California State Board of Optometry
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DEPARTMENT OF CONSUMER AFFAIRS • CALIFORNIA STATE BOARD OF OPTOMETRY
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ISSUE MEMORANDIUM

DATE	May 31, 2024
TO	Members, California State Board of Optometry
FROM	Gregory Pruden, Executive Officer & Elizabeth Dietzen-Olsen, Regulatory Counsel
SUBJECT	Agenda Item #7 – **Discussion and Possible Action to Initiate a Rulemaking to Adopt Title 16 California Code of Regulations, Article 11.5, Section 1572, relating to radio frequency technology and devices.**

Background:
On April 5, 2024, the California State Board of Optometry's Consumer Protection, Public Relations, and Outreach Committee, heard a presentation regarding the use of radiofrequency (RF) technology by Optometrist's to treat Dry Eye Disease. At the conclusion of the meeting, the committee members directed staff to bring to the full board for discussion and possible approval, a regulatory proposal, including information from studies in other states, that would authorize California-licensed optometrists to use RF technology for the use of treating Dry Eye Disease. Under the authority of Business and Professions Code (BPC) section 3041 (a)(5)(G)(ii),) staff presents this regulatory proposal today.

To date, several methods have been used by California Optometrist's to treat Dry Eye Disease. One technology that has been used and is authorized for use by California Optometrists pursuant to BPC 3041(a)(5)(F)(xii) is intense pulse light therapy (IPL). 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. 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. Other technologies are also authorized under state law, such as intranasal stimulators that are used to stimulate tear production. But there are other safe and effective technologies available to treat dry eye that do not yet have approval under state or federal law. One example is RF, a technology used to deliver electrical currents to the surface of skin to stimulate collagen growth.

RF has not yet 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. However, there are several RF devices that have received FDA approval for wrinkles and other aesthetic uses, and RF devices have been in the market for over-the-counter purchase since at least 2002, when the first RF device received FDA approval for

wrinkles and other aesthetic uses. Numerous variants are available for purchase via commonly known online retailers.

Studies Show RF Works in Treating Dry Eye

Additionally, there are studies that show the efficacy of RF for treating dry eye disease, including a 2023 study conducted by ophthalmologists that found RF treatment used along with expressing the meibomian glands reduced the signs and symptoms of dry eye syndrome.[1]

Other studies have examined the use of RF in combination with IPL and similarly found promising results for those suffering from dry eye syndrome. A 2023 study conducted by an ophthalmologist and an optometrist, but this time combining IPL, RF, and meibomian gland expression, found that patients suffering from moderate to severe dry eye syndrome, caused by meibomian gland dysfunction, had decreased symptoms, improved meibum quality and appearance, increased the number of expressible glands, and decreased meibomian gland loss. The study found that combining IPL, RF, and meibomian gland expression over four treatments had larger effects that when subjects were treated with just IPL and meibomian gland expression. The study concluded that "multi-frequency RF may have an added value on top of IPL and MGX [meibomian gland expression]."[2] No patient harm caused by RF was found in either study.

Currently, 17 states have a greater scope of practice for optometrists than California.[3] In states where optometrists have authority to use lasers and perform minor surgical procedures, they also have authority to use radiofrequency. California has three optometric colleges, more than any other state, and produces the most graduates every year. Because these graduates may opt to practice in other states, California optometric schools train students in techniques that may not be explicitly authorized for use in California. This may include, the use of lasers, performing minor surgical procedures, and radiofrequency.

Authority to Pursue Regulation

The scope of practice for California-licensed optometrists is found at Business and Professions Code section 3041. In addition to prescribing and limiting the actions of California-licensed optometrists, the law importantly also provides a mechanism to expand the scope of practice to include "additional noninvasive devices or technology" that have either received approval via the FDA or by Board regulation for a disease or condition within the scope of practice. Specifically, the Board's authority to pursue this regulation is found at Business and Professions Code section 3041(a)(5)(G)(2), which says that optometrists can use noninvasive devices or technology if they:

> 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

[1] Transcutaneous Radiofrequency-mediated Meibomian Gland Expression is an Effective Treatment for Dry Eye: A Prospective Cohort Trial

[2] Multi-Frequency RF Combined with Intense Pulsed Light Improves Signs and Symptoms of Dry Eye Disease Due to Meibomian Gland Dysfunction

[3] https://www.reviewofoptometry.com/article/equipping-your-office-for-minor-surgical-procedures

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."

RF technology is noninvasive and has been an FDA-approved technology used over the counter and in other settings for more than two decades. Studies show promise in treating patients suffering from dry eye syndrome caused by meibomian gland dysfunction, especially when combined with other treatments such as IPL and meibomian gland expression.

Authorizing this regulation proposal will enable California-licensed optometrists to offer RF technology to their patients and expand the legal treatment options available for patients suffering from dry eye syndrome caused by meibomian gland dysfunction.

Action Requested:
Option 1 [If the Board considers the proposed text acceptable as presented in the meeting materials, the Board may take the following action]:
Approve the proposed regulatory text and adoption of Section 1572 as provided in the materials and direct staff to submit all approved text to the Director of the Department of Consumer Affairs and the Business, Consumer Services, and Housing Agency for review. If the board does not receive any comments providing objections or adverse recommendations specifically directed at the proposed action or to the procedures followed by the board in proposing or adopting the action, then the Board authorizes the Executive Officer to take all steps necessary to initiate the rulemaking process, make any technical or non-substantive changes to the package, and set the matter for hearing. If no adverse comments are received during the 45-day comment period or at the hearing, authorize the Executive Officer to take all steps necessary to complete the rulemaking and adopt the proposed regulations at Section 1572 as noticed.

Option 2 [If the Board would like to make changes to the proposed text, the Board may take the following action]:
Approve the proposed regulatory text and adoption of Section 1572 as provided in the materials but with the changes approved at this meeting, and direct staff to submit all approved text to the Director of the Department of Consumer Affairs and the Business, Consumer Services, and Housing Agency for review. If the board does not receive any comments providing objections or adverse recommendations specifically directed at the proposed action or to the procedures followed by the board in proposing or adopting the action, then the Board authorizes the Executive Officer to take all steps necessary to initiate the rulemaking process, make any technical or non-substantive changes to the package, and set the matter for hearing. If no adverse comments are received during the 45-day comment period or at the hearing, authorize the Executive Officer to take all steps necessary to complete the rulemaking and adopt the proposed regulations at Section 1572 as noticed.

Attachments:
1. Title 16 Division 15 California Code of Regulations Section 1572

Attachment 1

Department of Consumer Affairs
Title 16. California State Board of Optometry

PROPOSED REGULATORY LANGUAGE
Radiofrequency Technology

Legend:	Added text is indicated with an underline. Omitted text is indicated by (* * * *) Deleted text is indicated by ~~strikeout~~.

Add section 1572 in Article 11 of Division 15 of Title 16 of the California Code of Regulations to read as follows:

§ 1572. Radiofrequency Technology; Authorization and Requirements

(a)The use of noninvasive medical devices or radiofrequency technology, as defined in this section, for treatment of dry eye disease or syndrome is authorized for use by Board licensed, TPA certified optometrists meeting the requirements of this section.

(b) The following requirements must be met prior to using radiofrequency technology or devices:

1) A TPA certified optometrist who uses radiofrequency technology must have proof as specified in this section of the optometrist's completion of appropriate clinical training available on-site for Board inspection and upon request. Proof of appropriate clinical training can be satisfied by the following:

   (A) a document signed and dated by an authorized representative of the manufacturer of the applicable medical device showing the optometrist received a training provided by the manufacturer on the use of the applicable radiofrequency technology or medical device of at least one (1) credit hour,

   (B) a certificate of completion or other document signed and dated by an authorized representative of a continuing education provider specifying that the optometrist completed a Board-approved continuing education course worth at least one (1) credit hour in radiofrequency technology, or,

   (C) original transcripts certified by the appropriate official responsible for the records such as the registrar, showing the optometrist received radiofrequency training at an optometric college as part of the curriculum required to obtain the optometric degree.

2) An optometrist shall only use noninvasive radiofrequency technology or devices on patients and only for the optometric purpose of treating dry eye disease or syndrome as documented in the patient's medical record. An optometrist shall

not provide radiofrequency treatment to a patient solely for aesthetic benefit or after the optometric purpose for the treatment has been achieved.

3) An optometrist shall not delegate the use of the radiofrequency technology or device to any other person, including opticians.

4) All equipment or medical devices should be maintained, tested and inspected according to the manufacturers' specifications. The optometrist must retain a copy of the manufacturer's specifications for the radiofrequency technology or medical device on-site for Board inspection and upon request.

(c) For the purposes of this section, the following definitions shall apply:

1) "Noninvasive medical devices or radiofrequency technology" means the use of noninvasive medical devices, that do not rely on laser technology, that deliver an electromagnetic current or wave to the skin of a patient for the purpose of heating the tissue.

2) "Credit hour" includes the definition prescribed by Section 1536.

3) "Board-approved continuing education course" shall include a course meeting the requirements of Section 1536.

Note: Authority cited: Sections 3025 and 3041, Business and Professions Code. Reference: Section 3041, Business and Professions Code.