

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: State Medical Board

Regulation/Package Title: Prescribing to self and family; mental or physical impairment

Rule Number(s): 4731-11-08 and 4731-18-01

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Rescinded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.

Rule 4731-11-08 clarifies for physicians, patients, and others situations in which prescribing controlled substances are prohibited.

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Rule 4731-28-01 defines terms relevant to mental or physical impairment as used in specified provisions of the Ohio Revised Code.

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

Rule 4731-11-08 is authorized by Sections 4731.05 and 47321.052 of the Revised Code.

Rule 4731-28-01 is authorized by Sections 4730.07, 4731.05, 4760.19, 4762.19, 4774.11, and 4778.12 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.

Neither rule implements a federal requirement. However, Rule 4731-11-08 is consistent with the federal Controlled Substances Act.

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)?

The public purpose of Rule 4731-11-08 is to prohibit medical practice patterns that would endanger the public. The minimal standards of care require that prescribing decisions be made objectively and based upon medical knowledge and expertise rather than upon relationships.

Rule 4731-28-01 serves the public good by defining terms used in provisions of law that authorize the Medical Board to take action based upon allegations of mental illness or certain types of physical illness.

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

The success of Rule 4731-11-08 will be measured by the number of disciplinary actions taken against licensees who violate it.

The success of Rule 4731-2-8-01 cannot be directly measured as the incidence of mentally or physically impaired licensees is unpredictable.

Development of the Regulation

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7. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.

Both rules were distributed via email to the medical organizations and associations, attorneys, lobbyists for medical related entities, and individuals who have indicated interest in Medical Board rule activities. The recipients include the Ohio State Medical Association, Ohio Osteopathic Association, Ohio Academy of Physician Assistants, Academy of Medicine of Cleveland and Northern Ohio, numerous physicians, lobbyists for a wide variety of medical related organizations, and health care systems.

If applicable, please include the date and medium by which the stakeholders were initially contacted.

The stakeholders were sent the draft rules by email on December 11, 2015.

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

No comments from stakeholders were received on the draft rules.

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?

Rule 4731-11-08 is based upon the language of American Medical Association Code of Ethics Opinion No. 8.19.

Rule 4731-28-01 is based upon the “Policy on Physician Impairment” first adopted by the Federation of State Medical Boards in 1999 and revised in 2011.

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.

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.*

Rule 4731-11-08 is a performance based rule. Rule 4731-28-01 is a definitional 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 agency that is authorized to promulgate rules regulating physicians, physician assistants, massage therapists, cosmetic therapists, anesthesiologist

assistants, acupuncturists, oriental medicine practitioners, radiologist assistants, and genetic counselors.

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.

Rule 4731-11-08 as currently worded has been basis to administratively discipline physicians for prescribing controlled substances to themselves or family members. There is a disciplinary guideline grid to assist the Medical Board in determining the proper discipline for violation of Rule 4731-11-08. However, there is not a discipline that is automatically imposed. The discipline considered in each matter depends upon the facts, mitigating circumstances, and aggravating circumstances. The grid is based upon an overview of the discipline imposed for violations of the rule over a period of time.

Rule 4731-28-01 is a definitional rule. Its application to a licensee first requires assessment, diagnosis, and prognosis by a board-certified physician who is not a member of the Medical Board.

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 is comprised of all licensees of the Medical Board. This includes physicians, physician assistants, massage therapists, cosmetic therapists, anesthesiologist assistants, acupuncturists, oriental medicine practitioners, radiologist assistants, and genetic counselors.

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

As to Rule 4731-11-08, a physician may argue that the rule is an unnecessary restriction on the ability to practice medicine as he/she believes is appropriate.

The nature of the adverse impact from Rule 4731-28-01 is that licensee who is determined to have an inability to practice according to acceptable and prevailing standards of care by reason of mental illness or physical illness may have their license suspended or be put on probation, with conditions to satisfy before probation is terminated. The conditions would most likely include obtain professional treatment. It should be noted, however, that this adverse impact would result when the Medical Board takes an action Section 4731.(B)(19), ORC, even if the rule did not define the terms.

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.

There is no monetary adverse impact on a physician who complies with Rule 4731-11-08.

There is not good data upon which to base a monetary estimate of adverse impact on a licensee who is found to have conditions that fall within the definitions set out in Rule 4731-28-01. The impact depends upon the specific diagnosis, current medical condition, treatment provider chosen by the licensee, the licensee’s compliance with the treatment program determined by the treatment provider, and the length of licensure suspension, if any, and the length of and activities required during any probationary time that might be imposed on the licensee.

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

For Rule 4731-11-08, the practice of medicine requires that a prescriber of controlled substances make the prescriptive decision based on objective criteria. As stated in AMA Code of Ethics Opinion 8.19, professional objectivity may be compromised when an immediate family member or the physician is the patient; the physician’s personal feelings may unduly influence his or her professional medical judgment, thereby interfering with the care being delivered; physicians may fail to probe sensitive areas when taking the medical history or may fail to perform intimate parts of the physical examination; patients, such as minor children, may feel uncomfortable disclosing sensitive information or undergoing an intimate examination when the physician is an immediate family member; and when treating themselves or immediate family members, physicians may be inclined to treat problems that are beyond their expertise or training. In addition, the Medical Board has disciplined physicians for writing controlled substance prescriptions to their spouses when the spouses were concurrently receiving controlled substances from their personal physicians.

Rule 4731-28-01 is needed to define terms to clarify the terms used in Section 4731.22(B)(19), ORC, to clarify for licensees, attorneys, health care entities, and the public the types of conditions that may result in a disciplinary action under that statutory provision.

Regulatory Flexibility

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

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There is no exemption or alternative means of compliance for small businesses. Many physicians practice either as sole practitioners or in a practice with a small number of other physicians. Patients deserve the same quality of care whether the physician practices as a sole practitioner or in a major health care facility.

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 rules do not require that reports be submitted to the Medical Board.

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

Medical Board staff members respond promptly to inquiries concerning Medical Board statutes and rules. When questions are numerous, guidance documents are created and posted on the Medical Board's website.

4731-11-08

Utilizing controlled substances for self and family members.

- (A) Accepted and prevailing standards of care presuppose a professional relationship between a patient and physician when the physician is utilizing controlled substances. By definition, a physician may never have such a relationship with himself or herself. Thus, a physician may not self-prescribe or self-administer controlled substances. This paragraph does not prohibit a physician from obtaining a schedule V controlled substance for personal use in conformance with state and federal laws, in the same manner that a non-physician may obtain a schedule V controlled substance.

- (B) Accepted and prevailing standards of care require that a physician maintain detached professional judgment when utilizing controlled substances in the treatment of family members. A physician shall utilize controlled substances when treating a family member only in an emergency situation which shall be documented in the patient's record.

- (C) For purposes of this rule, "family member" means a spouse, parent, child, sibling or other individual in relation to whom a physician's personal or emotional involvement may render that physician unable to exercise detached professional judgment in reaching diagnostic or therapeutic decisions.

4731-28-01

Mental or physical impairment.

For the purposes of division (B)(4) of section 4730.25 of the Revised Code, division (B)(19) of section 4731.22 of the Revised Code, division (B)(5) of section 4760.13 of the Revised Code, division (B)(5) of section 4762.13 of the Revised Code, **and** division (B)(5) of section 4774.13 of the Revised Code, [and division \(B\)\(5\) of section 4778.14 of the Revised Code](#), the following definitions apply:

- (A) "Mental illness" includes, but is not limited to, mental disorder; and
- (B) "Inability to practice according to acceptable and prevailing standards of care by reason of mental illness or physical illness, including, but not limited to, physical deterioration that adversely affects cognitive, motor, or perceptive skills", includes inability to practice in accordance with such standards without appropriate treatment, monitoring, or supervision.