

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: State Medical Board of Ohio

Regulation/Package Title: Anesthesiologist Assistant Rules

Rule Number(s): NO CHANGE: 4731-24-01, 4731-24-02, and 4731-24-03

RESCIND: 4731-24-04

Date: _____

Rule Type:

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 Rescinded X |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

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

Rules 4731-24-01, 4731-24-02, and 4731-24-03 set forth definitions and standards for supervision of an anesthesiologist assistant and for enhanced supervision during the first four years of the anesthesiologist assistant's practice.

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117
CSIOhio@governor.ohio.gov

Rule 4731-24-04 sets forth prohibitions in anesthesiologist assistant practice. It prohibits the performance of epidural and spinal anesthetic procedures, practice by an anesthesiologist assistant in a location other than a hospital or ambulatory surgical center, and practice not under the direct supervision of and in the immediate presence of a supervising anesthesiologist. The current rule is proposed to be rescinded without a replacement rule.

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

Sections 4760.08 and 4760.19 of the Revised Code.

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.

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)?

Section 4760.08 states that an anesthesiologist shall supervise an anesthesiologist assistant, in part, in compliance with rules adopted by the Medical Board. The statute also states that the rules shall include requirements for enhanced supervision during the first four years of the anesthesiologist assistant's practice. Therefore, current rules 4731-24-02 and 4731-24-03 are mandated by statute. Rule 4731-24-01 defines terms to clarify usage in rules 4731-24-02 and 4731-24-03.

At the time Rule 4731-24-04 was adopted, the Medical Board believed that the anesthesiologist assistant was not legally authorized to perform epidural and spinal anesthetic procedures and the other procedures listed in paragraph (A) of the rule. However, paragraph (A) of the rule was declared unconstitutional as contrary to statute by the Ohio Supreme Court in *Hoffman v. State Med. Bd. of Ohio*, 113 Ohio St.3d 376, 2007-Ohio-2201.

Paragraphs (B) and (C) only mimic provisions of the Ohio Revised Code and are not required to be in rule. Therefore, the Medical Board concluded that Rule 4731-24-04 is unnecessary and should be rescinded without replacement.

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

Rules 4731-24-01, 4731-24-02, and 4731-24-03 have been successful in that no disciplinary action has been taken against an anesthesiologist or anesthesiologist assistant for failure to comply, and throughout their time in effect no negative comments or suggestions for amendment have been received from licensees or others. Also, in response to the Medical Board's request for comments on the current rules, no comments were received concerning the current language of the three rules. Success will continue to be measured by the input of licensees in their attempts to comply with the rules.

Rule 4731-24-04 has not been a success in that paragraph (A) was declared unconstitutional and unenforceable. The Medical Board is proposing to rescind the rule in total without replacement.

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.

Information on the input of the profession in the original development of the rules is included in the response to Question 9.

In February 2013 an invitation to comment on the rules in Chapter 4731-24, OAC, was sent to all physicians, physician assistants, and anesthesiologist assistants licensed by the Medical Board; associations including, but not limited to, the Ohio State Medical Association, Ohio Hospital Association, Ohio Osteopathic Association, Ohio Podiatric Medical Association, Academy of Medicine of Cleveland and Northern Ohio, Ohio Society of Anesthesiologists, and county/city medical societies; persons and groups who have requested notice of proposed Medical Board rules; attorneys who represent parties before the Medical Board; and governmental affairs representatives for numerous medical specialty associations. The invitation included notification that paragraph (A) of Rule 4731-24-04 must be rescinded because it is unconstitutional.

In addition, the governmental affairs representative for the Ohio Society of Anesthesiologists, the organization largely responsible for the establishment of the anesthesiologist assistant profession in Ohio, was contacted for discussion of the Medical Board's proposed actions concerning the rules in Chapter 4731-24.

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

The only comment received from the February 2013 invitation to comment was from a physician who opined that Rule 4731-24-04 needs to better reflect anesthesiologist assistant practice.

The governmental affairs officer for the Ohio Society of Anesthesiologists concurred with the proposed action of filing Rules 4731-24-01, 4731-24-02, and 4731-24-03 as “no change rules” and rescinding Rule 4731-24-04.

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?

All four rules were developed during 2002 and 2003 via the input from an advisory committee consisting of three anesthesiologists, an anesthesiologist assistant, and a Medical Board physician member. The committee issued an 84-page final report that discussed, among other things, the evolution of the team concept in anesthesiology and the anesthesiologist assistant’s roll in it. The rules proposed were consistent with the suggestions from the committee. Subsequent to the public hearings on the proposed rules in 2003, the only amendments to the proposed rules was to the language proposed for rule 4731-27-04, that being to allow the anesthesiologist assistant to perform a service that had originally been proposed as prohibited. However, as discussed below, Rule 4731-24-04 as it was enacted in 2003 is proposed to be rescinded and not replaced. As discussed elsewhere, no comments were submitted indicating that the current wording of Rules 4731-24-01, 4731-24-02, and 4731-24-03 no longer conform to practice expectations of the anesthesiology specialty.

The proposal to rescind Rule 4731-24-04 is supported by the opinion of the Ohio Supreme Court that paragraph (A) is unconstitutional. Paragraphs (B) and (C) of the rule are not necessary because they merely duplicate language from the Revised Code.

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?

No alternative regulations were considered for Rules 4731-24-01, 4731-24-02, and 4731-24-03 as the Medical Board has not received feedback that alternatives should be considered. Rule 4731-24-04, however, is no longer required.

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 4731-24-02 and 4731-24-03 are performance based. Rule 4731-24-02 sets standards to implement the requirement in Section 4760.08 of the Revised Code, that the anesthesiologist assistant may only provide services under the direct supervision and in the immediate

presence of the supervising anesthesiologist according to the terms of the protocol developed by the anesthesiologist. The wording of the rule does not dictate how supervision is to be provided, but allows the supervising anesthesiologist flexibility in providing the supervision required by statute. Rule 4731-24-03 sets standards for enhanced supervision, which require increased quality assurance review and observation of the anesthesiologist assistant's practice without mandating specific criteria and procedures for the review and observation.

Rule 4731-24-04 is proposed to be rescinded without adoption of a replacement 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 state agency that regulates anesthesiologist 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 Medical Board will publish the rescission of Rule 4731-24-04 and continuation of Rules 4731-24-01, 4731-24-02, and 4731-24-03 on its website and in its newsletter, will notify the Ohio Society of Anesthesiologists and the various medical associations and societies, and notify its licensees (including physicians, physician assistants, podiatrists, and anesthesiologist assistants) concerning the status of the rules.

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 includes anesthesiologist assistants and anesthesiologists, as well as hospitals and ambulatory surgical centers that use anesthesiologist assistants as part of the anesthesiology team.

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

Section 4760.02(A), Ohio Revised Code, requires that anesthesiologist assistants be licensed. For anesthesiologist assistants, the licensure fee is \$100.00 (Section 4760.03, ORC), with biennial renewal of \$100.00 (Section 4760.06, ORC).

There is no requirement that anesthesiologists, ambulatory surgical centers, or hospitals use anesthesiologist assistants as part of the anesthesiology team. For anesthesiologists, ambulatory surgical centers, or hospitals who use them, the adverse

impact is the time required to provide the appropriate level of supervision and the difference in the cost of hiring licensed assistants as opposed to unlicensed assistants.

For the following salary information, please note that salary surveys by medical associations are proprietary and require a subscription for access. According to the American Association of Anesthesiologist Assistants, the most recent graduating class at Case Western University averaged a low-end salary of \$95-100 thousand per year, and a high-end of \$120 thousand. (See <http://www.anesthetist.org/factsaboutaaas/consideringacareer.iphtml>.) However, the purpose of anesthesiologist assistants is to free up the higher paid anesthesiologist to perform other services with additional patients. One source states that typical salary for an anesthesiologist in the U.S. is \$344,929.00. (See <http://www1.salary.com/anesthesiologist-Salary.html>.) Therefore, even if the employer pays the licensure and renewal fees for the anesthesiologist assistant, the cost should be far less than the additional revenue gained by allowing the anesthesiologist to provide services to multiple patients.

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 anesthesiologist assistants, the licensure fee is \$100.00 (Section 4760.03, ORC), with biennial renewal of \$100.00 (Section 4760.06, ORC).

It is impossible to reasonably estimate the cost to anesthesiologists, hospitals, and ambulatory surgical centers. But see the salary estimates provided in the response to question 14b, above.

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

The provision of anesthesia is fraught with risks for the patient. Rules 4731-24-02 and 4731-24-03 are required by Section 4760.08 of the Revised Code. The rules were written with input of the affected community and in such a way as to provide standards while allowing flexibility in compliance with those standards.

Regulatory Flexibility

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

There are no exemptions or alternative means of compliance for small business. There are currently 200 licensed Anesthesiologist Assistants in Ohio who are primarily concentrated in urban areas.

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?

There are no paperwork violations associated with the rules. The rules do not require that any reports or other documents be filed with the Medical Board. Failure to comply with the rules may result in administrative discipline of the anesthesiologist assistant's license pursuant to Section 4760.13(B)(2), Ohio Revised Code. Failure of the anesthesiologist to supervise the anesthesiologist assistant in compliance with Chapter 4760, Ohio Revised Code, and the rules may result in administrative discipline of the anesthesiologist's medical license under Section 4731.22(B)(36), Ohio Revised Code.

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

The Medical Board staff is available to answer questions concerning compliance with the rules.