Ohio | 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 C. Anderson (email: Kimberly.Anderson@med.ohio.gov); phone: 614-466-7207

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

Light based procedures

Rule Number(s): 4731-18-01 Definitions; 4731-18-02; Use of light based medical devices; 4731-18-03 Delegation of the use of light based medical devices for specified non-ablative procedures; 4731-18-04 Delegation of phototherapy and photodynamic therapy

Date of Submission for CSI Review: May 12, 2020

Public Comment Period End Date: May 27, 2020

Rule Type/Number of Rules:

New/ X rules — No Change/____ rules (FYR? ___)

Amended/__x__ rules (FYR?yes ___) — Rescinded/____ rules (FYR? ___)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

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):

   a. ☒ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**

   b. ☒ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**

   c. ☐ **Requires specific expenditures or the report of information as a condition of compliance.**

   d. ☐ **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.

4731-18-01: Definitions

- Consolidates all definitions in the chapter and adds new definitions including: "phototherapy" (B), "phototherapy devices" (C), "photodynamic therapy" (D), "ablative dermatologic procedure" (E), "non-ablative dermatologic procedure", "physician" (G), and "delegation" (H).

4731-18-02 Use of light based medical devices

- Lays out framework for physician delegation of the application of light based medical devices.
- Paragraph (B) states that a physician shall not delegate application of light based medical devices for ablative procedures.

- Paragraphs (C), (D), and (E) provide for the delegation of the application of light based medical devices for specific types of non-ablative procedures according to the requirements in subsequent rules.

4731-18-03: Delegation of the use of light based medical devices for specified non-ablative procedures

- Paragraph (A) adds the ability of physicians to delegate vascular laser non-ablative dermatologic procedures to a physician assistant, R.N., or L.P.N. if specified conditions are met including: physician evaluates patient before and after the first application of the vascular laser; delegate has completed eight (8) hours of education; observed fifteen (15) procedures; performed twenty (20) procedures under direct physical oversight of physician; and physician provides on-site supervision.
- Paragraph (B) retains current rule on laser hair removal delegation by a physician, but adds robust education and training requirements including eight (8) hours of education; observation of fifteen (15) procedures; and performance of twenty (20) procedures under direct physical oversight of physician.

4731-18-04: Delegation of phototherapy and photodynamic therapy

- Paragraph (A) adds specificity to physician delegation of the application of phototherapy in the treatment of hyperbilirubinemia in neonates to include a physician assistant, R.N., and L.P.N. This paragraph also requires training and on-site physician supervision.
- Paragraph (B) also adds specificity to physician delegation of phototherapy for psoriasis and other skin diseases to include a physician assistant, R.N., L.P.N., and certified medical assistant who has successfully completed training. This paragraph requires on-site physician supervision as well.
- Adds photodynamic therapy delegation by a physician to a physician assistant, R.N. and L.P.N. in paragraph (C) with the requirements that the delegate complete training and that the physician provides on-site supervision.
- Requires reporting of adverse events and failure of treatment by all delegates, and requires physician to personally evaluate patient when this occurs in paragraph (D).
- Lays out the disciplinary framework for violations of (A), (B), (C), and (D).

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.

The Medical Board is authorized to issue rules by R.C. 4730.07, R.C. 4731.05, and R.C. 4731.15. There is no specific statutory direction on the application of light based medical devices. However, the general rulemaking authority to regulate the practice of medicine and

surgery gives the Medical Board authority to amend its rules in the evolving area of light based medicine in the practice of medicine and surgery.

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.

   The proposed regulations do not implement a federal requirement, nor are they being adopted or amended in connection with administering or enforcing a federal law or participating in a federal program.

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

   The question is 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)?**

   The public purpose of the proposed rules is to ensure public safety in the practice of medicine and surgery and the competent application of certain light based medical devices.

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 the safe application of certain light based medical devices with minimal adverse events; the rules being written in plain, 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. The rules are not being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931.

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.

On January 13, 2016, the Policy Committee of the Medical Board discussed the light based medical device rules in chapter 4731-18 and recommended that technical and medical expertise related to light based procedures be obtained.
Subsequently, Board staff communicated with an initial panel of five medical experts with experience in the application of light based medical devices. The expert panel included Dr. Mark Bechtel, Dr. Stephen Smith, Dr. Georgann Poulos, Dr. Eric Bernstein, and Dr. Ronald Siegle. These experts provided verbal or written comments on the existing Chapter 4731-18 rules and suggestions how to improve the rules. Doctors Smith and Poulos provided additional written comments to the initial circulation draft of the proposed rule as well.

Board staff also conducted extensive research into the regulation of light based medical device procedures by other states, adverse events involved in application of light based medical devices, and the light based medical device procedures themselves.

After obtaining the required technical and medical information through consultation with the expert panel and independent research, Board staff drafted the proposed rules. During the drafting process, Board Staff met with Dr. Bechtel, a member of the Board and the expert panel, to develop and review the draft of the proposed rules. Dr. Bechtel provided additional input for the draft on the issues of supervision and appropriate light based medical device education and training from his informal survey of doctors and residents associated with his practice with The Ohio State University Wexner Medical Center.

On January 10, 2018, the Board's Policy Committee publicly reviewed, discussed, and approved the proposed rules for initial circulation with a few amendments that did not change the overall substance of the rule. Board staff then circulated the proposed rules for comment to interested parties and all licensed doctors, physician assistants, and cosmetic therapists.

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

In response to the initial circulation, the Board received 46 written comments which can be categorized as follows:
1. Seven comments were generally supportive of the rules with no suggested changes.
2. Three comments raised questions and expressed concerns about the rules' lack of regulation of nurse practitioners and the interplay of the rules with Nursing Board regulation of nurse practitioners' application of light based medical devices.
3. Two comments were concerned with the definition of phototherapy for the treatment of hyperbilirubinemia in neonates. Two other comments expressed concern that the definition was too narrow for cosmetic procedures not regulated in these rules.
4. Five comments sought a definition or clarification of the term "vascular laser".

5. Seven comments supported expanding the application of non-ablative light based medical devices beyond vascular lasers for dermatologic procedures and hair removal. Five of these seven comments supported expanding delegation to fractionated lasers often used for cosmetic procedures.
6. Four comments opposed expanding delegation of light based medical devices beyond hair removal to vascular lasers, or did not support physician's delegating the application of light based medical devices at all.
7. Two comments favored delegating light based medical device procedures to only physician assistants due to their more extensive education and training than that of other delegates. Two other comments were in favor of delegation to physician assistants and nurses, but not cosmetic therapists.
8. Three comments advocated delegating all light based medical device procedures, including ablative procedures, to physician assistants.
9. Three comments encouraged extending delegation of phototherapy and photodynamic therapy to cosmetic therapists.
10. Eight comments favored expanding off-site physician supervision beyond cosmetic therapists to all other delegates.
11. Nine comments did not agree with the requirements that the physician personally see patients before and after the initial application of a light based medical device, and sought to eliminate the initial evaluation, the follow-up evaluation, or both.
12. One comment requested clarification on whether the phrase "the physician has seen and personally evaluated the patient" allows for video or picture review by the physician instead of the physician being in the same room as the patient.
13. Five comments sought various changes to the rule's delegation of phototherapy in the treatment of hyperbilirubinemia in neonates.
14. One comment advocated extending the delegation of light based medical devices to tattoo removal, and allowing non-medical technicians to perform these procedures along with laser hair removal, skin rejuvenation, and acne treatment.
15. One comment argued that the rules' limited delegation of non-ablative dermatologic procedures was too restrictive and could possibly be in violation of antitrust laws.
16. Four comments had questions about or suggested changes to the new training requirements for delegates applying light based medical devices.
17. One comment inquired into whether delegates who had been lawfully practicing laser hair removal could be exempted from the rule's new education and training requirements. One other comment suggested a grandfather clause for practitioners who had been performing photodynamic therapy for years without regulation.

Board staff also met with two additional Board members, Dr. Andrew Schachat and Dr. Kim Rothermel, to discuss the effect of the proposed rules in their fields of ophthalmology and

pediatrics respectively. Dr. Schachat expressed concern about the danger of delegating light based medical device procedures for purposes other than dermatologic ones due to the great potential for patient harm in areas like ophthalmology. Dr. Rothermel reported concerns in the hospital community about regulating phototherapy in the treatment of jaundice beyond what the hospital protocols were already successfully accomplishing.

On February 12, 2018, the initial circulation draft of the proposed rules was presented to the Physician Assistant Policy Committee ("PAPC") where comments were received regarding the application of phototherapy in the treatment of jaundice by hospital protocol, and regarding the amount and frequency of appropriate training and education to delegates. Based on the comments received from Board members and members of the PAPC as well as written comments provided by interested parties and licensees during the initial circulation of the proposed rules, the following changes were made to the proposed rules:

1. Added definition of vascular laser;
2. Clarified and distinguished definition of phototherapy applied in the treatment of jaundice in infants versus application in the treatment of psoriasis and similar skin diseases.
3. Simplified delegation of phototherapy in the treatment of jaundice in infants by aligning it with hospital standards of care found in their existing protocols and policies.
4. Clarified that the physician evaluation provisions are per type of procedure delegated rather than per procedure, and that the evaluation must occur in person by the physician rather than through video or photograph.
5. Explained the specific education requirements; and clarified that the training must be done per type of procedure rather than per delegating physician.
6. Added a clause that would allow delegates who had been successfully applying a specific type of light based medical device procedure for hair removal to be exempted from education and training requirements if they provided a written certification from a delegating physician stating that the delegate has received sufficient education and training to competently apply that type of light based medical device procedure for hair removal.

11. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

The Board consulted with a panel of medical experts to develop the rules. These experts used their own experience and medical texts to guide the development of the rule.

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?

The Medical Board considered a multitude of comments across a wide spectrum of opinion regarding the degree of regulation desired and the types of light based medical devices that should be delegated by physicians.

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 Medical Board did not consider a performance-based regulation because these proposed rules do not define the required outcome and instead seek to prevent adverse events.

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

    Medical Board staff reviewed the proposed regulations and all relevant Medical Board related Ohio Administrative Code chapters to assure there was no duplication of existing Ohio regulations.

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 rules will be posted on the Medical Board's website and notice of the rules will be circulated to the interested parties. Medical Board staff members will be available to answer questions regarding the rule. Board staff will be made aware of the rule's provisions so that the rule can be fairly, consistently, and predictably applied to the regulated community.

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**
    b. **Identify the nature of all adverse impact (e.g., 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 impacted business community includes physicians utilizing light-based medical devices in their practice, licensees to whom tasks are delegated such as physician assistants, registered nurses, licensed practical nurses and cosmetic assistants. The nature of the adverse impact is the eight hours of basic education that must be completed for the delegation of non-ablative

procedures and laser hair removal. In addition, the physicians will need to have the delegated licensees observe 15 procedures and then provide direct physical oversight of 20 procedures before the licensees can perform on their own. In addition, physicians who violate these rules are subject to disciplinary action and fines up to $20,000 from the Medical Board.

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

The Medical Board determined that the regulatory intent justifies the adverse impact to the regulated business community because the Board endeavors to protect patients and ensure the competent application of the specified light based medical devices. In these proposed rules, the Board is expanding the ability of physicians to delegate the application of certain light based medical devices which helps rather than harms the regulated business community.

Regulatory Flexibility

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

No, the regulation does not provide exemptions or alternative means of compliance for small business. All practitioners utilizing light-based medical devices need to follow the same regulations for patient safety.

19. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

Due process requires the Medical Board to consistently apply its rules such that all licensees using light-based medical devices are equally treated.

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

Medical Board staff members are available by telephone and e-mail to answer questions.