



MEMORANDUM

TO: Ohio State Medical Board

FROM: Common Sense Initiative Office

DATE: December 13, 2019

RE: R.C. §107.56 Referral—*Proposed light-based medical device procedure rules*

The Ohio State Medical Board (“Medical Board”) has self-referred for review under Ohio Revised Code (R.C.) §107.56 proposed amendments to its administrative rules regarding the application of light-based medical devices. The Medical Board states that it seeks to protect patient safety by strengthening the supervision, education, and training requirements for the delegation of the application of light-based medical devices. This memo represents the Common Sense Initiative office’s (“CSI’s”) determination under that statute.

ANALYSIS

I. The action is consistent with a clearly articulated state policy.

The Medical Board’s proposed changes to the light-based medical device procedure rules are consistent with clearly articulated state policy. The Ohio General Assembly’s stated purpose for the Medical Board gives broad authority to set the scope of practice for physicians, physician assistants, and cosmetic therapists. Specifically, it establishes the Medical Board’s authority to regulate the practice of medicine and surgery, osteopathic medicine and surgery, and podiatric medicine and surgery, including physician assistants and the limited branches of medicine.¹

Ohio law specifically tasks the Medical Board with establishing standards for a physician’s delegation of medical tasks to those who are not licensed or specifically authorized by law to perform the task.² In order to accomplish these purposes, the legislature grants the Medical Board broad rulemaking authority to “carry out the purposes of the Chapter.”³ Establishing guidelines

¹ R.C. 4730.07; 4731.05; 4731.20; 4731.41.

² R.C. 4731.053.

³ R.C. 4731.05.

for how its physician licensees delegate the application of light-based medical devices to the non-physician operators they supervise falls well within a clearly articulated state policy to establish physician scope of practice and delegation standards.

II. The state policy is not merely a pretext for anticompetitive conduct that could be subject to state or federal antitrust law.

The policy effectuated by the Medical Board's proposed administrative rule changes is not a pretext for anticompetitive conduct. The proposed delegation permission relates to the scope of practice of an occupation the Revised Code specifically grants authority for the Medical Board to regulate. It provides a framework within a physician's scope of practice for delegating procedures to the non-physician healthcare personnel a physician typically oversees. There is no evidence in the referral materials or interested party comments of the Medical Board taking action against license holders of occupations for which it does not set the scope of practice.

The Medical Board rule's definition of the application of light-based medical devices to the human body as the practice of medicine and surgery has been consistent since 2000, and its proposed rule amendments do not change the definition.⁴ The practice of medicine and surgery has evolved significantly since 2000, though, and it has seen an increase in the frequency of medical and surgical procedures using light-based medical devices. As those procedures become more common, the Medical Board has tracked incidents of patient harm by professionals using light-based medical devices, and it is those incidents that have triggered the Medical Board's proposed rule changes.

The Medical Board cites evidence of harm associated with misapplication of light-based medical devices, including burns, scarring, and even eye injuries when physicians delegated the application to undertrained or undersupervised non-physician operators.⁵ The Medical Board even points to its own disciplinary case of a physician who lost his license after the improper delegation of the application of a light-based medical device that resulted in injury to a patient.⁶ In an effort to protect the public and licensed physicians, the Medical Board now has closely tailored its proposed rule amendments to broaden, strengthen, and clarify the guidelines its licensed physicians must follow when they delegate the application of light-based medical devices to the properly trained non-physician operators they oversee. The proposed amendments strike a balance between concerns about patient safety and a desire to make effective light-based procedures available in the practice of medicine.

⁴ See OAC 4731-18-02, currently in effect and proposed edits as included in the Medical Board's referral.

⁵ "Who is Qualified to Perform Laser Surgery and in What Setting," *Seminars in Plastic Surgery*, 2007; "Increased Risk of Litigation Associated with Laser Surgery by Nonphysician Operators," *JAMA Dermatology*, April 2014.

⁶ Disciplinary case of Ali Kahn, M.D., cited in the Medical Board's referral.

Determination

Accordingly, CSI determines that the proposed rules from the Medical Board are supported by and consistent with a clearly articulated state policy and are not a pretext for anticompetitive conduct.