

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: State Medical Board of Ohio

Regulation/Package Title: Rules regarding Military Service, Limited Branches, Medical Board meetings, and Controlled Substances

Rule Number(s): 4731-1-02, 4730-1-06.1, 4731-24-05, 4762-1-01, 4774-1-02.1, 4778-1-02.1, 4731-6-35, 4731-7-01, 4731-9-01, 4731-11-02, 4731-11-03, 4731-11-04, 4731-11-04.1, 4731-11-05, and 4731-11-07

Date: January 8, 2015

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☐ Rescinded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.

Current rule **4731-1-02** sets out general provisions applicable to the limited branches of medicine, namely cosmetic therapy and massage therapy. The proposed amendments use

more active tense, strike unnecessary words, and change the national organization's code of ethics that will serve as the code of ethics for cosmetic therapists.

Proposed rules **4730-1-06.1**, **4731-24-05**, **4762-1-01**, **4774-1-02.1**, **4778-1-02.1**, and **4731-6-35** consider military education, skills training, and service for equivalency for licensure and continuing education purposes; permit renewal of expired licenses without a penalty if the license expired while the licensee was on active duty; grant licensees who are service members returning from service additional time to complete continuing education requirements for renewal; and set the process by which applications from service members or veterans and their spouses will be identified and expedited.

Proposed rule **4731-7-01** sets out the methods by which a person may determine the time and place of all regularly scheduled meetings of the Medical Board. The proposed amendments clarify and simplify the language.

Proposed rule **4731-9-01** sets the standards for persons who wish to broadcast or record meetings of the Medical Board and designates the approved minutes of the Medical Board meetings as the official record of the proceedings. The amendments clarify the rule. Paragraph (D) is added to include court reporters as a means of recording.

The proposed amendments to current rules **4731-11-02**, **4731-11-03**, and **4731-11-05** are interrelated. The provisions of the three rules are proposed to be consolidated where possible, resulting in the proposal to rescind current rule 4731-11-05. The three rules are applicable to physicians and podiatric physicians, and are applicable to physician assistants pursuant to rule **4730-1-07**, Ohio Administrative Code. Current rule **4731-11-02** generally addresses overall requirements that relate to the utilization of controlled substances. The proposed amendments to **4731-11-02** include deleting paragraph (B), which relates to restrictions on the use of cocaine hydrochloride, and moving that provision to rule **4731-11-03**, which has more similar subject matter. In addition, the penalty provisions in paragraph (E) are restructured into a more readable outline format. Because the current rule will be amended by more than fifty percent, the current rule is proposed to be rescinded and the "amended" rule proposed as a new rule, pursuant to LSC Rule Drafting Manual, Item 4.3.1.

Current rule **4731-11-03** sets limitations on the utilization of schedule II controlled substance stimulants, for example, methamphetamine, dextroamphetamine, methylphenidate, etc. Proposed amendments to rule **4731-11-03** include adding the language concerning cocaine hydrochloride currently in rule **4731-11-02** and also adding the restrictions on utilizing anabolic steroids (performance enhancing drugs) currently found in rule **4731-11-05**. The proposed revisions would result in the consolidation of prohibitions/restrictions relating to schedule II controlled substance stimulants, cocaine hydrochloride, and performance

enhancing steroids into one rule. In addition, the relocation of the restrictions on performance enhancing drugs from **4731-11-05** to **4731-11-03** would permit the rescission of **4731-11-05**. Because the current rule will be amended by more than fifty percent, current rule 4731-11-03 is proposed to be rescinded and the “amended” rule proposed as a new rule, pursuant to LSC Rule Drafting Manual, Item 4.3.1.

Current rule **4731-11-04** regulates the utilization of schedule III and IV controlled substance stimulants for weight loss purposes that have been FDA approved “for a few weeks” (“short term anorexiant”). The proposed amendments include a new requirement for physicians to access the Ohio Automated Prescription Reporting System (OARRS) to discern the controlled substance prescription history of potential weight loss patients prior to prescribing, dispensing or otherwise utilizing short term anorexiant. In addition, the amendments include the use of an outline format in more portions of the rule to improve readability, replacing the words “thorough examination” with “appropriate examination,” and adding dietitians as appropriate sources of information regarding a patient’s prior treatment for weight loss. Finally, portions of current rule **4731-11-04** that refer to the use of controlled substance medications that in the past were FDA approved for “weight loss and maintenance of weight loss” were deleted as those medications are no longer on the market. Proposed amended rule **4731-11-04** relates strictly to the use of short term anorexiants. Because the current rule will be amended by more than fifty percent, the current rule is proposed to be rescinded and the “amended” rule proposed as a new rule, pursuant to LSC Rule Drafting Manual, Item 4.3.1.

Proposed new rule **4731-11-04.1** was developed to regulate the use of new FDA approved controlled substance medications for chronic weight management (long term anorexiants). Separating the regulations for long term anorexiants from the regulations for short term anorexiants will provide clearer guidance to Medical Board licensees regarding controlled substance weight loss medication utilization.

Current rule **4731-11-05** is proposed to be rescinded because its provisions have been relocated to proposed amended rule **4731-11-03**.

Current rule **4731-11-07** provides an exception to the regulation of controlled substances used in research settings when the specified conditions are met. The proposed language adds an additional option for meeting the exemption for clinical research when the research is not conducted under the auspices of a medical school. Because the current rule will be amended by more than fifty percent, the current rule is proposed to be rescinded and the “amended” rule proposed as a new rule, pursuant to LSC Rule Drafting Manual, Item 4.3.1.

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

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Proposed amended rule **4731-1-02** is authorized by Sections 4731.15 and 4731.22(B)(18) of the Revised Code.

Proposed rules **4730-1-06.1, 4731-24-05, 4762-1-01, 4774-1-02.1, 4778-1-02.1**, are authorized for adoption by Section 5903.03 of the Ohio Revised Code, which requires each licensing board or commission to adopt rules identifying substantial military equivalents for its licensing education and experience requirements as well as waiver of late license renewal fees and extensions of time to complete continuing education requirements for licensure.

Proposed rule **4731-6-35** is authorized by Section 5903.04 of the Ohio Revised Code, effective September 16, 2014, which requires each licensing agency to adopt rules to set a process for identifying and expediting applications received from military personnel or veterans or the spouses of a service member or veteran.

The above rules are also authorized under the general rule making authority found in Sections 4730.07, 4731.05, 4760.19, 4762.19, 4774.11, and 4778.12, Ohio Revised Code.

Proposed rule **4731-7-01** is authorized by Sections 121.22 and 4731.05 of the Ohio Revised Code. Proposed rule **4731-9-01** is authorized by Section 4731.05, Ohio Revised Code.

Rules **4731-11-02, 4731-11-03, 4731-11-04, 4731-11-04.1, 4731-11-05, and 4731-11-07** are authorized by Section 4731.05, Ohio 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.

The proposed rules do not implement a federal requirement.

- 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)?**

Rule **4731-1-02** carries out the Medical Board's duty to regulate the practice of the limited branches of medicine (namely cosmetic therapy and massage therapy) as required by Section 4731.15 of the Revised Code. Section 4731.22(B)(18) of the Revised Code states that the code of ethics of a national association of the profession constitutes the code of ethics for Ohio licensees, and is therefore applicable to the limited branches of medicine pursuant to Section 4731.20 of the Revised Code. The rule is necessary to specify the code of ethics

appropriate to the professions of cosmetic therapy and massage therapy so that those licensees will be notified of the standard to which they will be held.

Proposed rules **4730-1-06.1, 4731-24-05, 4762-1-01, 4774-1-02.1, and 4778-1-02.1** are required by Section 5903.03, Ohio Revised Code. Proposed rule **4731-6-35** is required by Section 5903.04, Ohio Revised Code. They are intended to lead to increased employment opportunities among Ohioans who have served in the military by considering relevant military education, skills training, and service in the professional licensure process to establish the applicant's competency and sufficiency of education and training needed for safe practice. The public purpose of the proposed rules is to recognize a veteran's education and experience obtained in the military that is substantially equivalent to or exceeds training and education required for professional licensure. In addition, the proposed rules are intended to reduce demands on members of the armed forces returning from service by expediting their application processing time, extending the time period for fulfilling continuing educational requirements, and providing for a waiver of a late fee for renewing a license past the deadline date.

The purpose of rule **4731-7-01** is to implement the mandate of Section 121.22, Ohio 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. Rule **4731-9-01** has a related purpose, in that it notifies persons that recording the Medical Board's meetings is permissible within certain parameters, but that the approved minutes of the meeting will constitute the official record of the proceedings.

Proposed rules **4731-11-02, 4731-11-03, 4731-11-04, 4731-11-04.1, 4731-11-05, and 4731-11-07**, focus on the issues related to the utilization of controlled substances by licensees of the Medical Board. Ohio has seen exploding numbers of prescriptions for controlled substances that can feed illegal diversion and abuse of those medications. The Medical Board's goal in proposing the new and amended rules was to balance the needs of those Ohioans who need controlled substances for legitimate medical purposes against the need to limit controlled substance access in order to reduce diversion and addiction. The proposed rules are intended to strike the proper balance in that approach.

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

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The success of rule **4731-1-02** cannot be reliably measured, but should provide limited practitioners with more easily understood language and an up to date, identifiable and accessible code of ethics for cosmetic therapists.

Regarding proposed rules **4730-1-06.1**, **4731-24-05**, **4762-1-01**, **4774-1-02.1**, **4778-1-02.1**, and **4731-6-35**, the State Medical Board of Ohio will track the number of veterans and their spouses who apply for licensure and will determine the expediency to which licensure is received in comparison with non-veteran applicants. The number of persons applying for an extension of time for completion of continuing education and/or a late renewal without a monetary penalty will also be tracked. The success of these regulations will be measured by a reduced processing time for military personnel or veterans or their spouses, military service and education credited towards licensure eligibility, and the maintaining of licensure by service personnel and veterans.

The success of proposed rules **4731-7-01** and **4731-9-01** 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 as well as the use of recording devices for Medical Board meetings.

The success of proposed regulations, **4731-11-02**, **4731-11-03**, **4731-11-04**, **4731-11-04.1**, **4731-11-05**, and **4731-11-07** will be measured by licensee compliance with the rules and low incidence of diversion of the pertinent drugs being traced back to physician prescriptive practices.

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.

The proposed amendments to **4731-1-02** were sent to interested parties, including the Cosmetic Therapy Association of Ohio, in October 2014. No comments on this rule were received, and at its November 2014 meeting, the Medical Board approved the proposed rule for filing with CSI. However, the Cosmetic Therapy Association of Ohio subsequently suggested that the national association whose code of ethics will constitute the code of ethics for Ohio licensees be changed. As a result, at its December 2014 meeting, the Medical Board amended the rule to reflect the association's comment.

Military service rules

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Proposed rules **4731-24-05**, **4762-1-01**, **4774-1-02.1**, and **4778-1-02.1**, were e-mailed to interested parties, including the associations and persons involved in supporting the original licensing bill and/or determining the profession's scope of practice, in July 2014. Rule **4730-1-06.1** was reviewed by the Physician Assistant Policy Committee on September 9, 2014. Rule **4731-24-05** was sent to the Academy of Anesthesiologist Assistants on July 15, 2014. Rule **4762-1-01** was sent to the Acupuncture and Oriental Medicine Advisory Panel, a member of which represents the Acupuncture and Oriental Medical Association, on July 15, 2014. Rule **4774-1-02.1** was sent to individuals who had identified themselves as interested in the regulation of radiologist assistants, including a representative of the Ohio State Radiologist Society. Rule **4778-1-02.1** was sent to genetic counselors and other persons who were key to enactment of Chapter 4778, Ohio Revised Code.

Rules circulated in October 2014

In October 2014, proposed Rules **4731-7-01**, **4731-9-01**, **4731-11-02**, **4731-11-03**, and **4731-11-05** were 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 rules.

Proposed amended rule 4731-11-04 and new rule 4731-11-04.1

Regarding proposed amended rule **4731-11-04** and proposed new rule **4731-11-04.1**, over a period of several years the Medical Board collected input on current rule 4731-11-04 from physicians who specialize in treating patients for weight loss. Rule 4731-11-04 is applicable to prescribing controlled substances approved by the FDA for weight loss for a few weeks ("short term anorexiant"). The phrase "for a few weeks" is defined in the rules as twelve weeks. In Summer 2013, Medical Board staff members held conversations with physicians, the Pharmacy Board, and drug representatives concerning Rule **4731-11-04** and its application to a new class of controlled substances for chronic weight management, for which the FDA approved labeling sets no time limit for use. Discussion with staff members of the Pharmacy Board and, in June, July, and August 2013, the pharmaceutical companies who make the two new drugs, Vivus (Qsymia™) and Esai, Inc. (Belviq™), highlighted the differences between the new drugs and the short term anorexiant that are regulated under rule **4731-11-04**. With input of the pharmaceutical companies, in August 2013 the Medical Board adopted a guideline for physician prescribing of Qsymia™ and Belviq™ within the parameters of rule **4731-11-04**, as an aid during the time required to amend Rule **4731-11-04**.

In December 2013, the Medical Board sent an e-mail blast to all physicians for whom it has an e-mail address to solicit comments on current Rule **4731-11-04**. The Medical Board received over 40 comments, approximately half of which were in favor of the current rule wording or requested further regulation, and about half of which wanted reduced or no regulation of controlled substance anorexiant. Several commenters suggested requiring prescribers to access OARRS concerning the potential patient's controlled substance prescription history prior to prescribing controlled substance anorexiants to the potential patient.

At the January 9, 2014 meeting of the Medical Board, the two pharmaceutical companies made informative presentations to the Medical Board. At its February 2014 meeting, the Medical Board gave direction to staff for drafting amendments to Rule **4731-11-04** based upon comments received and the pharmaceutical company presentations. An amended rule was presented to the Policy Committee of the Medical Board in May 2014. However, the memo accompanying the amended rule pointed out that as staff strived to write the rule covering two very different classifications of weight loss drugs it had become apparent that two separate rules would be easier to follow. The Medical Board authorized the creation of a new rule that became **4731-11-04.1**, to be applicable to the new drugs for chronic weight management. For purposes of amending Rule 4731-11-04, the Medical Board approved additional research on the diversion of, and addiction to, short term anorexiants in bordering states having less restrictive rules.

In June 2014 proposed new rule **4731-11-04.1** was sent to interested parties for comment. Interested parties included: 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, persons who had submitted comments on Rule **4731-11-04** in December 2013 – January 2014, Ohio Hospital Association, Ohio Academy of Nutrition and Dietetics, State Pharmacy Board, and individuals and groups who receive notice of all Medical Board rules activities. Twenty-one comments were received. Review was also completed by the Physician Assistant Policy Committee. The draft rule was revised subsequent to comments, and in September 2014 was approved by the Medical Board for filing with CSI.

Work continued on possible amendments to Rule **4731-11-04** based on comments already received and further research on the statistics for diversion/abuse of the short term anorexiants in Kentucky. The Medical Board approved the current wording for amending Rule **4731-11-04** at its November 2014 meeting.

Rule 4731-11-07

Rule **4731-11-07** provides an exception to compliance with all the other rules in Chapter 4731-11, OAC, for research studies involving controlled substances that meet the requirements of the rule. The proposed amendments to Rule **4731-11-07** resulted from communications with the pharmaceutical company Esai, Inc., Quorum Review IRB, and physicians interested in participating in a research study of the cardiovascular effects of Belviq™. The study was to be conducted under the auspices of Quorum Review IRB (“Quorum”), an independent Investigational Review Board (“IRB”), which meant that the study did not meet the criteria specified in the current rule. Medical Board staff worked with Esai, Quorum, and the numerous Ohio physician researchers to find a way for the study to meet current criteria and to solicit suggestions for amending the rule. The proposed amendments reflect those discussions.

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

The only comment received concerning proposed rule **4731-1-02** was from the Cosmetic Therapy Association of Ohio. It suggested that the proposed national professional organization originally named in paragraph (D) of the rule be changed to The Society for Clinical and Medical Hair Removal, Inc. The suggestion was adopted by the Medical Board at its December 2014 meeting and the proposed language revised as presented in this filing.

All of the interested parties who responded concerning draft rules **4730-1-06.1**, **4731-24-05**, **4762-1-01**, **4774-1-02.1**, and **4778-1-02.1** were supportive of the language. The Physician Assistant Policy Committee suggested amendments to paragraph (B)(1) of proposed rule **4730-1-06.1** to clarify that persons in the armed forces may complete physician assistant education at a program which meets the licensing eligibility requirements, and that suggestion was adopted by the Medical Board and is included in the proposed rule. However, the Medical Board has always recognized the physician assistant education that is completed in the armed forces.

As to proposed rules **4731-11-04**, **4731-11-04.1**, and **4731-11-07**, please see the discussion under “Development of the Regulation.”

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?

Scientific data is not applicable to proposed rules **4730-1-06.1**, **4731-24-05**, **4762-1-01**, **4774-1-02.1**, **4778-1-02.1**, and **4731-6-35**. However, the Medical Board performed research within the websites for the U.S. Army, Air Force, Marines, Coast Guard, and Navy in

February, May, and June 2014, prior to drafting the proposed rules. Drafts of the proposed rules were then sent via e-mail to interested parties representing physician assistants, anesthesiologist assistants, acupuncturists, oriental medicine practitioners, radiologist assistants, and genetic counselors. The draft of proposed rules **4730-1-06.1** and **4731-6-35** were also reviewed by the Physician Assistant Policy Committee of the Medical Board.

After conducting research, the State Medical Board of Ohio determined that there are no military programs of training, military primary specialties, or lengths of service that are substantially equivalent to or exceed the educational and experience requirements for licensure as an anesthesiologist assistant (proposed rule **4731-24-05**); an acupuncturist or oriental medicine practitioner (proposed rule **4762-1-01**); a radiologist assistant (proposed rule **4774-1-02.1**); or a genetic counselor (proposed rule **4778-1-02.1**). The military training programs for physician assistants meet the educational requirements for licensure and are already accepted for Ohio licensure (proposed rule **4730-1-06.1**).

Rules **4731-7-01** and **4731-9-01** are not amenable to scientific data. They are based on open government balanced with the need for efficient administration.

For proposed rule **4731-11-04**, which regulates the prescribing of controlled substance short term anorexiant for weight loss, the requirements are based upon the FDA's determination that the drugs have addiction potential, therefore placing them in the controlled substance category. Also provisions of the rule prohibiting physicians from prescribing to patients with less than the required body mass index and the requirement that the drug be prescribed for only a short term are based upon the FDA approved packaging for the drugs. The requirement that OARRS be checked before prescribing is based upon the state-wide effort to reduce inappropriate controlled substance prescribing and drug diversion.

In addition, the requirements for the physician to meet personally with the patient and for the patient to have a holiday from the drug after six months of use is supported by the statistics showing higher incidences of abuse and diversion under the less restrictive rules in Kentucky. Research on Kentucky's experience with controlled substance short term anorexiant revealed enlightening information. Kentucky's rules regarding the utilization of controlled substance short term anorexiant are much more lax than Ohio's. Even though Kentucky had a population of 4,395,295 and Ohio had a corresponding population of 11,570,808 in 2013, Kentucky had 14,343,878 dosage units of controlled substance

anorexiant dispensed compared to Ohio's 2,648,804 dosage units. Thus, although Ohio has 2.63 times the population of Kentucky, Kentucky had 4.86 times as many controlled substance short term anorexiants prescribed or dispensed as were in Ohio.

In addition, whereas Ohio law enforcement refers to the "drug cocktail" for over prescribers as comprised of opiates, benzodiazepines and muscle relaxants, Kentucky law enforcement's definition of a "drug cocktail" refer to opiates, benzodiazepines and controlled substance anorexiants.

Undercover Kentucky law enforcement personnel described many instances in which Kentucky patients indicated that they need the anorexiants, which are stimulants, to counteract the sedative effects of the opiates and benzodiazepines that they are also taking. Undercover personnel further described cases in which moderately tall, thin female patients left physicians' offices with short term anorexiant prescriptions, despite the apparent failure to meet even Kentucky's reduced Body Mass Index (BMI) standard for prescribing anorexiants. In addition, several criminal cases were described in which emergency room physicians prescribed short term anorexiants to nurses for wakefulness purposes. In Kentucky, approximately thirty percent of physicians criminally investigated by Kentucky law enforcement prescribe and/or dispense controlled substance anorexiants. Six physicians, two advanced practice nurses, and ten patients have been criminally prosecuted in Kentucky over the last five years for issues involving trafficking, overprescribing or diversion of phentermine, the primary ingredient in most short term anorexiants. Several physicians are under active criminal investigation for these issues as of October 2014.

Further, a letter from the Ohio State Board of Pharmacy supports the requirements of the proposed rule **4731-11-04** as a means to prevent abuse, diversion, and profiteering. The letter states that Ohio is seeing a resurgence of unscrupulous providers with inappropriate prescribing and drug trafficking of controlled substance stimulants for weight reduction and/or the prescribing of the drugs for financial gain rather than legitimate medical purposes. The letter also supports the rule's provisions as a means to ensure that patients are closely monitored to prevent abuse and diversion of these potentially addictive drugs.

For proposed rule **4731-11-04.1**, the rule regulates the prescribing of controlled substance anorexiants pursuant to the requirements established on the FDA approved packaging for drugs for which there is no time limit for usage. As approved by the FDA, there are specific weight loss goals that must be met within stated timeframes in order for the physician to

continue prescribing the drug to the patient. The proposed rule reflects the package information approved by the FDA.

Proposed amended rules **4731-11-02** and **4731-11-03** are based upon generally accepted standards for the practice of medicine. They are also consistent with the “Guidelines for Prescribing Opioids for the Treatment of Chronic, Non-terminal Pain” approved by the Medical Board on May 9, 2013, and also approved by Ohio State Medical Association, Ohio Osteopathic Association, Ohio Academy of Family Physicians, Ohio Chapter of the American College of Emergency Physicians, Ohio Pharmacists Association, Ohio Board of Nursing, Ohio State Dental Board, Ohio State Board of Pharmacy, Ohio Hospital Association, Ohio Association of Health Plans, and the Ohio Bureau of Workers' Compensation.

Proposed rule **4731-11-07** is based upon the input of researchers and is consistent with the requirements for an institutional review board for an exception to the regulations for pain clinics established in Section 4731.054, Ohio Revised Code.

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 regarding proposed rules **4730-1-06.1**, **4731-24-05**, **4762-1-01**, **4774-1-02.1**, **4778-1-02.1**, and **4731-6-35** because the Ohio Revised Code is prescriptive.

Regarding proposed rules **4731-11-02**, **4731-11-03**, **4731-11-05**, and **4731-11-07**, the original drafts were substantively the same as is proposed. No alternative language was considered since no comments were received regarding these proposed rules.

The first draft for proposed rule **4731-11-04** included the substantive provisions that eventually became proposed rule **4731-11-04.1**, as discussed in the response to Question 8 above. Changes were made from the original draft to reflect the input of physicians who provide the treatment, and other interested parties, and to add an OARRS access requirement which is consistent with newer Medical Board statutes and rules and helps provide some assurance that diversion and drug abuse issues will be learned prior to prescribing or otherwise utilizing controlled substance anorexiants. Moreover, dieticians were added as a proper source of information regarding a potential patient's prior non-medication assisted

attempts to lose weight. The proposed rules balance the Medical Board's duty to protect the public with the need for access to controlled substances for appropriate medical purposes.

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.

With respect to proposed rules **4730-1-06.1, 4731-24-05, 4762-1-01, 4774-1-02.1, 4778-1-02.1, 4731-6-35, and 4731-7-01**, the Medical Board did not consider a performance based regulation because the statutes are prescriptive in what is required.

Rule **4731-9-01** is a performance based rule. It provides options for those who might want to record the Medical Board's meetings, but does not dictate what systems must be used.

Proposed rules **4731-11-02, 4731-11-03, 4731-11-04, 4731-11-04.1, 4731-11-05, and 4731-11-07** set out requirements for physicians who utilize controlled substance medications in the treatment of their patients. The requirements in the rules focus on the specific problems of over-prescribing, diversion, and addiction. The rules do not otherwise address the process the physician must use in providing medical services.

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

The State Medical Board of Ohio is solely responsible for the licensure of the affected professionals. The Board conferred with the State Board of Pharmacy where appropriate and reviewed federal laws regulating controlled substances to prevent any inconsistencies.

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.

The rules will be posted on the Medical Board's website, information concerning the rules will be included in informational materials and newsletters e-mailed to licensees, and notices will be sent to associations, individuals, and groups. The associations include national associations that provide summary information of licensure requirements in all states. 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 practice regulations.

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.

- a. Regarding proposed rules **4730-1-06.1, 4731-24-05, 4762-1-01, 4774-1-02.1, 4778-1-02.1, and 4731-6-35**, the business community includes Ohio military members, veterans, and their respective spouses who are licensees of the professions regulated by the State Medical Board of Ohio.

Regarding proposed regulations **4731-11-02, 4731-11-03, 4731-11-04, 4731-11-04.1, 4731-11-05, and 4731-11-07**, the business community includes licensees of the professions regulated by the State Medical Board of Ohio.

The public is the business community for purposes of rules **4731-7-01 and 4731-9-01**.

- b. Regarding proposed rules **4730-1-06.1, 4731-24-05, 4762-1-01, 4774-1-02.1, 4778-1-02.1, and 4731-6-35**, the nature of the adverse impact would include the time and effort required to complete an application, any application fees, and the time and effort required to request additional time to complete continuing medical education. The proposed rules do not impose adverse impact that is not already imposed by the provisions of the Ohio Revised Code.

Regarding proposed regulations **4731-11-02, 4731-11-03, 4731-11-04, 4731-11-04.1, 4731-11-05, and 4731-11-07**, violation of the rule may result in administrative licensure discipline for the physician or physician assistant. Discipline might include reprimand, suspension of the license, required course work, and/or revocation of the license. **The cost of course work is borne by the licensee.** There are fees connected with a licensee obtaining and maintaining several licenses or registrations, as well as required education, which are detailed below. There will be licensee and/or staff time associated with completing the paperwork described below, as well as time related to obtaining and reviewing an OARRS report.

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It may also be argued that requiring the physician to personally meet with the patient for purposes of prescribing controlled substance anorexiant, as is required by both **4731-11-04** and **4731-11-04.1**, is an adverse impact on the physician's medical practice and patient care. However, the regulatory intent of reducing the diversion of the drugs outweighs any such adverse impact.

- c. The specific changes being proposed in rules **4730-1-06.1**, **4731-24-05**, **4762-1-01**, **4774-1-02.1**, **4778-1-02.1**, and **4731-6-35** are intended to reduce the adverse impacts of normal licensure which could hamper a veteran's efforts toward gainful employment.

Regarding proposed rules **4731-11-02**, **4731-11-03**, **4731-11-04**, **4731-11-04.1**, and **4731-11-05**, the U.S. Drug Enforcement Administration (DEA) requires that a prescriber of controlled substances have a current DEA certificate of registration (also known as a DEA number). The fee associated with the DEA number is \$731.00 for the initial application and for every three year renewal cycle.

The quantifiable costs associated with becoming licensed as a physician are, respectively, \$335.00 for the application fee, a \$22 fee for the Ohio Bureau of Criminal Identification and Investigation (BCII), and a \$24 fee for the federal bureau of investigation (FBI). The BCII and FBI fees are required by Section 4776.02, ORC. Maintaining licensure in Ohio involves a biennial renewal fee of \$305.00.

The costs associated with becoming licensed as a physician assistant include the \$200 Ohio application fee, the \$100 fee for renewal every two years, and, if the physician assistant has a certificate to prescribe, the \$50 biennial renewal fee for the certificate to prescribe.

Proposed rules **4731-11-04** and **4731-11-04.1** require that the controlled substance anorexiant prescriber/dispenser check OARRS to discern the controlled substance prescription history of potential weight loss patients prior to prescribing, dispensing or otherwise utilizing FDA approved anorexiant for both short term weight loss purposes and for maintenance of weight loss. OARRS can be accessed by the physician and/or a delegatee of the physician. The time and costs associated with that OARRS access will vary based on who accesses the database. Accordingly, no reasonable estimate can be made about the costs associated with this requirement.

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

Rules **4730-1-06.1, 4731-24-05, 4762-1-01, 4774-1-02.1, 4778-1-02.1, 4731-6-35, 4731-7-01, and 4731-9-01** are required by the Ohio Revised Code. Moreover, the rules assist the person in obtaining or maintaining a license. There is no requirement that a licensee take advantage of the assistance offered by the rules.

Regarding proposed regulations **4731-11-02, 4731-11-03, 4731-11-04, 4731-11-04.1, 4731-11-05, and 4731-11-07**, see answers to questions 5 and 9.

Regulatory Flexibility

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

Not applicable to proposed rules **4730-1-06.1, 4731-24-05, 4762-1-01, 4774-1-02.1, 4778-1-02.1, 4731-6-35, 4731-7-01, and 4731-9-01**.

Regarding proposed regulations **4731-11-02, 4731-11-03, 4731-11-04, 4731-11-04.1, 4731-11-05, and 4731-11-07**, the prescribing and utilization of controlled substances is among the most important and potentially dangerous aspects of the practice of medicine. The Medical Board recognizes that controlled substance medications should be available to those who need them, but, by the same token, those same medications can prove deadly if taken inappropriately and spur criminal diversion and abuse in the absence of sufficient regulation. Thus, public safety requirements relative to the rules require consistency in their application to all licensees and are not amenable to exemptions or alternative means of compliance for small businesses.

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?

Proposed rules **4730-1-06.1, 4731-24-05, 4762-1-01, 4774-1-02.1, and 4778-1-02.1**, contain a provision that waives the late fee for returning military service member licensees who fail to timely file for renewal of their professional license due to deployment of themselves or their spouses.

The medical board does not have authority to fine physicians or impose penalties for paperwork violations reflected in proposed rules **4731-11-02, 4731-11-03, 4731-11-04, 4731-11-04.1, 4731-11-05, and 4731-11-07**.

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

The rules will be posted on the Medical Board's website. 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.