



# Common Sense Initiative

Mike DeWine, Governor  
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## Business Impact Analysis

Agency, Board, or Commission Name: State Medical Board of Ohio

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Regulation/Package Title (a general description of the rules' substantive content):

Anesthesiologist Assistants

Rule Number(s): 4731-24-01, 4731-24-02, 4731-24-03

Date of Submission for CSI Review: 1/14/25

Public Comment Period End Date: 1/31/25

**Rule Type/Number of Rules:**

New/\_\_\_ rules

No Change/ 3 rules (FYR? y)

Amended/\_\_\_ rules (FYR? \_\_\_)

Rescinded/\_\_\_ rules (FYR? \_\_\_)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

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### **Reason for Submission**

1. R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.

Which adverse impact(s) to businesses has the agency determined the rule(s) create?

The rule(s):

- a. ☒ Requires a license, permit, or any other prior authorization to engage in or operate a line of business.
- b. ☒ Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.
- c. ☐ Requires specific expenditures or the report of information as a condition of compliance.
- d. ☐ Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.

### **Regulatory Intent**

2. Please briefly describe the draft regulation in plain language.  
*Please include the key provisions of the regulation as well as any proposed amendments.*

#### **4731-24-01-Definitions**

This rule sets forth the definitions used in this chapter of the Ohio Administrative Code. No changes are proposed.

#### **4731-24-02-Anesthesiologist Assistants: Supervision**

This rule sets forth the requirements for a supervising anesthesiologist and the tasks that can be performed by an anesthesiologist assistant. No changes are proposed.

#### **4731-24-03-Anesthesiologist Assistants: Enhanced Supervision**

This rule sets forth the requirements related to enhanced supervision by a supervising anesthesiologist during the first four years of an anesthesiologist assistant's practice. No changes are proposed.

3. Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.

Rule 4731-24-01: Authorized by: 4760.08, 4760.19; Amplifies: 4760.08, 4760.09

Rule 4731-24-02: Authorized by: 4760.08, 4760.19; Amplifies: 4731.22, 4760.08, 4760.09

Rule 4731-24-03: Authorized by: 4760.08, 4760.19; Amplifies: 4760.08

4. **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 rules do not implement a federal requirement.

5. **If the regulation implements a federal requirement, but 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)?**

Section 4760.08, Ohio Revised Code, requires the Medical Board to promulgate rules for the supervision and enhanced supervision of anesthesiologist assistants. The rules provide notification to the anesthesiologist, anesthesiologist assistant, the public and medical administrators of the standards and procedures for practice.

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 clear language resulting in few inquiries from regulated parties.

8. **Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**

*If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.*

No.

### **Development of the Regulation**

9. **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 were reviewed and approved by the Medical Board for initial circulation to interested parties in March 2024. The rules were posted on the Medical Board's website and circulated via e-mail to interested parties with comments due no later than April 19, 2024. The interested parties included the Ohio State Medical Association, Ohio Hospital Association, Academy of Medicine of Cleveland and Northern Ohio and the Ohio Osteopathic Medical Association, as well as individuals who have asked to be notified of rule filings. No comments were received.

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

No comments were received.

**11. 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 rules are proposed as no change rules, and are largely unchanged from the original language adopted in 2003. The rules were originally written through a process that involved an ad hoc committee of a physician Medical Board member, anesthesiologists and an anesthesiologist assistant.

**12. 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?**  
*Alternative regulations may include performance-based regulations, which define the required outcome, but do not dictate the process the regulated stakeholders must use to comply.*

The rules are proposed as no change rules because the language is clear, in line with the requirements of R.C. 4760.08, and no concerns have been raised by the regulated licensees.

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

The Medical Board is the sole agency authorized to regulate anesthesiologist assistants. The rules follow the requirements of Section 4760.08, Ohio Revised Code.

**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.**

The rules are available on the Medical Board's website and Medical Board staff are available to answer questions regarding the rule requirements.

**Adverse Impact to Business**

**15. Provide a summary of the estimated cost of compliance with the rule(s). Specifically, please do the following:**

**a. Identify the scope of the impacted business community, and**

The impacted business community includes anesthesiologists and anesthesiologist assistants.

**b. Quantify and identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance, etc.).**

*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.*

The adverse impact includes time required by the supervising anesthesiologist to provide enhanced supervision for the first four years of the anesthesiologist's practice and then supervision after that.

- 16. Are there any proposed changes to the rules that will reduce a regulatory burden imposed on the business community? Please identify. (*Reductions in regulatory burden may include streamlining reporting processes, simplifying rules to improve readability, eliminating requirements, reducing compliance time or fees, or other related factors*).**

The rules are proposed as unchanged, so there is no reduction in the regulatory burden. The rules implement a statutory requirement.

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

The rules are required by Section 4760.08, Ohio Revised Code. The language of the rules closely follows the statutory requirements.

### **Regulatory Flexibility**

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

There are no exemptions or alternatives for compliance for small businesses. The requirements for safe practice for anesthesiologist assistants are consistent no matter the size or ownership structure of the anesthesiologist assistant's practice location.

- 19. 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 require the submission of any paperwork related to these rules.

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

The rules will be posted on the Medical Board's website and Medical Board staff are available to respond to inquiries or questions,

4731-24-01

**Definitions.**

As used in Chapter 4731-24 of the Administrative Code:

- (A) "Administer" means to apply directly a drug, whether by injection, inhalation, ingestion, or any other means, and the infusion of blood, blood products and supportive fluids.
- (B) "Assist" means to carry out procedures as requested by the supervising anesthesiologist, provided that the requested procedure is within the anesthesiologist assistant's training and scope of practice, is authorized by the practice protocol adopted by the supervising anesthesiologist, and is not prohibited by Chapter 4731. or 4760. of the Revised Code, or by any provision of agency 4731 of the Administrative Code.
- (C) "Drug" has the same meaning as in division (E) of section 4729.01 of the Revised Code.
- (D) "Direct supervision, and in the immediate presence of" means the following:
  - (1) The supervising anesthesiologist shall remain physically present and available for immediate diagnosis and treatment of emergencies;
  - (2) The supervising anesthesiologist shall be physically present in the anesthetizing area or operating suite, as defined by the hospital or ambulatory surgical facility, and accessible by page, telephone, or overhead page, such that he or she is immediately available to participate directly in the care of the patient with whom the anesthesiologist assistant and the supervising anesthesiologist are jointly involved;
  - (3) The supervising anesthesiologist shall personally participate in the most demanding procedures in the anesthesia plan, which shall include induction and emergence; and
  - (4) "Direct supervision and the in immediate presence of" shall not be interpreted to:
    - (a) Require the supervising anesthesiologist's presence in the same room as the anesthesiologist assistant for the duration of the anesthetic management; or
    - (b) Prohibit the supervising anesthesiologist from addressing an emergency of short duration, administering labor analgesia, or performing duties of

short duration as required of a perioperative specialist in another location in the hospital or ambulatory surgical facility.

4731-24-02

**Anesthesiologist assistants: supervision.**

- (A) A supervising anesthesiologist shall supervise an anesthesiologist assistant within the terms, conditions, and limitations set forth in a written practice protocol that is consistent with section 4760.08 of the Revised Code and this chapter of the Administrative Code. The supervision shall be direct supervision and in the immediate presence of the anesthesiologist assistant, as that term is defined in rule 4731-24-01 of the Administrative Code.
- (B) An anesthesiologist assistant shall only perform those tasks assigned on a case-by-case basis by the supervising anesthesiologist. The anesthesiologist assistant shall implement the personalized plan for a patient as individually prescribed by the supervising anesthesiologist after the physician has completed a specific assessment of the patient.
- (C) In determining which anesthetic procedures to assign to an anesthesiologist assistant, a supervising anesthesiologist shall consider all of the following:
- (1) The education, training, and experience of the anesthesiologist assistant;
  - (2) The anesthesiologist assistant's scope of practice as defined in section 4760.09 of the Revised Code and this chapter of the Administrative Code;
  - (3) The conditions on the practice of the anesthesiologist assistant set out in the written practice protocol;
  - (4) The physical status of the patient according to the physical status classification system of the American society of anesthesiologists, as in effect at the time the assignment of procedures is made. The classification system is available from the American society of anesthesiologists and shall be posted on the board's website at [med.ohio.gov](http://med.ohio.gov).
  - (5) The invasiveness of the anesthetic procedure;
  - (6) The level of risk of the anesthetic procedure;
  - (7) The incidence of complications of the anesthetic procedure;
  - (8) The physical proximity of the supervising anesthesiologist and the anesthesiologist assistant or assistants being supervised concurrently; and
  - (9) The number of patients whose care is being supervised concurrently by the



supervising anesthesiologist.

- (D) During the first four years of an anesthesiologist assistant's practice, the supervising anesthesiologist shall provide enhanced supervision as defined in this chapter of the Administrative Code.
- (E) The supervising anesthesiologist shall retain responsibility for the anesthetic management in which the anesthesiologist assistant has participated.

4731-24-03

**Anesthesiologist assistants: enhanced supervision.**

(A) A supervising anesthesiologist shall provide enhanced supervision of an anesthesiologist assistant during the first four years of the anesthesiologist assistant's practice.

(B) "Enhanced supervision" means the following:

(1) The supervising anesthesiologist shall require regular, documented quality assurance interactions between the supervising anesthesiologist and the anesthesiologist assistant .

(a) The regularly scheduled quality assurance interactions shall occur in greater number and with greater frequency during the first four years of an anesthesiologist assistant's practice than would be required for quality assurance purposes for anesthesiologist assistants in practice for more than four years and shall take place no less frequently than once every three months.

(b) The anesthesiologist assistant shall be required to file on a monthly basis during the first two years of practice a separate record of the cases of anesthetic management in which he or she participated. The record shall be reviewed by a supervising anesthesiologist as a component of the quality assurance interactions.

(c) The reviewing supervising anesthesiologist shall file a report of each quality assurance interaction with the appropriate committee.

(2) The supervising anesthesiologist shall make direct observations of the anesthesiologist assistant during the course of each case of anesthetic management.

(a) During the first year of an anesthesiologist assistant's practice, the direct observations of each case of anesthetic management shall be made more frequently than for comparable procedures for anesthesiologist assistants practicing beyond their first year, and include direct observation of induction and emergence.

(b) The supervising anesthesiologist shall document the enhanced supervision in the anesthetic record.

(3) The period of enhanced supervision for an anesthesiologist assistant who has practiced in another state prior to beginning practice in Ohio shall be

determined as follows:

- (a) The anesthesiologist assistant shall be given credit for the time practiced in another state.
- (b) The credit shall be on a year-for-year basis, except that the supervising anesthesiologist shall provide enhanced supervision as defined in this rule for the first three months of the anesthesiologist assistant's practice in Ohio.