**TITLE 16. California State Board of Optometry**

**DEPARTMENT OF CONSUMER AFFAIRS**

**INITIAL STATEMENT OF REASONS**

**Hearing Date:** No hearing scheduled.

**Subject Matter of Proposed Regulations**: Optometry; Radio Frequency Technology and Devices; Authorization and Requirements

**Section(s) Affected**: Adopt Title 16, California Code of Regulations (CCR), Article 11.5, Section 1572.

**Background and Statement of the Problem:**

The California State Board of Optometry (Board) currently licenses and regulates approximately 9,200 optometrists and 4,200 dispensing opticians. Business and Professions Code (BPC) section 3010.1 provides protection of the public is the highest priority for the Board in exercising its licensing, regulatory and disciplinary functions. BPC sections 3021 and 3025 authorize the Board to adopt regulations as may be necessary to enable the Board to effectuate the practice of optometry and opticianry.

Business and Professions Code section 3041 (a)(5)(G)(2) says that that practice of optometry may include "Using additional noninvasive medical devices or technology that have been approved by the board through regulation for the rational treatment of a condition or disease authorized by this chapter. Any regulation under this paragraph shall require a licensee to successfully complete an appropriate amount of clinical training to qualify to use each noninvasive medical device or technology approved by the board pursuant to this paragraph."

Dry eye disease or syndrome is a common eye condition that occurs when tears do not adequately lubricate the eye. This can cause the eye to feel uncomfortable and can cause vision problems. Dry eye disease is often caused by meibomian gland dysfunction (MGD) which is a disorder that occurs when the oil produced in the eyes is insufficient in quantity or quality. In many cases of MGD, the glands that produce the oil get clogged and the oil doesn't drain. MGD is a common cause of dry eye syndrome and licensed optometrists are primary providers of treatment for this condition.

The authorized treatments for dry eye in California include the following:

- Over the counter eye drops.
- Prescription medicines.
- Lifestyle changes.
- Tear duct plugs.
- Surgery (ophthalmologists only; California-licensed optometrists are not authorized to perform surgery, with limited exception).
- Intense pulsed light (IPL).

Innovative treatments are available to treat MGD and dry eye syndrome. IPL is a technology used to deliver pulses of light to liquefy and release oils that have hardened and clogged glands in the eyelids. The technology is intended to reduce eyelid redness and stimulate healthy gland function. Radiofrequency, or RF, is a technology used to deliver high frequency electrical currents to the surface of skin to stimulate collagen growth.

IPL and RF technology, administered individually or as part of a combination regime, are often offered as a treatment for MGD and dry eye syndrome. In California, the law authorizes the use of IPL but does not authorize the use of RF unless the technology or device receives FDA or Board regulatory approval for the treatment of a disease or condition of the visual system. IPL received an FDA authorization in February 2021 for dry eye disease and the scope of practice for California optometrists has also explicitly authorized its use since January 1, 2022.

To date, RF has not received approval under state law for use by optometrists within their scope of practice and the FDA has not issued any approvals for RF devices with an indication that is within the scope of practice for California-licensed optometrists.

Existing regulations do not explicitly provide authorization for licensed optometrists to use radiofrequency technology or devices to treat diseases or conditions of the visual system. This proposal would provide such clarity in regulation by adopting Article 11, section 1572, of Title 16, CCR.

This proposal would include the following requirements in regulation:

(1) Authorization to use radiofrequency technology or devices for treatment of dry eye disease or syndrome is limited to Therapeutic Pharmaceutical Agent (TPA)-certified optometrists.
(2) TPA-certified optometrists using radiofrequency technology or devices must have proof of their completion of appropriate clinical training available on-site for Board inspection and upon request.
(3) Appropriate clinical training may be acquired by the TPA-certified optometrist through one of three ways:
    a. Training received from the manufacturer.
    b. Continuing education training.
    c. Training received during the curriculum to obtain the optometric degree.
(4) A restriction on the optometrist using radiofrequency technology or devices that is must be used noninvasively and only for a documented purpose within the scope of practice.
(5) A prohibition on delegating the use of radiofrequency technology or devices to any other person, including opticians.
(6) A requirement for the optometrist using radiofrequency technology or devices to ensure that the technology or device used meets state and federal requirements.
(7) A requirement for the optometrist to maintain a copy of the manufacturer's

instructions for the radiofrequency technology or device on-site available for Board inspection.

(8) A prohibition on the optometrist using radiofrequency technology or devices for any purpose outside the scope of practice, including a restriction on using radiofrequency technology or devices solely for aesthetic benefit or continuing to use after the optometric purpose of treatment has been achieved.

The effort to enact this proposal began at the April 5, 2024, Consumer Protection, Public Relations, and Outreach Committee. At that meeting, the Consumer Protection, Public Relations, and Outreach Committee, directed staff to bring to the full board for discussion and possible approval a regulatory proposal that would explicitly authorize California-licensed optometrists to use radiofrequency technology and devices.

At the May 31, 2024, regular Board Meeting reviewed the proposed text and approved the proposal and delegated authority to the Executive Officer to make any technical, non-substantive changes, if necessary.

**Anticipated benefits from this regulatory action:**

The Board has determined that this regulatory proposal will have the following benefits to the health and welfare of California residents. The anticipated benefits of authorizing the use by optometrists of RF technology and devices are substantial and wide-reaching, positively impacting both regulatory alignment and public welfare. Here are the key advantages:

The proposal authorizes a noninvasive technology or device that has shown effectiveness in treating dry eye disease, a common eye condition impacting millions of Californians. Under present law, California-licensed optometrists are not authorized to use RF technology or devices on their patients, even though they were trained in the technology as part of their required education and studies show that it works, especially when the RF technology or device is used in combination with other proven techniques such as IPL and meibomian gland expression. Expanding the allowable treatment options that an optometrist can use to include RF will positively benefit Californians who are suffering from dry eye disease. As patients suffering from this condition have their symptoms alleviated, their quality of life should also improve.

The proposal authorizes TPA-certified optometrists who have completed clinical training to use RF technology or devices and defines clinical training to mean that training received from the manufacturer of the device, Board-approved continuing education courses, or by receiving RF training in optometric college as part of the curriculum required to obtain the optometric degree. This implements the requirement contained in the authorizing statute that requires “a licensee to successfully complete an appropriate amount of clinical training to qualify to use each noninvasive medical device or technology approved by the board pursuant to this paragraph.”

The proposal also prohibits the use of RF technology or devices for any purpose which is

outside the scope of practice of optometry in California, including an explicit prohibition on using the technology on a patient solely for aesthetic benefit and on using it after the optometric purpose for the treatment has been achieved. This language intends to protect consumers by ensuring that licensed optometrists are only using the technology for a legitimate condition of the visual system.

**Specific purpose of, and rationale for, each adoption, amendment, or repeal:**

**Adopt Article 11.5, Section 1572 and title – Radiofrequency Technology;**

**Authorization and Requirements**

**Subdivision (a)**

Purpose:

This proposal adopts a new article, section, and title, and subdivision (a) establishes the authority for TPA-certified optometrists to use radiofrequency technology or devices for treatment of dry eye disease or syndrome. The proposal also establishes requirements that the TPA-certified optometrist must meet prior to using radiofrequency technology or devices, as discussed below in subdivisions (b)(1) – (4).

Rationale:

Existing regulations and law do not explicitly authorize the use of radiofrequency technology or devices for use by California-licensed optometrists. This section would authorize TPA-certified optometrists to use radiofrequency technology or devices for treatment of dry eye disease or syndrome. The authority to establish this proposal is found at Business and Professions Code section 3041 (a)(5)(G)(2). This proposal was created to expand the available treatments that optometrists can legally offer patients suffering from dry eye disease. Expanding the treatment options available for dry eye disease to include radiofrequency technology or devices will benefit the public by authorizing the use of a treatment that works to alleviate the symptoms of a common eye condition impacting millions of Californians.

**Subdivision (b)**

Purpose:

This proposal would establish the requirements that a TPA-certified optometrist must meet prior to using radiofrequency technology or devices.

Rationale:

The proposed language requires the TPA-certified optometrist to have demonstrated training in the technology or device prior to being able to use it as a consumer protection measure to ensure the practitioner is trained and has the skills necessary to use the technology or device. The proposal is also necessary because Business and Professions Code section 3041 (a)(5)(G)(2) mandates that any regulation the Board promulgates to require a licensee to successfully complete an appropriate amount of clinical training to qualify to use each noninvasive medical device or technology approved by the board…"

**Subdivision (b)(1)**

Purpose:

This proposal would establish three ways in which the TPA-certified optometrist may qualify to use radiofrequency technology: A) a document signed and dated by the manufacturer showing the optometrist received training provided by the manufacturer on the use of the technology or device and that this training be at least one credit hour; B) a certificate of completion specifying the optometrist completed a Board-approved continuing education course worth at least one credit hour in radiofrequency technology; or, C) original transcripts showing the optometrist received radiofrequency training at an optometric college as part of the curriculum required to obtain the degree.

Rationale:

The proposed language protects consumers by ensuring that the TPA-certified optometrist has received training in the use of radiofrequency technology. The proposal is also necessary because Business and Professions Code section 3041 (a)(5)(G)(2) mandates that any regulation the Board promulgates to require a licensee to successfully complete an appropriate amount of clinical training to qualify to use each noninvasive medical device or technology approved by the board…"

**Subdivision (b)(2)**

Purpose:

This proposal restricts the optometrist to only use the radiofrequency technology or device in a noninvasive way and only for the optometric purpose of treating dry eye disease or syndrome. The proposal prohibits the use of radiofrequency technology or devices for aesthetic benefit or after the optometric purpose for the treatment has been achieved.

Rationale:

The proposed language restricts the optometrist to only using the

radiofrequency technology or device for authorized optometric purposes and only within the scope of practice and prohibits the invasive use of the technology. The proposal is necessary because the authorizing statute, Business and Professions Code section 3041 prohibits optometrists from using invasive medical devices or technology and prohibits optometrists from performing surgery. The requirement to only use the radiofrequency technology or device for a document purpose within the scope of practice and a prohibition on the use of the technology or device for aesthetic benefit is to implement the requirement in Business and Professions Code section 3041 (a)(5)(G)(2) that the noninvasive medical device or technology must be "for the rational treatment of a condition or disease authorized by this chapter." Optometrists are not authorized to provide aesthetic or dermatological treatments.

**Subdivision (b)(3)**

Purpose:

This proposal prohibits the optometrist from delegating use of radiofrequency technology or device for treatment to any other person, including opticians.

Rationale:

This proposal is necessary because the authorizing statute provides no authority to delegate the use of the noninvasive medical device or technology. Additionally, the authorizing statute requires a training component for the licensee and this requirement cannot be delegated to another person.

**Subdivision (b)(4)**

Purpose:

This proposal requires the radiofrequency equipment or device to be maintained, tested, and inspected according to the manufacturers' specifications and requires the optometrist to retain a copy of the manufacturer's instructions for the radiofrequency technology or device on-site and to make it available for Board inspection upon request.

Rationale:

The proposal is necessary to be consistent with requirements in subdivision (b)(1) section 1572, which require the optometrist to obtain appropriate training prior to using radiofrequency technology or devices. Requiring the optometrist to maintain a copy of the manufacturers' instructions ultimately protects the consumer by ensuring the optometrist remains knowledgeable about how to use the technology or device.

**Subdivision (c)**

Purpose:

This proposal establishes definitions for the following terms: “noninvasive medical devices or radiofrequency technology”, “credit hour”, and “Board-approved continuing education course”.

Rationale:

This proposal is necessary to establish definitional terms used in the regulation so that licensees seeking to qualify to use radiofrequency technology or devices understand the requirements. “Noninvasive medical devices or radiofrequency technology” is defined consistent with Business and Professions Code section 3041 which does not authorize licensed optometrists to use laser technology. The definition of “credit hour” and “Board-approved continuing education course” is included to be consistent with the existing definition of these terms as they are found at Section 1536, of Division 15, of Title 16 of the California Code of Regulations.

**Underlying Data**

1. Business and Professions Code section 3041
2. April 5, 2024, Consumer Protection, Public Relations, and Outreach Committee Agenda; Relevant Meeting Materials; Minutes
3. Studies:
    a. Transcutaneous Radiofrequency-mediated Meibomian Gland Expression is an Effective Treatment for Dry Eye: A Prospective Cohort Trial
    b. Multi-Frequency RF Combined with Intense Pulsed Light Improves Signs and Symptoms of Dry Eye Disease Due to Meibomian Gland Dysfunction
4. May 31, 2024, Board meeting Agenda; Relevant Meeting Materials; Minutes

**Business Impact:**

The California State Board of Optometry has determined that this regulatory proposal will not have a significant impact on the creation of jobs or new businesses or the elimination of jobs or existing businesses or the expansion of businesses in the State of California. Authorizing RF technology and devices for use by optometrists when treating dry eye disease is intended to provide greater access to treatment for individuals afflicted by dry eye disease.

**Economic Impact Assessment:**

This regulatory proposal would have the following effects:

- It will not create or eliminate jobs within the State of California because the

proposed regulation only aims to improve care for consumers by expanding the treatment options for dry eye disease or syndrome.

- It will not create or eliminate existing businesses within the State of California because businesses, such as an optometric corporations employing optometrist who provide optometric services to patients for payment, already treat patients with dry eye disease or syndrome.

- It will not affect the expansion of businesses currently doing business within the State of California, including those that offer optometric care, because these businesses already treat patients with dry eye disease or syndrome.

- This regulatory proposal benefits the health and welfare of California residents because the proposed regulations will expand the treatment options available for dry eye disease or syndrome, a condition that impacts millions of Californians.

- It does not affect worker safety because the proposed regulation is not related to worker safety.

- It does not affect the state's environment because the proposed regulation is unrelated to the state's environment.

**Specific Technologies or Equipment:**

This regulatory proposal does not mandate the use of specific technologies or equipment to provide optometric services. Instead, it authorizes the use of radiofrequency technology or devices for treatment of dry eye disease or syndrome. Radiofrequency technology devices use safe levels of low-frequency electromagnetic waves to generate heat. The device is usually a modular, handheld item that is controlled by the practitioner and applied to a patient. The proposal does not require the use of any specific device.

**Consideration of Alternatives:**

No reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed or would be as effective or less burdensome to affected private persons and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the law being implemented or made specific.

No such alternatives have been proposed; however, the Board welcomes comments from the public.

**Description of reasonable alternatives to the regulation that would lessen any adverse impact on small business**:

No such alternatives have been proposed; however, the Board welcomes comments from the public.