



Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

Joseph Baker, Director

MEMORANDUM

TO: Kimberly Anderson, State Medical Board of Ohio

FROM: Michael Bender, Business Advocate

DATE: December 22, 2022

RE: **CSI Review – Light Based Medical Device Rules (OAC 4731-18-01, 4731-18-02, and 4731-18-03)**

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This rule package consists of one new rule, two amended rules, and one rescinded rule proposed by the State Medical Board of Ohio (Board). This rule package was submitted to the CSI Office on September 22, 2022, and the public comment period was held open through October 14, 2022. Unless otherwise noted below, this recommendation reflects the version of the proposed rules filed with the CSI Office on September 22, 2022.

Ohio Administrative Code (OAC) 4731-18-01 specifies definitions pertaining to light based medical devices. The rule is amended to remove the term "off-site supervision." OAC 4731-18-02 outlines the situations in which a physician is and is not allowed to delegate application of light based medical devices to the human body. The rule is amended to update a citation regarding the application of light-based medical devices for the purpose of hair with Ohio statute regarding the delegation of light based medical devices for hair removal. OAC 4731-18-03, the proposed new rule, authorizes a physician to delegate the application of a vascular laser for non-ablative dermatologic procedures and the application of light based medical devices for the purpose of hair removal under certain conditions.

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During early stakeholder outreach, the Board posted the rules on its website and circulated them in November 2021 to interested parties including the Ohio State Medical Association, the Academy of Medicine of Cleveland and Northern Ohio, the Ohio Hospital Association, the Ohio Association of Physician Assistants (OAPA), the Ohio Board of Nursing, and certain interested attorneys. One individual from the OAPA requested that the definition of “ablative dermatologic procedure” be updated because physician assistants already perform procedures in office beneath the dermo-epidermal junction to the subcutaneous fat without direct supervision, that OAC 4731-18-02(D) be changed to state that a physician may delegate the application of light based medical devices for hair removal, resurfacing, and dermatologic purposes because the current language is restrictive to specialty physician practices, and that paragraphs (A)(3), (4), and (5) in OAC 4731-18-03 be removed because the requirement for the physician to evaluate the patients creates more work for the provider. Two individuals from Removery, LLC recommended that the rules be changed to allow delegation of laser tattoo removal to cosmetic therapists, physician assistants (PAs), registered nurses (RNs), and licensed practical nurses (LPNs). The Cosmetic Therapy Association of Ohio (CTAO) recommended changes to the rules allowing cosmetic therapists to be delegated the use of light based medical devices for non-ablative vascular treatments. The Board reviewed these comments at its April 2022 meeting and decided not to make the proposed changes due to its intent to correct any discrepancies between the rules and statute and because tattoo removal does not use a non-ablative vascular laser and is more complicated due to the different pigments used in tattoos. Furthermore, the Board determined to keep the physician evaluation to ensure patient safety and that the use of the non-ablative vascular laser was appropriate for the patient’s condition. The Board also provided the proposed rules in February 2022 to the members of the Physician Assistant Policy Committee, who did not recommend any specific changes.

During the CSI public comment period, the Board received comments from the CTAO and an individual cosmetic therapist in support of the CTAO’s comments which advocated for cosmetic therapists being allowed to receive delegation of vascular lasers from physicians. The Board did not make this change, replying that the proposed change presented patient safety concerns due to the fact that vascular lasers are different than lasers used for hair removal. Additionally, after discussions with CSI, the Board emphasized that the medical training received by PA’s, RN’s, and LPN’s make them professionally capable of handling medical situations that may occur when using lasers on veins or other blood vessels. The Board did make typographical and grammatical corrections upon inquiry from the CSI Office.

The business community impacted by the rules includes physicians utilizing light based medical devices in their practice as well as licensees to whom tasks are delegated such as PAs, RNs, and LPNs. The adverse impacts created by the rules include eight hours of basic education that must be completed for the delegation of non-ablative procedures, the requirement for delegated licensees to observe procedures, the requirement for physicians to provide direct physical oversight before

licensees can perform on their own, and disciplinary action and fines of up to \$20,000 by the Board for physicians who violate the rules. The Board states that the adverse impacts to business are justified to protect patients and ensure the competent application of the specified light based medical devices, in addition to aligning the rules with the ORC.

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.