

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: State Medical Board

Regulation/Package Title: Physician Assistant Delegation

Rule Number(s): 4730-1-08 to rescind; 4730-1-08 replacement

Date: _____

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Rescinded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.

Effective October 15, 2015, the statutes regulating the practice of physician assistants were significantly changed. As a result current rule 4730-1-08, which sets the standards and procedures for approval of a special services plan, is inconsistent with current statutory

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

CSIOhio@governor.ohio.gov

provisions and is unnecessary. Moreover, effective October 15, 2015, Section 4730.203, O.R.C., authorizes a physician assistant to delegate the performance of a medical task to implement a plan of treatment and to delegate the administration of drugs when certain criteria are met. Accordingly, replacement rule 4730-1-08 is proposed to set standards for the delegation of medical tasks and the administration of drugs in accordance with the same standards that physician must follow. (See Chapter 4731-23, Ohio Administrative Code, and Section 4731.053, O.R.C., for standards for physician delegation.)

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

Current Rule 4731-1-08 was authorized by Section 4730.07, O.R.C. Proposed replacement rule 4731-1-08 is authorized by Sections 4730.07 and 4730.39, O.R.C.

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.

No. The rule is not a federal requirement nor will it enable the state to obtain or maintain approval to administer and enforce a federal law or participate in a federal program.

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

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)?

Current Rule 4731-1-08 is proposed to be rescinded because its entire purpose was to set standards for the special services plans required under former Sections 4730.09, 4730.15, 4730.16, and 4730.17. All of the specified sections were repealed effective October 15, 2015.

Replacement Rule 4731-1-08 is needed to inform physician assistants, supervising physicians, other participants in health care, and patients about the standards to which physician assistants will be held when delegating medical tasks and the administration of drugs. In addition, the proposed rule is needed to clearly define “delegate” and “task.” For example, the proposed rule defines “delegate” as it is defined for physicians in Rule 4731-23-01, O.R.C. The definition of “delegate” clarifies that it is to authorize an unlicensed person to perform a medical activity. In contrast when the medical , a nurse, who is licensed by the

Ohio Board of Nursing, is “directed” to perform duties within the scope of the nurse’s licensure.

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

The success of the rule will be measured by a dearth of complaints that allege a patient was harmed in the delivery of a medical service where the investigation discloses that a physician assistant failed to apply the proposed standards when delegating delivery of a task or drug administration by an unlicensed person.

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 first step in proposing to rescind the current rule and adopt the proposed replacement rule was to obtain recommendations to do so by the Physician Assistant Policy Committee (“PAPC”). Pursuant to Section 4730.05, O.R.C., PAPC membership consists of three physician assistants, three physicians (including a physician member of the Medical Board) and a public member. Two pharmacists also participate in formulary and prescribing rules and decisions. Once PAPC recommended that the proposed rescinded and replacement rules be considered by the Medical Board, the Medical Board approved the proposals for circulation to interested parties.

The proposed rules were sent to organizations such as, but not limited to, the Ohio Association of Physician Assistants, Ohio State Medical Association, Ohio Academy of Family Physicians, Academy of Medicine of Cleveland and Northern Ohio, Ohio Osteopathic Association, medical societies across Ohio; governmental affairs representatives for numerous organizations; individuals who on their own behest or the behest of their health care system employer have requested notice of Medical Board rule activities; attorneys who represent licensees and applicants before the Medical Board; and state licensing agencies such as the Ohio Board of Nursing and Board of Pharmacy.

The proposed replacement rule was also posted on the Medical Board’s website with a statement soliciting comments on the proposed rule.

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

PAPC first approved the plan to overhaul the physician assistant rules to reflect the significant statutory changes. The plan includes rescinding several rules and, where possible,

issuing additional guidance documents that explain the provisions of Chapter 4730, O.R.C., in lieu of promulgating rules. PAPC agreed that the promulgation of a rule setting standards for physician assistant delegation should be the priority for rule promulgation, and that replacing current Rule 4730-1-08 with the new delegation rule was appropriate. The members appreciated that the proposed delegation rule applied to physician assistants the same standards and criteria applied to physicians and made no substantive amendments to the draft language presented.

The proposed replacement rule language concerning physician assistant delegation was sent to interested parties for comment on November 9, 2015, with a deadline of December 10, 2015. No comments were received.

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 language of the proposed replacement rule is based upon the physician delegation rules in Chapter 4731-23, O.A.C. The physician delegation rules have been in place since 2001.

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?

It was determined that the physician assistant delegation standards should be the same as those of physicians since a physician assistant serves as the agent for the supervising physician (See Section 4730.22, O.R.C) and works under the supervision, control, and direction of the supervising physician (See Section 4730.21, O.R.C.); and the supervising physician may not authorize a physician assistant to perform a service that is not within the physician's normal course of practice and expertise (See Section 4730.02, O.R.C.). Moreover, the rule incorporates the mandates and prohibitions for delegation of the administration of drugs that are specified in Section 4730.203, O.R.C.

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 proposed replacement rule is performance-based. It sets the standards, but does not dictate the process by which the physician assistant complies with the standards. For example, the physician assistant must determine that the person to whom a medical task will be delegated is competent to perform it, but the means by which the physician assistant reaches that determination is not prescribed.

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 authorized to regulate physician assistant practice. The Medical Board purposefully based the language of the proposed replacement rule on the rule the supervising physicians must follow when delegating medical tasks and the administration of drugs so that there would not be a conflict between the standards.

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 rule will be implemented by distributing it widely and creating a guidance document should that be needed. Prior to the effective date of the replacement rule it will be emailed to all physician assistants holding an active license, the Ohio Association of Physician Assistants (which posts information concerning statutes and rules on its website), and all persons and organizations who regularly receive updates on Medical Board rule activity; information will be posted on the Medical Board's website; and information will be provided in the Medical Board e-News that is sent to all licensees and others.

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 business community impacted includes physician assistants, supervising physicians, medical practice entities (including urgent care centers, clinics, and nursing homes, and retail clinics), and health care facilities (including hospitals and ambulatory surgical centers).

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

The nature of the adverse impact for physician assistants is that pursuant to Section 4730.02, O.R.C., the person must hold a license to practice as a physician assistant issued by Medical Board. Also, the physician assistant will may have to perform certain medical tasks or drug administration him/herself instead of having free range to delegate.

The nature of the adverse impact for supervising physicians is that pursuant to Sections 4730.01 and 4730.02, O.R.C., they must be licensed to practice medicine in Ohio in order to supervise a physician assistant. According to Section 4730.203,

O.R.C., the physician must indicate in the supervision agreement that the physician assistant may delegate tasks and/or drug administration.

The nature of the adverse impact for medical practice entities and health care facilities is that they may not have policies that authorize a physician assistant to delegate medical tasks and/or drug administration in violation of the rule, and Section 4730.203(C), O.R.C., where applicable.

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.

Effective October 15, 2015, the physician assistant license fee is \$500.00. The biennial renewal fee is \$200.00. The cost of the physician assistant performing some medical task or drug administration instead of delegating it depends upon the rate of pay of the physician assistant.

The licensure fee for physicians is \$335. The licensure renewal fee is \$305.00.

The Medical Board is unable to quantify the costs to physicians, medical practice entities, and health care facilities resulting from a physician assistant not having unfettered ability to delegate medical tasks and/or drug administration. The costs would depend on the policies related to physician assistant practice, the usage or not of unlicensed support personnel, and the rates of pay for physician assistants.

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

Patient protection requires that physician assistants be held to the same standards as physicians when authorizing an unlicensed person to perform medical tasks and administer drugs.

Regulatory Flexibility

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

No. Patient protection requires that the same standards be applied to all practice by physician assistants regardless of the setting.

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 rule does not require paperwork to be submitted to the Medical Board. There are no fines for violation of the rule. Each allegation of a violation will be evaluated on a case-by-case fact specific basis.

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

The Medical Board staff is available to answer questions. If needed, a “frequently asked questions” or guidance document will be created and posted on the website and circulated widely.

4730-1-08

Special services plan TO BE RESCINDED.

- (A) For a physician assistant who practices in an office-based setting, a special services plan approved by the board is required for all services beyond the scope of the services authorized under paragraph (A) of section 4730.09 of the Revised Code.
- (B) An application for approval of a service under a special services plan shall be made in the manner provided in section 4730.15 of the Revised Code. The following information is necessary to process the application and must be included with the application:
- (1) Documentation of the supervising physician's normal course of practice, experience and training to perform the requested service, and any board certification;
 - (2) The minimum education, training, and experience required for any physician assistant providing service under the plan, including the following:
 - (a) Any formal postgraduate physician assistant training that will be provided to the physician assistant;
 - (b) The minimum number of procedures the physician assistant will observe the supervising physician in performing; and
 - (c) The minimum number of procedures performed by the physician assistant under the direct observation of the supervising physician in order to be certified by that physician as competent.
 - (3) The location or locations in which the service will be performed;
 - (4) The criteria that will be used in granting authority for the specific service to be performed by the physician assistant and the quality assurance process that will be utilized to review the performance of that service;
 - (5) Whether the service will be performed under direct supervision, on-site supervision, or off-site supervision, as those terms are defined in rule 4730-1-01 of the Administrative Code;
 - (6) The quality assurance process that will apply to the physician assistant in the performance of the special service;
 - (7) The minimum number of procedures per year the physician assistant will be

required to perform in order to maintain authority to perform the service;

- (8) If the service is a diagnostic procedure, whether a permanent visual record is maintained for the supervising physician's review and interpretation;
 - (9) A listing of all significant complications associated with the requested procedure and the processes in place to document and respond to those complications, should they occur;
 - (10) Any peer-reviewed articles on physician assistant or other ancillary personnel performance of the requested service and rate of complications, as applicable; and
 - (11) Any other information required by the board.
- (C) The board may approve or deny a special services plan upon consideration of factors including, but not limited to, the following:
- (1) Whether performance of the service will likely require complex observations or critical decision making during the performance of the service;
 - (2) Whether the potential complications that may occur if the service is not performed properly will likely include life threatening consequences or the danger of immediate and serious harm to the patient;
 - (3) Whether medical judgment requiring the exclusive expertise and training of a physician must ordinarily be exercised during the performance of the service;
 - (4) Whether the performance of the service is otherwise prohibited by statute or rule;
 - (5) Whether the supervision proposed is appropriate for the level of service to be performed;
 - (6) Whether the education and/or training proposed for the physician assistant will adequately and appropriately prepare the physician assistant to perform the service;
 - (7) Whether the service to be performed is within the routine scope of practice of the supervising physician;

- (8) Whether, as proposed, performance of the service will not conform to the minimal standard of care of similar practitioners under the same or similar circumstances; and
 - (9) Whether the quality assurance system proposed presents sufficient opportunities for feedback to the physician assistant concerning the quality of the physician assistant's practice under the special services plan, including the frequency of performance of the special service to ensure competency.
- (D) The approval of a special services plan may require the supervising physician to submit quarterly reports for one year following the date the service was approved by the board, including that the reports list the number of times each procedure was performed by the physician assistant and any complications that occurred

4730-1-08

Physician assistant delegation of medical tasks and administration of drugs.

(A) As used in this rule:

- (1) "Administer" means the direct application of a drug, whether by injection, inhalation, ingestion, or any other means to a person.
- (2) "Delegate" means to transfer authority for the performance of a medical task or drug administration to an unlicensed person.
- (3) "On-site supervision" means that the physical presence of the physician assistant is required in the same location (for example, the medical practice office suite) as the unlicensed person to whom the medical task or drug administration has been delegated while the medical task or drug administration is being performed. On-site supervision does not require the physician assistant's presence in the same room.
- (4) "Physician" means an individual authorized by Chapter 4731. of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery.
- (5) "Task" means a routine, medical service not requiring the special skills of a licensed provider.
- (6) "Unlicensed person" means an individual who is not licensed or otherwise specifically authorized by the Revised Code to perform the delegated medical task or drug administration.
- (7) "Drug" means the same as in section 4729.01(E) of the Revised Code.
- (8) "Supervision agreement" means the document signed by the supervising physician and physician assistant in compliance with section 4730.19 of the Revised Code.

(B) When acting pursuant to a supervision agreement, a physician assistant may delegate the performance of a medical task or, under the conditions specified in section 4730.203 of the Revised Code, the administration of a drug to an unlicensed person.

- (1) The physician assistant shall comply with all of the requirements of section 4730.203 of the Revised Code and this rule when delegating a medical task or the administration of a drug.
- (2) A physician assistant shall not authorize or permit an unlicensed person to whom a medical task or the administration of a drug is delegated to further delegate the performance of the task or administration to third person.

(3) The physician assistant shall provide on-site supervision of the unlicensed person to whom the medical task or administration of a drug is delegated.

(C) Prior to the delegation of the performance of a medical task or the administration of a drug, the physician assistant shall ensure that each of the following requirements is met:

(1) That the supervision agreement and any applicable healthcare facility policies authorize the physician assistant to delegate the performance of a medical task or the administration of a drug;

(2) That the task or administration of the drug is within that physician assistant's practice authority;

(3) That the task or administration of the drug is indicated for the patient;

(4) That no law prohibits the delegation;

(5) That the unlicensed person to whom the task or drug administration will be delegated is competent to perform that service;

(6) That the task or drug administration itself is one that should be appropriately delegated when considering the following factors:

(a) That the task or drug administration can be performed without requiring the exercise of judgment based on medical knowledge;

(b) That results of the task or drug administration are reasonably predictable;

(c) That the task or drug administration can safely be performed according to exact, unchanging directions;

(d) That the task or drug administration can be performed without a need for complex observations or critical decisions;

(e) That the task or drug administration can be performed without repeated medical assessments;

(f) That the task or drug administration, if performed improperly, would not present life threatening consequences or the danger of immediate and serious harm to the patient; and

(7) That the delegation of the administration of a drug is in compliance with paragraph (D) of this rule.

(D) In addition to the requirements of paragraph (C) of this rule, prior to delegating the

administration of a drug, the physician assistant shall ensure that all of the following requirements are met:

- (1) The physician assistant holds a current license with a valid prescriber number issued under section 4730.11 of the Revised Code and has been granted physician-delegated prescriptive authority by the supervising physician.
- (2) The drug is included in the formulary established under division (A) of section 4730.39 of the Revised Code;
- (3) The drug is not a controlled substance;
- (4) The drug will not be administered intravenously;
- (5) The drug is not an anesthesia agent; and
- (6) The drug will not be administered in any of the following locations:
 - (a) A hospital inpatient care unit, as defined in section 3727.50 of the Revised Code;
 - (b) A hospital emergency department;
 - (c) A freestanding emergency department; or
 - (d) An ambulatory surgical facility licensed under section 3702.30 of the Revised Code.

(E) Violations of this rule.

- (1) A violation of any provision of this rule, as determined by the board, shall constitute "a departure from, or the failure to conform to, minimal standards of care of similar physician assistants under the same or similar circumstances regardless of whether actual injury to a patient is established," as that clause is used in division (B)(19) of section 4730.25 of the Revised Code.
- (2) A violation of any provision of this rule, as determined by the board, shall constitute "violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provision of this chapter, Chapter 4731. of the Revised Code, or the rules of the board," as that clause is used in division (B)(3) of section 4730.25 of the Revised Code.
- (3) A violation of any provision of this rule that pertains to the administration of drugs, as determined by the board, shall constitute "administering drugs for purposes other than those authorized under this chapter" as that clause is used

*** DRAFT - NOT YET FILED ***

4730-1-08

4

in division (B)(6) of section 4730.25 of the Revised Code.