



Common Sense Initiative

Mike DeWine, *Governor*
Jon Husted, *Lt. Governor*

Joseph Baker, *Director*

x

Business Impact Analysis

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

Rule Contact Name and Contact Information: Kimberly Anderson,
Kimberly.Anderson@med.ohio.gov, (614) 466-7207

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

Surgery Privileges of Podiatrist

Rule Number(s): 4731-20-01, 4731-20-02

Date of Submission for CSI Review: 11.9.23

Public Comment Period End Date: 11.24.23

Rule Type/Number of Rules:

New/___ rules

No Change/ 2 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Rescinded/___ rules (FYR?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.

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

CSIPublicComments@governor.ohio.gov

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):

- Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**
- Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**
- Requires specific expenditures or the report of information as a condition of compliance.**
- 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.

Rule 4731-20-01 provides clarification on the definition of “foot” as used in section 4731.51 of the Revised Code.

Rule 4731-20-02 sets forth requirements for a podiatric physician to perform surgery on the ankle joint.

- 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.**

Authorized by: 4731.05

Amplifies: 4731.51

- 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 regulation does 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)?**

Both rules have been in effect since 1997, and they provide guidance to licensees and the public regarding the proper scope of practice and the requirements necessary for podiatric medicine licensees to perform foot and ankle surgery in Ohio.

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

The success of the rules in Chapter 4731-20 will be measured by the number of disciplinary actions the Medical Board takes for failure to observe the proper scope of practice or to follow the requirements for foot and ankle surgery by podiatric medicine licensees.

- 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 sent to interested parties, including the Ohio State Medical Association, Ohio Foot and Ankle Association, and the Ohio Hospital Association on or about October 16, 2023. The rules were also posted on the Medical Board's website.

- 10. 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 a letter from the Ohio Foot and Ankle Association requesting that the rules remain as they currently exist. No other written 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 language in Rule 4731-20-01 is based upon basic human anatomy regarding the ankle joint.

- 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.

No alternative regulations were considered. The rules have been in existence for many years and have been widely accepted in the podiatric medical community. No changes to the current rules are proposed at this time.

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 state agency that regulates podiatric physicians.

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.

Notice of the filing of the no change rules will be sent to licensees and interested parties and posted on the Medical Board’s website. Medical Board staff will be available to address questions that may arise.

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 consists of podiatric physicians.

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 podiatrist must pay a \$225 application fee for the Part I Certification Examination, and a \$425 fee for the written examination. Once receiving the board qualified certification, the physician must pay an annual fee of \$205.00. (See <https://www.abfas.org/become-board-certified/annual-fees> .)

The fee for the Part II certification examination is \$425.00. The fee for the required Foot Surgery Case Review is \$475.00. Once receiving the board certification, the podiatrist must pay an annual fee of \$440.00.

(See <https://www.abfas.org/become-board-certified/annual-fees> .)

Licensure actions against licensees who violate rules 4731-20-01 and 4731-20-02 include administrative actions up to and including permanent license revocation and fines not to exceed \$20,000. See, Section 4731.225, Ohio Revised Code.

- 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 have been in effect for many years and no changes are proposed at this time.

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

The rules set forth education, training, experience, and hospital privileging requirements for podiatric physicians performing foot and ankle surgery to ensure patient safety.

Regulatory Flexibility

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

The rules are uniformly applied to all podiatric physicians performing foot and ankle surgeries, regardless of the size of the business. This is necessary to ensure that all podiatric physicians are compliant with minimal standards of care to ensure patient safety.

- 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?**

Given the potential harm to the public for noncompliance with the rules, any waiver would be inappropriate.

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

The Medical Board provides information regarding newly filed rules on its website and through a newsletter sent via e-mail to licensees. Medical Board staff is available for questions via telephone and e-mail.

4731-20-01

Definition of foot.

"Foot," as used in section 4731.51 of the Revised Code, means the terminal appendage of the lower extremity and includes the ankle joint which consists of the tibial plafond, its posterolateral border (posterior malleolus), the medial malleolus, distal fibula (lateral malleolus) and the talus.

4731-20-02

Surgery: ankle joint.

- (A) A podiatric physician may perform surgery on the ankle joint, when both of the following requirements are met:
- (1) The podiatric physician holds privileges to perform surgery on the ankle joint from one or more of the following entities:
 - (a) A college of podiatric medicine and surgery approved by the board pursuant to section 4731.51 of the Revised Code;
 - (b) A hospital approved by the "Joint Commission" or the "American Osteopathic Association"; or
 - (c) An ambulatory surgical facility approved by the department of health pursuant to its authority under Chapter 3702. of the Revised Code; and
 - (2) The podiatric physician can demonstrate adequate education, training and experience needed to conform to minimal standards of care of similar practitioners under the same or similar circumstances by meeting either of the following criteria:
 - (a) Having attained board qualified status from the "American Board of Foot and Ankle Surgery" and having successfully completed at least a twenty-four month residency in podiatric surgery approved by the "Council on Podiatric Medical Education," or
 - (b) Holding privileges to perform surgery on the ankle joint from an institution meeting criteria under paragraph (A)(1) of this rule, providing that such privileges were granted prior to January 30, 1997.
- (B) A podiatric physician who performs surgery on the ankle joint other than in accordance with all the terms of this rule violates divisions (B)(6) and (B)(20) of section 4731.22 of the Revised Code.