

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: State Medical Board of Ohio

Regulation/Package Title: Massage Therapy, Notice of Meetings, Use of OARRS

Rule Number(s): 4731-1-24; 4731-1-25; 4731-7-01; 4731-11-11

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Rescinded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 4731-1-24 is a new rule proposed under Section 4731.155 of the Revised Code, effective September 15, 2014. The rule establishes renewal and continuing education requirements for massage therapists, including provisions related to licensees having military service.

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Rule 4731-1-25 is a new rule proposed in compliance with Section 5903.03 of the Revised Code, concerning any military training programs, military primary specialties, or lengths of service applicable to the educational and experience requirements for licensure as a cosmetic therapist or massage therapist.

Rule 4731-7-01, which sets out the methods by which a person may determine the time and place of all regularly scheduled meetings of the Medical Board, is proposed to be amended. The proposed amendments clarify and simplify the language. This rule was included in the CSI package filed on January 8, 2015. However, an incorrect version of the proposed amendments was included in that filing and it is being re-submitted with the correct language.

Rule 4731-11-11 is proposed to be amended by more than fifty percent and, therefore, the current rule is proposed to be rescinded and the amended language adopted as a new rule. The rule establishes the standards and procedures for a physician's review of the Ohio Automated Rx Reporting System (hereinafter "OARRS"). The amendments reflect the provisions of Section 4731.055 of the Revised Code, effective April 1, 2015, and the state policy that physicians should utilize OARRS information when prescribing controlled substances. The rule incorporates the exceptions contained in Section 4731.055 of the Revised Code.

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

Proposed Rule **4731-1-24** is authorized by Sections 4731.05, 4731.15, 4731.155, 4743.04, and 5903.10 of the Revised Code.

Proposed Rule **4731-1-25** is authorized by Section 5903.03 of the Revised Code.

Proposed Rule **4731-7-01** is authorized by Sections 121.22 and 4731.05 of the Revised Code.

Proposed Rule **4731-11-11** is authorized by Sections 4731.05 and 4731.055 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.

None of the proposed rules are being adopted to implement a federal requirement or to enable the state to obtain or maintain approval to administer or enforce a federal law or to participate in a federal program.

4. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

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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 provisions of proposed **Rule 4731-1-24** formalize the staggered renewal periods for massage therapists based upon the first letter of the last name of licensees as is authorized in Section 4731.15(C)(2) of the Revised Code; establishes continuing education requirements for massage therapy licensure renewal, as authorized in Section 4731.155 of the Revised Code; and implements for massage therapists the mandate in Section 5903.10 of the Revised Code for expired licenses to be renewed without penalty and re-examination if the license was not renewed because of the licensee's or licensee's spouse's service in the armed forces or a reserve component of the armed forces and certain other requirements are met.

The provisions of proposed Rule **4731-1-25** implement the requirements of Section 5903.03 of the Revised Code that a licensing agency determine which military training programs, military primary specialties, and lengths of service are substantially equivalent to or exceed the educational and experience requirements for each license type issued. The rule addresses this determination for both cosmetic therapy and massage therapy.

Proposed amended Rule **4731-7-01** implements the mandate of Section 121.22 of the Revised Code, that each agency establish a reasonable method whereby any person may determine the time and place of all regularly scheduled meetings and the time, place, and purpose of all special meetings.

The proposed new Rule **4731-11-11** amends current Rule 4731-11-11 to implement the authorization granted to the Medical Board in Section 4731.055 of the Revised Code to promulgate rules to establish standards and procedures to be followed by a physician regarding the review of patient information available through OARRS when opioid analgesics or benzodiazepines are prescribed. The amendments also clarify and simplify the current standards for the review of patient information available through OARRS when prescribing controlled substances that are not opioid analgesics or benzodiazepines. The rule facilitates the goal of the executive agencies and legislature for wider utilization of OARRS by Ohio physicians in the prescribing of controlled substances in Ohio.

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

The success of **Rule 4731-1-24** will be measured by the efficiency of the renewal process for massage therapists under the staggered renewal scheme, the availability of approved continuing massage therapy education, and the ease with which expired massage therapy licenses are

renewed if the license was not renewed timely due to the licensee's or licensee's spouse's service in the armed forces.

Rule 4731-1-25 will be a success if new information is not brought forward that contradicts the language of the rule.

The success of **Rule 4731-7-01** cannot be reliably measured, but should provide the general public and licensees with more easily understood language describing how they can determine the time and place of Medical Board meetings.

The success of **Rule 4731-11-11** will be measured by the increase in the utilization of OARRS by physicians. Statistics on OARRS usage are available to the Medical Board.

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.

Proposed rules **4731-1-24** and **4731-1-25** were developed with the input of the members of the massage therapy community elicited through conference call discussions with Medical Board staff members. Participants included practicing massage therapists and massage therapy educators. Telephone conferences were held on August 21, 2014, October 16, 2014, and March 24, 2015.

In October 2014, proposed **Rule 4731-7-01** was one of several rules distributed to such organizations as: Ohio State Medical Association, Ohio Osteopathic Medical Association, Ohio Academy of Family Physicians, Academy of Medicine of Cleveland and Northern Ohio, all county and city medical associations, Ohio Hospital Association, attorneys who represent respondents before the Medical Board, and other individuals and groups who receive notice of all Medical Board rules activities. No comments were received on the proposed amended rule.

The proposed changes to **Rule 4731-11-11** reflect the mandates of Section 4731.055 of the Revised Code, effective April 1, 2015, the need to harmonize the requirements of Section 4731.055 with those in the current version of the rule, and the need to clarify the expectations for physicians who prescribe controlled substances. The language of the proposed rule was submitted for interested party comments in January 2015. Interested parties included, but were not limited to: Ohio State Medical Association, Ohio Osteopathic Association, Ohio

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Academy of Family Physicians, Academy of Medicine of Cleveland/Northern Ohio Medical Association, Ohio Hospitals Association, various healthcare attorneys, and physicians who have asked to be notified of Medical Board rule activities. Comments were received from the Ohio Board of Nursing and from two physicians. Subsequently, the Medical Board staff spoke to a meeting of the Ohio Osteopathic Association about the rule and also worked with the staffs of the nursing and dental boards so that the requirements for each set of licensees would be similar or the same.

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

Proposed rules **4731-1-24 and 4731-1-25** were discussed during telephone conferences of the Massage Therapy Advisory Committee (“MTAC”), a non-statutorily created group of massage therapists organized to provide input to the Medical Board on massage therapy matters. Participants in the calls also included other massage therapists, massage therapy educators, and representatives of the American Massage Therapy Association – Ohio Chapter (“Association”). For several years the members of MTAC and the Association have lobbied the Medical Board to require twenty-four hours of continuing education for massage therapy licensure renewal. Most, but not all, participants in the telephone conferences supported adding a requirement for massage therapists to complete continuing education as a requirement for license renewal. The objectors indicated that the cost of attending courses would be a hardship. There were differing opinions concerning the number of hours that should be required, with some arguing that six hours per two years are sufficient. However, the association and most participants agreed that twenty-four hours are appropriate. A few participants objected to requiring human trafficking awareness training. However, the Medical Board staff explained that the Governor’s direction is to incorporate awareness training for all licensees.

For Rule 4731-7-01, no comments were received on the proposed amended rules.

The one physician who commented on proposed **Rule 4731-11-11** expressed opposition to the requirement to check OARRS every ninety days when prescribing opioid anagesics or benzodiazepines. However, the requirement is set in Section 4731.055 of the Revised Code. At first, the language proposed deleted the “red flags” that are included in the current rule. However, input from the Nursing Board included the suggestion that the “red flags,” which are indications of possible drug diversion or addiction, should be included. That suggestion was adopted and several of the red flags suggested by the National Association of Boards of Pharmacy are included in the current proposed rule. The other physician who

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submitted comments requested that physicians who only prescribe ADHD medications be exempt from ever having to check OARRS. However, the requirement remains in the proposed rule because law enforcement and the Pharmacy Board have indicated that in some cases ADHD medications are diverted.

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 4731-1-24 was developed to reflect the number of hours of continuing education required by the American Massage Therapy Association and the National Certification Board for Therapeutic Massage and Body Work, and the encouragement of the American Massage Therapy Association – Ohio Chapter. The recommendation of the Federation of State Massage Therapy Boards that six hours per year be completed was considered but not adopted because it does not provide sufficient opportunities for professional growth.

Rule 4731-1-25 required a review of military training programs.

Scientific data was not required to develop **Rule 4731-7-01**.

Rule 4731-11-11 reflects the mandates of Section 4731.055 of the Revised Code, effective April 1, 2015, and the policy of the executive agencies and legislature to encourage the increased use of OARRS as a means to deter prescription drug diversion and overuse. The rule also reflects several of the red flags identified in a recent document promulgated by National Association of Boards of Pharmacy [NABP], *Stakeholders' Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances* [Guidelines]. The document was the result of a two year process involving pharmacy, medical, and industry stakeholders and is supported by the following: American Academy of Family Physicians, American College of Emergency Physicians, American Medical Association, American Osteopathic Association, American Pharmacists Association, American Society of Anesthesiologists, American Society of Health-System Pharmacists, Cardinal Health, CVS Health, Healthcare Distribution Management Association, National Association of Chain Drug Stores, National Community Pharmacists Association, Pharmaceutical Care Management Association, Purdue Pharma L.P., Rite Aid, and Walgreen Company. See: <https://www.nabp.net/news/nabp-stakeholders-release-consensus-document-on-the-challenges-and-red-flag-warning-signs-related-to-prescribing-and-dispensing-controlled-substances>.

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?

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No regulatory alternatives were considered for the proposed rules. Various provisions of the Ohio Revised Code require that the rules be promulgated. Moreover, it is clear under Ohio law that a standard to which all licensees will be held must be promulgated as a rule or the standard is not enforceable. In order to facilitate the state policy of encouraging use of OARRS, therefore, Rule 4731-11-11 includes red flags that require the physician to run an OARRS check when prescribing a controlled substance.

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.

The proposed rules are performance based to the extent possible. **Rule 4731-1-24** requires continuing education, but only specifies the subject matter for three of the required twenty-four hours of continuing education. It also provides numerous options for satisfying the requirement.

It is not possible to have a performance based regulation for **Rule 4731-1-25**.

Rule 4731-7-01 is performance based in that it provides options by which persons may determine the time and place of all meetings of the Medical Board.

Rule 4731-11-11 is performance based to the extent possible. The rule requires the physician to take into account various factors as part of the decision whether to prescribe a controlled substance that is reported to OARRS, but does not dictate the weight to be attributed to the various factors. While the rule specifies that OARRS must be checked in certain situations, it does not specify whether the physician must personally check OARRS or might delegate the check to an employee who is properly registered with the Board of Pharmacy. The rule does not prohibit the prescribing of controlled substances but instead requires the physician to document the reasons for the prescribing decision.

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 regulates the affected parties.

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.

In recent years the Medical Board has had success with issuing guidance documents, including Frequently Asked Questions summaries, and will do so for Rules 4731-1-24 and 4731-11-11.

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

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 business community affected by **Rule 4731-1-24** is composed of massage therapists. The application fee for a massage therapy license is \$150. The biennial renewal fee is \$100. Continuing education courses may be free, provided by the employer, free with attendance any professional society annual meetings, or require a registration fee. Examples of the range of prices include \$30 for three hours of on-line coursework (<https://www.amtamassage.org/courses/listing.html?CategoryId=3>) to \$450 for 24 hours of credit (<http://hai.edu/massage-for-people-with-cancer/>).

The business community impacted by **Rule 4731-1-25** is made up of massage therapists and cosmetic therapists. There is no cost for massage therapists or cosmetic therapist to comply with Rule 4731-1-25.

There is no cost to the public or the press to comply with **Rule 4731-7-01**. Although paragraph (C) mimics Section 121.22, Ohio Revised Code, in stating that the Medical Board may assess a reasonable fee for notices of meetings mailed to persons, it is the policy of the Medical Board to charge the \$.05 per page fee only for 100 pages or more. Meeting notices are typically one or two pages.

Physicians and entities that employ physicians compose the community impacted by **Rule 4731-11-11**. The cost for physicians to comply with Rule 4731-11-11 is the cost of the physician either signing up and checking OARRS themselves or filling out the paperwork for a staff person

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to be capable of checking OARRS, and the cost for the physician or staff to actually check OARRS. The cost depends on the salary of the physician and rate of pay of the employee.

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

For numerous years, the massage therapy community has lobbied for a continuing education requirement. Continuing education fosters protection of the public by encouraging licensees to keep current on procedures and treatments and reinforcing core profession competencies. The costs to individual massage therapists that will arise due to Rule 4731-1-24 are in line with the costs for continuing education for other professions.

The regulatory intent of Rule 4731-11-11 justifies the adverse impact because of the state policy to encourage the use of OARRS by physicians who prescribe controlled substances. According to the Governor's Opioid Action Team website, prescription drugs are involved in most unintentional drug overdoses and have largely driven a rise in overdose deaths. Prescription pain medications (opioids) and multiple drug use are the largest contributors to the epidemic. <http://www.opioidprescribing.ohio.gov/>. In enacting Section 4731.055 of the Revised Code, the General Assembly and Governor agreed that the use of OARRS should be mandatory when prescribing opioid analgesics and benzodiazepines. The American Society of Addiction Medicine recommends that use of prescription monitoring programs be part of medication management for controlled substance prescriptions.

<http://www.asam.org/docs/publicity-policy-statements/1-counteract-drug-diversion-1-12.pdf>.

Health related press stories report the diversion of stimulants legitimately prescribed for attention deficient conditions by college students for non-medical purposes. For example see: <http://add.about.com/od/treatmentoptions/fl/Diversion-of-ADHD-Medication-on-College-Campuses.htm>. Law enforcement agencies have reported concerns about the diversion of prescribed non-opioid, non-benzodiazepine controlled substances to the Medical Board. Accordingly, the addition of the red flags provisions to the rule is justified to encourage the use of OARRS.

Regulatory Flexibility

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

The proposed rules do not provide any exemptions or alternative means of compliance for small businesses. For purposes of Rule 4731-1-24, each massage therapist must be considered to be a small business. For purposes of Rule 4731-11-11, the benefit of checking OARRS in the battle against drug diversion and prescription drug abuse is not relative to the size of the medical practice.

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?

Rule 4731-1-24 requires a license massage therapist to maintain continuing education documentation for submission to the Medical Board if the massage therapist is audited for compliance with the continuing education requirement. However, any fine or penalty imposed would be for the failure to complete required continuing education, not for failure to maintain documentation.

Rule 4731-11-11 requires a physician to document in the patient record various factors and decisions concerning the prescribing of controlled substances. A waiver of penalties for failure to document has the potential to cause serious harm to the public interest in that the documentation is required to establish that the controlled substances were prescribed for an appropriate medical reason in the context of a legitimate physician-patient relationship.

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

18. The rules will be posted on the Medical Board's website, along with appropriate guidance documents. Medical Board staff members are available by telephone and e-mail to answer questions. Medical Board staff members also give presentations to groups and associations who seek an update on physician practice regulations.