DEPARTMENT OF CONSUMER AFFAIRS
TITLE 16. PROFESSIONAL AND VOCATIONAL REGULATIONS
DIVISION 15.
CALIFORNIA STATE BOARD OF OPTOMETRY

NOTICE OF PROPOSED REGULATORY ACTION CONCERNING:

Optometry; Radio Frequency Technology and Devices; Authorization and Requirements

Adopt Title 16, California Code of Regulations (CCR), Article 11.5, Section 1572

NOTICE IS HEREBY GIVEN that the California State Board of Optometry (Board) is proposing to take the action described in the Informative Digest below, after considering all comments, objections, and recommendations regarding the proposed action.

PUBLIC HEARING

The Board has not scheduled a public hearing on this proposed action. However, the Board will hold a hearing if it receives a written request for a public hearing from any interested person, or his or her authorized representative, no later than 15 days prior to the close of the written comment period. A hearing may be requested by making such request in writing addressed to the individuals listed under “Contact Person” in this notice.

WRITTEN COMMENT PERIOD

Written comments relevant to the action proposed, including those sent by mail, facsimile, or e-mail to the addresses listed under “Contact Person” in this Notice, must be **received by the Board at its office no later than by Monday, September 23, 2024** or must be received by the Board at the hearing, should one be scheduled.

AUTHORITY AND REFERENCE

Pursuant to the authority vested by section(s) 3010.1, 3025, and 3025.5 of the Business and Professions Code (BPC), and to implement, interpret, or make specific BPC section 3041 the Board is considering adopting Article 11.5, section 1572, of title 16 of the California Code of Regulations (CCR).

INFORMATIVE DIGEST / POLICY STATEMENT OVERVIEW

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. 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.

Additionally, there are studies that show the efficacy of RF for treating MGD and 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 MGD and 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 MGD, 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.

The scope of practice for California-licensed optometrists is found at Business and Professions Code section 3041. There, the law both prescribes and limits 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 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 available for purchase over the counter for more than two decades. Studies show promise in treating patients suffering from dry eye syndrome caused by MGD, especially when combined with other treatments such as IPL and MGD 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 MGD.

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[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

Anticipated Benefits of Proposal

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 Therapeutic Pharmaceutical Agent (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.

Evaluation of Consistency and Compatibility with Existing State Regulations
During the process of developing this regulatory proposal, the Board has conducted a search of any similar regulations on these topics and has concluded that these regulations are neither inconsistent nor incompatible with existing state regulations.

DISCLOSURES REGARDING THIS PROPOSED ACTION

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State:
The regulations do not result in a fiscal impact to the state.

The regulations do not result in costs or savings in federal funding to the state.

Nondiscretionary Costs/Savings to Local Agencies: None.

Cost to any Local Agency or School District for which Government Code Sections 17500 – 17630 Require Reimbursement: None.

Mandate Imposed on Local Agencies or School Districts: None.

Significant Effect on Housing Costs: None.

BUSINESS IMPACT ESTIMATES

Significant, Statewide Adverse Economic Impact
The Board has made the initial determination that the proposed regulatory action will not have a significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

Cost Impact on Representative Private Person or Business
The Board is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

RESULTS OF ECONOMIC IMPACT ASSESSMENT / ANALYSIS

Impact on Jobs / Businesses

The California State Board of Optometry has determined that this regulatory proposal will not have a significant impact on the following:

1) the creation or elimination of jobs within the state,
2) the creation of new businesses or the elimination of existing businesses within the state, or,
3) the expansion of businesses currently doing business within the state.

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. This proposal would not have any of the above-referenced impacts as explained in the “Business Impact Estimates” section of this notice.

Benefits of Regulation:

The California State Board of Optometry has determined that this regulatory proposal will have the following benefits to the health and welfare of California residents. The proposed regulations will authorize the use of RF technology and devices on patients with dry eye disease. By authorizing the use of this technology, consumers and patients of optometric services may benefit by having their provider be authorized to use a proven treatment.

Licensed optometrists will also benefit by being able to offer their patients a treatment that works, especially in combination with other proven and legal treatments. Authorizing optometrists to use a proven technology that works in treating a common eye condition will improve the visual health of Californians.

This regulatory proposal does not affect or relate to either worker safety or the state’s environment, as this proposal is not related to any of those issues.

Business Reporting Requirements

The proposal does not require businesses to file a report with the Board.

Effect on Small Business

The Board has determined that the proposed regulations may affect small businesses, but the regulations will not have a significant statewide adverse economic impact on small businesses because the proposal authorizes the use of a technology and device

that is used to treat an eye condition for which optometrists are primary treatment providers.

CONSIDERATION OF ALTERNATIVES

In accordance with Government Code section 11346.5, subdivision (a)(13), the Board must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention would be more effective in carrying out the purpose for which the action is proposed; would be as effective and less burdensome to affected private persons than the proposal described in this Notice; or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Any interested person may submit comments to the Board in writing relevant to the above determinations at 2450 Del Paso Road, Suite 105, Sacramento, California 95834 during the written comment period, or at the hearing if one is scheduled or requested.

AVAILABILITY OF STATEMENT OF REASONS AND RULEMAKING FILE

The Board has compiled a record for this regulatory action, which includes the Initial Statement of Reasons (ISOR), proposed regulatory text, and all the information on which this proposal is based. This material is contained in the rulemaking file and is available for public inspection upon request to the contact persons named in this notice.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations, and any document incorporated by reference, and of the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained upon request from the Board, at 2450 Del Paso Road, Suite 105, Sacramento, California 95834.

AVAILABILITY OF CHANGED OR MODIFIED TEXT

After considering all timely and relevant comments, the Board, upon its own motion or at the request of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal, with the modifications clearly indicated, will be available for review and written comment for 15 days prior to its adoption from the person designated in this Notice as the Contact Person and will be mailed to those persons who submit written comments or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

You may obtain a copy of the Final Statement of Reasons once it has been prepared by making a written request to the Contact Person named below or by accessing the website listed below.

CONTACT PERSONS

Inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name:	Gregory Pruden
Address:	California State Board of Optometry 2450 Del Paso Road, Suite 105, Sacramento, CA 95834
Telephone No.:	916-574-7808
E-Mail Address:	Gregory.Pruden@dca.ca.gov

The backup contact person is:

Name:	Randy Love
Address:	California State Board of Optometry 2450 Del Paso Road, Suite 105, Sacramento, CA 95834
Telephone No.:	279-895-1471
E-Mail Address:	Randy.Love@dca.ca.gov

AVAILABILITY OF DOCUMENTS ON THE INTERNET

Copies of the Notice of Proposed Action, the Initial Statement of Reasons, and the text of the regulations with modifications noted, as well as the Final Statement of Reasons when completed, and modified text , if any, can be accessed through the Board's website at https://optometry.ca.gov/lawsregs/propregs.shtml