



Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

Carrie Kuruc, Director

MEMORANDUM

TO: Kim Anderson, State Medical Board of Ohio

FROM: Jacob Ritzenthaler, Regulatory Policy Advocate

DATE: April 5, 2021

RE: **CSI Review – Light-Based Procedures (OAC 4731-18-01, 4731-18-02, 4731-18-03, and 4731-18-04)**

On behalf of Lt. Governor Jon Husted, and pursuant to the authority granted to the Common Sense Initiative (CSI) Office under Ohio Revised Code (ORC) section 107.54, the CSI Office has reviewed the abovementioned administrative rule package and associated Business Impact Analysis (BIA). This memo represents the CSI Office's comments to the Board as provided for in ORC 107.54.

Analysis

This rule package consists of three amended rules and one new rule proposed by the State Medical Board of Ohio (Board) pursuant to statutory five-year review requirements. This rule package was submitted to the CSI Office on May 12, 2020, and the public comment period was held open through May 27, 2020. On March 15, 2021, the Board submitted a memo to the CSI Office detailing amendments made to rules in this package as a result of feedback received from 14 stakeholder groups during the CSI public comment period.

Ohio Administrative Code Chapter 4731-18 establishes requirements for the use of light-based medical devices for the treatment of various skin conditions, such as psoriasis or for ablative procedures. OAC 4731-18-01 is a new rule that contains definitions of terms used throughout the Chapter. The rule is amended to consolidate the rule content and includes a new definition for "vascular laser." OAC 4731-18-02 establishes guidelines for the use of light-based medical devices. The rule is being amended to remove definitions that are now found in OAC 4731-18-01 and introduce language allowing physicians to delegate the application of light-based medical devices in subsequent rules. OAC 4731-18-03 sets forth the procedure for delegating the use of

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light-based medical devices for specified non-ablative procedures. The rule is amended to add conditions for delegation of vascular laser procedures and training requirements for delegates. Further amendments allow delegation to an eligible cosmetic therapist, remove certain uses of “in-person” or “personally” from delegation requirements, and are intended to comply with ORC 4730.21 for training, education, and supervision. OAC 4731-18-04 establishes requirements for the delegation of phototherapy and photodynamic therapy by a physician for various types of treatment. The rule is amended to require that delegating physicians typically practice certain types of care, specify that certain types of medical staff are qualified for delegation, and include a disciplinary framework for violations of the rule.

During early stakeholder outreach, the Board reviewed the rules during public Board meetings and with groups of medical experts with experience in the field of light-based procedures. In response to stakeholder feedback during that time, the Board amended the rules to update definitions, include clarifying language regarding education and physician evaluation, and simplify delegation requirements for certain procedures. During the CSI public comment period, the Board received 17 comments related to various portions of the rule package, including expanding or restricting the personnel approved to perform certain procedures. In response to stakeholder comments, the Board added new amendments that clarify the delegation and training requirements for PAs and nurses. The Board did not make amendments to decrease the level of supervision or expand the procedures available for delegation, citing patient safety.

The business community impacted by these rules includes physicians who utilize light-based procedures and the licensees who are delegated certain procedures. The adverse impact created by the rules includes the time necessary for delegates to complete eight hours of education in the performance of light-based procedures, observation 15 procedures, and providing physical oversight to 20 procedures before being allowed to perform the procedure on their own. Physicians who have violated the provisions of the rules are subject to disciplinary action and potential fines of up to \$20,000. The Board states that the rules are necessary to ensure the safety of patients and that medical professionals perform procedures in a competent manner.

Recommendations

Based on the information above, the CSI Office has no recommendations on this rule package.

Conclusion

The CSI Office concludes that the Board should proceed in filing the proposed rules with the Joint Committee on Agency Rule Review.