the Medical Board's internet address at which the prescribed application may be found.

Rule 4730-2-03 (Application for a provisional certificate to prescribe) contains only a technical amendment by the addition of the Medical Board's internet address at which the prescribed application may be found.

Rule 4730-2-05 (Certificate to prescribe) contains only a technical amendment by the addition of the Medical Board's internet address at which the prescribed application may be found.

Rule 4730-2-06 (Physician assistant formulary) contains the standards applicable to a physician assistant in prescribing, and the physician assistant formulary in Appendix A. The rule is proposed to be amended to reflect that physician assistants now have authority to prescribe Schedule II drugs in compliance with Section 4730.411 of the Revised Code, to clarify the current language of paragraph (H), and to rescind Appendix A. Appendix A is proposed to be rescinded consistent with Am. Sub. H.B. 284 of the 129th General Assembly, effective March 22, 2013, which amended Section 4730.39, O.R.C., by deleting the requirement that the formulary be promulgated in rule.

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Rule 4730-2-10 (Standards and procedures for review of “Ohio Automated Rx Reporting System”) is proposed as a new rule to set standards and requirements for the physician assistant to use OARRS when prescribing Schedule II drugs, as is required by Section 4730.053, O.R.C.

Rules 4730-3-01 and 4730-3-02 (Criminal records checks). The rules set out the procedures and requirements for the criminal records check that is required of applicants for initial licensure and license restoration. The rules are proposed to be amended in order to decrease the onus on out of state applicants. Paragraph (D) of proposed rule 4730-3-02 retains from the current rule a listing of criteria the Medical Board may apply, as applicable, when reviewing the criminal record of an applicant to determine whether the applicant should be granted a license.

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

The proposed rules are authorized by Sections 4730.07, 4730.39, 4730.53, and 4776.03, ORC.

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 rules do not implement a federal requirement.

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

This question is not applicable.

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)?

In addition to rules that are specifically required or authorized by statute, Section 4730.07, ORC, authorizes the Medical Board to adopt rules necessary to govern the practice of physician assistants. Except as discussed below, the rules are proposed under this statutory authority in order to facilitate compliance with the provisions of Chapter 4730, ORC, and to promote public protection.

Section 4730.14(C), ORC, requires the Medical Board to adopt rules specifying the types of continuing medical education that must be completed to fulfill the requirements specified in that section of law. Proposed rule 4730-1-06 fulfills this mandate.

Section 4730.39, ORC, authorizes the Medical Board to adopt rules governing the physician assistant's physician-delegated prescriptive authority. The version of Section 4730.39, ORC, effective through March 21, 2013, also required the Medical Board to promulgate in rule a physician assistant formulary. The public purpose of Rule 4730-2-06 is to set the standards for physician assistant exercise of physician-delegated prescriptive authority. At this time, Appendix A of Rule 4730-2-06 is proposed to be rescinded, consistent with the language of Section 4730.39, ORC, effective March 22, 2013.

Section 4730.53, ORC, requires the Medical Board to adopt rules setting the standards and procedures to be followed by a physician assistant who is authorized to prescribe controlled substances regarding the viewing of information contained in the prescription monitoring program maintained by the Ohio Board of Pharmacy "(OARRS)". The public purpose of Rule 4730-2-10 is to set the required standards and procedures consistent with those required of physicians and consistent with the quality assurance requirements provided in Section 4730.21, ORC.

Section 4776.03, ORC, requires all licensing agencies to adopt rules establishing procedures and processes for required criminal records checks. Rule 4730-3-01 and 4730-3-02 provide the required procedures and processes.

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

The success of the regulations 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

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 rules that are proposed to be continued without change were effective in 2007. The Physician Assistant Policy Committee, which is a statutory advisory committee to the Medical Board, met monthly from August through December 2006 to recommend language for the rules to the Medical Board. Significant input was received from the Ohio Association of Physician Assistants during this process. The recommendations from the Physician Assistant Policy Committee were accepted by the Medical Board without major amendments.

In January 2013, an invitation to comment on the existing rules in Chapter 4730, OAC, was e-mailed to all physician assistants and physicians for whom the Medical Board has e-mail addresses; Ohio associations, including but not limited to: Ohio Physician Assistant Association, Ohio State Medical Association, Ohio Osteopathic Association, Ohio Association of Family Physicians, Ohio Dermatology Association, Ohio Orthopedic Society, all city and county medical societies of which the Medical Board is aware, Ohio Hospital Association, and Ohio Chapter of American College of Emergency Physicians; attorneys who appear before the Medical Board; and individuals who have indicated an interest in Medical Board rules. The current rules were then reviewed with the Physician Assistant Policy Committee pursuant to Sections 4730.06 and 4730.07, ORC, in March, June, July, and August of 2013.

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

The Medical Board received twenty comments in response to the January 2013 invitation to comment. One commentator objected to any changes to the current rules. Two comments suggested that physician assistants have too much practice authority.

Only two associations provided comments. The Ohio Osteopathic Association responded by stating that it had no comments. Comments suggested by the Ohio Association of Physician Assistants are discussed below.

Several of the comments proposed changes that would require statutory changes to Chapter 4730, ORC. For example, several comments suggested that the physician assistant should be allowed to delegate functions, including the administration of drugs, to medical assistants. It was determined that legislation would be needed to clarify the physician assistant's ability to delegate since Chapter 4730, ORC, does not contain express authority for the physician assistant to delegate functions to unlicensed persons, and the prescriptive authority of physician assistants is itself delegated to them by supervising physicians. Three comments suggested that the special services plans required by Section 4730.09, ORC, should be abolished. Several comments suggested repeal of the requirement in Section 4730.21(A), ORC, that the supervising physician be no more than sixty minutes travel time away from the site at which the physician assistant is practicing. It was determined that these suggestions conflict with current statutes.

Other comments suggested language that is contained in the provisions of Am. Sub. H.B. 284, effective March 22, 2013, and is now statutory language in Chapter 4730, ORC.

The Ohio Association of Physician Assistants submitted suggestions several times during the review period. One suggestion was that the rules address with specificity the role of physician assistants for purposes of honoring Do Not Resuscitate Comfort Care orders. The

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Medical Board is not proposing rules concerning the Do Not Resuscitate Comfort Care orders as such rules are under the jurisdiction of the Ohio Department of Health.

The Ohio Association of Physician Assistants also proposed that Rule 4730-1-03 include language reflecting Section 4730.04, Ohio Revised Code, as enacted in Am. Sub. H.B. 284, effective March 22, 2013. That suggestion is reflected in the proposed paragraph (F) for Rule 4730-1-03.

The Ohio Association of Physician Assistants also suggested that the definition of the phrase “setting in which the supervising physician routinely practices,” in Rule 4730-1-01(B)(1) of the current rule be amended to read, “a practice setting in which the supervising physician has oversight and control.” The suggestion was not adopted by the Medical Board as being beyond the scope of the language used in Section 4730.21(D)(1), ORC.

The Ohio Association of Physician Assistants also suggested that the rules require that the military experience for applicants seeking to be granted a certificate to practice based on military experience, as authorized in Section 4730.11(C) enacted by Am. Sub. H.B. 284, effective March 22, 2013, have been attained within a specified time period prior to application. The Medical Board determined that adding such a requirement would be in conflict with statutory language.

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?

Scientific data was not used to develop the rule. However, input was solicited from physician assistants, physicians who supervise physician assistants, and hospital based practitioners.

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 Medical Board considered repealing rules that in large part collect the language of two or more statutes into one rule, such as Rule 4730-1-02. However, the members of PAPC supported retaining those rules as they facilitate compliance with Chapter 4730, Ohio Revised Code.

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.*

Rules 4730-1-04, 4730-1-05, 4730-1-08, 4730-2-02, 4730-2-04, 4730-2-07, 4730-2-08, 4730-2-09, 4730-2-10, and 4730-3-02 are performance based in that they define the desired

outcomes without dictating the process used to achieve compliance or specifying detailed activities. In general, however, the proposed rules are procedural in nature or collect various provisions of Chapter 4730, ORC, on one related topic into one rule.

12. 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 physician assistants in Ohio. However, physician assistants are now authorized to honor Do Not Resuscitate Comfort Care orders, regulation of which is under the Ohio Department of Health. Therefore, the Medical Board declined the request to promulgate rules on that topic specifically for physician assistants.

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.

The rules will be posted on the Medical Board's website, information concerning the rules will be included in informational materials e-mailed to licensees, and notices will be sent to associations, individuals, and groups. Medical Board staff members are available by telephone and e-mail to answer questions. Medical Board staff members also give presentations to groups and associations who seek an update on physician assistant practice regulations.

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 rules will impact licensed physician assistants and their employers, which may be physicians, medical practices, or medical facilities.

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

Violation of the rules may result in administrative licensure discipline for the physician assistant and/or the supervising physician. Discipline might include reprimand, suspension of the license, required course work, and/or revocation of the license. The cost of course work is borne by the licensee.

The supervision requirements carry with them the cost of the physician's time in being available to the physician assistant to discuss a patient's condition, supervising the physician assistant's practice, and conducting quality assurance of the physician

assistant's work. The monetary impact is not able to be determined and depends upon the work habits and office practices of all practitioners involved.

Rule 4730-3-02 also provides an adverse impact because of the processing fee charged by the agency taking the fingerprints as determined by the vendor selected, the \$22.00 BCI fee, and the \$24.00 FBI fee. The prospective employer or contractor may pay the fees. This rule implements the criminal background check requirement in Section 4776.02, ORC.

Proposed Rule 4730-1-06(C)(3) requires the applicant to submit all information mandated by Section 4730.10, ORC, and any other information required by the Medical Board. Rule 4730-1-06(C)(2), requires the applicant to submit verification of certification by the National Commission on Certification of Physician Assistants ("NCCPA"), as Section 4730.11(A)(3), ORC, requires that the applicant hold current NCCPA certification to be eligible for licensure. Attaining NCCPA certification requires passage of the NCCPA examination. One of the requirements for sitting for the NCCPA examination is that the person have graduated from a program accredited by the Accreditation Review Commission on Education for the Physician Assistant ("ARC-PA"). Therefore, all applicants for licensure as a physician assistant must have graduated with a two-year or four-year degree, master's degree, or degree higher than a master's from an ARC-PA accredited educational program at some point during their educational process. Although the general eligibility requirement in Section 4730.11, ORC, is that the applicant must have a master's degree, Section 4730.11(C), ORC, sets out three means by which an applicant may receive a physician assistant license without having obtained a master's degree. The time required to complete the educational and certification requirements depends upon whether the person attends school full-time or part-time and how long it takes the person to complete the entire NCCPA certification process.

Proposed Rule 4730-1-06(I) implements the biennial renewal requirements in Section 4730.14, ORC. According to the statute, to qualify for renewal the physician assistant must have completed 100 hours of continuing medical education and provide verification of holding NCCPA certification. The required 100 hours of continuing medical education is the same amount of continuing education required to be completed every two years to maintain NCCPA certification (See NCCPA certification information at <http://www.nccpa.net/CertificationProcess>). Proposed Rule 4730-1-06(I)(5) specifies that completion of the continuing medical education requirement may be satisfied by completion of courses acceptable for maintaining

NCCPA certification. Whether or not the continuing medical education may be obtained during the work day or must be completed during off- work hours, depends on the policies of the employer. It should be noted that many physician assistants work nights and/or weekends so determining whether continuing medical education courses conducted on the weekend are off-work hours or not is specific to an individual physician assistant. Certainly the courses may be obtained via conferences and courses offered by the Ohio Association of Physician Assistants (“OAPA”). (See OAPA website at: <http://www.ohiopa.com/aws/OAPA/pt/sp/conferences>) Courses are also available for home study. (See American Academy of Physician Assistants website at: <http://www.aapa.org/cme/resources/item.aspx?id=6204>.)

The amount of time it takes to complete the application process depends in large part upon the applicant’s organizational skills. The applicant must be able to write a compilation of their educational and work histories, contact the certification agency to send the Medical Board verification of certification, and obtain the required fingerprints for the criminal records check.

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.

For criminal records checks, the cost in dollars includes the processing fee charged by the agency taking the fingerprints as determined by the vendor selected, the \$22.00 BCI fee, and the \$24.00 FBI fee.

The cost of course work required as part of a disciplinary action depends upon the specific coursework required. For example, a course on medical ethics, professionalism, and boundaries at Case Western University Medical School is priced at \$1,050. (See

<http://casemed.case.edu/cme/activities/documents/MEDICALETHICS2013.pdf>.)

One vendor advertises a continuing medical education course on prescribing opioids, pain management, and addiction for \$1,150.00 (See:

https://professionalboundaries.com/registration.php?seminar_id=141.) Of course, coursework is not ordered in every disciplinary action, and disciplinary actions are taken on only a minute percentage of physician assistants and supervising physicians.

The cost of the education depends on whether the student attends a private or public institution. The 2013 tuition for the master's degree in physician assistant studies at Kettering College was \$10,390/semester. (See <http://www.kc.edu/tuition-and-fees>.) The 2013 tuition at the University of Findlay was \$13,770 per semester. (See <http://www.findlay.edu/healthprofessions/physicianassistant-ma/tuition-and-fees>.) Certification by the NCCPA requires the physician assistant to have completed an ARC-PA accredited program to receive a two-year or four-year degree, master's degree, or degree higher than a master's degree and successfully complete the certification examination. The cost of the certification examination is \$475.00 (See <http://www.nccpa.net/Pance>.)

The cost of continuing medical education varies upon the coursework chosen. The OAPA 2014 Pharmacology Conference provides 12.5 hours of continuing medical education on Friday, April 11, and Saturday, April 12, for a registration fee of \$275.00 (See <http://www.ohiopa.com/aws/OAPA/pt/sp/conferences>.) There are also at least some free on-line courses that are approved for physician assistant continuing medical education credit. (See http://cmeaccess.com/cme/JEM_ACS_program/index_main.asp?contID=34&link_id=21.)

Section 4730.14, ORC, provides that to qualify for renewal the physician assistant must have completed 100 hours of continuing medical education and provide verification of holding NCCPA certification.

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

The manner in which the physician assistant practices affects the care a patient receives and the patient's health. The rules are needed to facilitate the licensing of qualified applicants who are then expected to provide appropriate and safe medical services.

Requiring the criminal records check is required by Section 4730.101, ORC, and is a safeguard to protect vulnerable patients from practitioners whose actions indicate a lack of moral character or threat to the health and safety of patients.

The educational, certification, and continuing education requirements specified in the proposed rules are mandated in the Ohio Revised Code, as discussed in #14, above. The \$200 application fee is mandated by Section 4730.10(B), ORC.

Regulatory Flexibility

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

Physician assistants work at all types of medical sites, performing all types of medical services for patients who are at their most vulnerable condition. 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?

The Medical Board does not have authority to fine physician assistants or impose penalties for paperwork violations. Moreover, the failure of the supervising physician to document compliance with quality assurance requirements is not just a paperwork error as quality assurance by the physician is needed for oversight of physician assistants, who are mid-level providers.

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

Medical Board staff members are available by telephone and e-mail to answer questions. Medical Board staff members also give presentations to groups and associations who seek an update on physician assistant practice regulations.