



Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

Carrie Kuruc, Director

Business Impact Analysis

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

Rule Contact Name and Contact Information:

Kimberly Anderson, Chief Counsel, kimberly.Anderson@med.ohio.gov

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

Physician continuing medical education rules

Rule Number(s): 4731-10-10-01, 4731-10-02, 4731-10-03, 4731-10-04, 4731-10-05, 4731-10-06, 4731-10-07, 4731-10-08, 4731-10-09, 4731-10-10, 4731-10-11

Date of Submission for CSI Review: May 26, 2020

Public Comment Period End Date: June 12, 2020

Rule Type/Number of Rules:

New/___ rules

No Change/___ rules (FYR? ___)

Amended/ X rules (FYR? ___)

Rescinded/ X rules (FYR?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.

4731-10-01

- Adds definitions for applicable registration periods for holders of clinical research faculty certificates and certificates of conceded eminence
- Amends or deletes definitions to promote consistency and clarity

4731-10-02

- Makes the rule consistent with the statute by requiring physicians to complete fifty hours of CME and defines the type of activities that are eligible for credit
- Requires one hour of CME on the topic of a licensee's duty to report misconduct under section 4731.224 of the Revised Code pursuant to recommendations from the Governor's working group on reviewing the Medical Board's handling of the investigation involving Richard Strauss recommended the following:

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

CSIPublicComments@governor.ohio.gov

The Medical Board should require that physician continuing education requirements toward maintaining a medical license include training on the duty to report pursuant to Ohio Revised Code § 4731.224, including, as necessary, revising the Medical Board's rules contained in Ohio Administrative Code Ch. 4731-10, "Licensing; Continuing Education."

- Defines the type of CME that must be completed by holders of clinical research faculty certificates, certificates of conceded eminence, and volunteer's certificates

4731-10-03

- Clarifies that the waiver provisions apply to holders of clinical research faculty certificates, certificates of conceded eminence, and volunteer's certificates
- Removes restrictions on the granting of waivers in order to provide the board with more discretion

4731-10-04

- Clarifies the intent of this provision but no substantive change

4731-10-05

- Propose to rescind as provision is now in proposed 4731-10-02(D)

4731-10-06

- Propose to rescind as it reflects the prior process of mailing renewal applications and the use of staggered renewal system.

4731-10-07

- Propose to rescind as the provision has been amended and moved to 4731-10-02(A)(2)

4731-10-08

- Clarifies that that this rule applies to holders of clinical research faculty certificates, certificates of conceded eminence, and volunteer's certificates, and makes other textual changes

4731-10-09

- Propose to rescind as proration will no longer be necessary. Effective October 16, 2019, initial licenses will be issued for a full two years.

4731-10-10

- Propose to rescind as staff believes it is unnecessary considering the other provisions of the rules, and the fact that the total number of CME hours has been reduced from one hundred to fifty. Applicants for restoration are required to prove that CME has been completed within the prior twenty-four months prior to the restoration application, and if an applicant has not, then the

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

CSIPublicComments@governor.ohio.gov

applicant must do so before restoration. As a result, after restoration, licensees have generally met the applicable requirement at the time of the next renewal. It should also be noted that rule currently applies to less than two hundred individuals per year.

4731-10-11 Telemedicine Certificates

- Propose to rescind as telemedicine licenses will be abolished effective October 16, 2019

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.

Statutory authority: 4731.295, 4731.281, 4731.05

Amplifying statutes: 4731.281, 4731.296, 4731.295, 4731.294, 4731.293, 4731.292, 4731.291, 4731.282

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.

5. If the regulation 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)?

Continuing medical education is statutorily required by Revised Code Section 4731.282. The amendment to Rule 4731-10-02 fulfills Governor DeWine's recommendation to include required education on reporting misconduct. In addition, the rules protect the public by ensuring that physicians are up to date on current medical knowledge and procedures.

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

The success of these regulations will be measured by physician licensees completing the requisite number of continuing education hours; the rules being written in plain,

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

CSIPublicComments@governor.ohio.gov

understandable language; licensee compliance with the rules; and minimal questions from the licensees about the proposed rules.

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.

Interested parties that have requested notification of proposed rule changes, including the Ohio Academy of Family Physicians, Ohio State Medical Association, Cleveland Clinic Foundation, Ohio Osteopathic Association, Ohio Foot and Ankle Association, were notified via email on 10/29/19.

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

The Board received three comments. Ann Spicer, Executive Vice-President of the Ohio Academy of Family Physicians and Susan Hubbell, M.D., President of the Ohio State Medical Association objected to the addition of content specific CME to Rule 4731-10-02, OAC. James Young, MD, Chief Academic Officer for the Cleveland Clinic proposed using “credits” rather than “hours” in rules 4731-10-10, 4731-10-02 and 4731-10-08, OAC.

Section 4731.282, Ohio Revised Code, the statute which authorizes the CME rules utilizes the term “hours”, rather than “credits. The specific content in proposed Rule 4731-10-02, OAC, conforms to Governor DeWine’s recommendation to include required education on reporting misconduct.

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?

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

CSIPublicComments@governor.ohio.gov

The proposed rules are not amenable to scientific data.

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?

No alternative regulation was considered because no problems have been encountered with the current rules.

13. 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 rules are performance based.

14. 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 licenses physicians.

15. 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 posted on the Medical Board's website. Medical Board staff members are available by telephone and e-mail to answer questions.

Adverse Impact to Business

16. 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; and

The business community impacted is composed of physician licensees regulated by the Medical Board.

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

The adverse impact is that licensed physicians will be required to expend money for taking mandated continuing medical education.

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

CSIPublicComments@governor.ohio.gov

- 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.

The cost of continuing medical education varies greatly based upon the vendors, ranging from no cost to thousands of dollars, depending on the type and length of the course.

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

It is essential that the Medical Board and the general public is assured that physician licensees are up to date on medical knowledge and procedure, as well as Governor DeWine’s recommendation that licensees are aware of their obligations to report violations of the Medical Practices Act.

Regulatory Flexibility

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

There is no exemption or alternative means based upon the size of the business, as continuing medical education is required by statute. Rule 4731-10-03 does allow for a waiver if the physician is unable to complete the education due to illness, accident, or absence from the state.

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?

Fines for failing to complete continuing medical education are statutory, per Revised Code Section 4731.282.

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

Board staff is available to answer questions regarding the rule. The rules are posted and are available on the Board’s website.

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

CSIPublicComments@governor.ohio.gov