California State Board of Optometry
BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY • GAVIN NEWSOM, GOVERNOR
DEPARTMENT OF CONSUMER AFFAIRS • CALIFORNIA STATE BOARD OF OPTOMETRY
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ISSUE MEMORANDIUM

DATE	February 14, 2025
TO	Members, California State Board of Optometry
FROM	Gregory Pruden, Executive Officer & Elizabeth Dietzen-Olsen, Regulatory Counsel
SUBJECT	Agenda Item #3 – Discussion and Possible Action on adopting Title 16 California Code of Regulations (CCR), Article 11, Section 1572, related to Radiofrequency Technology; Authorization and Requirements

Summary:
On August 9, 2024, the Board submitted a regulatory proposal related to use of Optometric Radiofrequency Technology for treating meibomian gland dysfunction or dry eye disease to the Office of Administrative Law to be noticed to the public for a 45-day comment period. During that period, the Board received numerous comments in support and two comments in opposition to the proposal.

The purpose of this agenda item is to seek further public comment on this matter. The Board will defer considering the comments it received during the 45-day comment period related to this matter and evaluate those comments at a later date. The Board invites discussion on this matter to assist it with determining how to move forward with this regulation.

Background:
On May 31, 2024 the Board considered and approved a proposal to safely improve patient health by expanding the legal treatment options available for dry eye syndrome caused by meibomian gland dysfunction. The proposal would enable California-licensed TPA-certified optometrists to treat this syndrome using noninvasive radiofrequency (RF) technology and devices. This technology has long been approved by the Food and Drug Administration for aesthetic and dermatological purposes and several scientific studies have demonstrated its safe and efficacious use in treating meibomian gland dysfunction. The Board pursued this regulation under authority granted to it in Business and Professions Code section 3041 (a)(5)(G)(ii), which says that the practice of optometry includes:

> "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."

The 45-day comment period began on August 9, 2024, and ended on September 23, 2024. Of the letters in support, the Board received a letter from the California Optometric Association, letters from the three colleges of optometry located in California, and over 150 letters from California Optometrists. The two comments in opposition were received from the California Medical Association and the California Academy of Eye Care Physicians.

Supporters of the proposal note that RF technology is “non-invasive”, “does not cross the threshold into surgery”, is currently taught “during their education”, and that introducing “RF technology into the array of tools available to optometrists is not only consistent with modern optometric education but also aligned with the demonstrated efficacy of this noninvasive treatment in improving patient outcomes.”

Opponents, however, argue that the proposal “fails to conform with the statutory restrictions of optometric practice”, constitutes “surgery” under Business and Professions Code section 3041 (b)(6), which defines the word “surgery” to mean “any act in which human tissue is cut, altered, or otherwise infiltrated by any means”, and “contains substantive gaps” in its design.

At this meeting, the Board intends to receive further oral and written statements, arguments, or contentions regarding the proposal. In the interest of time, the Board is permitted to impose reasonable limitations on oral presentations to ensure all are heard. Depending on the interest and number of speakers, the time allotted may be limited to 3 minutes The Board will listen to public comment(s) and may ask clarifying questions to better understand the comment. The purpose of this agenda item is to assist the Board in determining how to move forward.

Attachments:
1. Proposed Regulatory Text
2. Notice
3. Initial Statement of Reasons

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.

Attachment #2

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

Attachment #3

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.