CALIFORNIA STATE BOARD OF OPTOMETRY

FINAL STATEMENT OF REASONS

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.

Updated Information: The Initial Statement of Reasons is included in the rulemaking file and incorporated as though set forth herein.

No public hearing was originally set for this proposal, and none was requested. Board staff noticed the proposed rulemaking on August 9, 2024, with a 45-day comment period ending on September 23, 2024. The Board received numerous comments; two of these comments were in opposition. The comments are summarized below.

After the conclusion of the 45-day public comment period, on February 14, 2025, the Board agendized the proposal for the purpose of seeking further public comment to assist the Board with determining how to move forward with the regulation.

On April 11, 2025, the Board considered and approved modified text and responses to comments and directed staff to commence a 15-day public comment period. That 15-day public comment period began on April 18, 2025, and ended on May 5, 2025, and the Board received three comments on the modified text; two of these comments were in opposition. The comments to the modified text are summarized below.
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The modified text included the following amendments:

A. **Replaced the phrase "heating the tissue" with "treating dry eye disease or syndrome" in subdivision (c)(1) of section 1572.**

   The Board deleted the phrase "heating the tissue" because the purpose of using radiofrequency technology is to treat dry eye disease or syndrome.

B. **Added "The electromagnetic current or wave frequency used for treating dry eye disease or syndrome shall be between 1 MHz and 6 MHz and the medical device which delivers the electromagnetic current or wave frequency shall contain a built-in temperature sensor which displays in real-time the temperature on the surface of the skin or contain temperature presets which shut down the device if the preset temperature is exceeded.**

The temperature applied to the surface of the skin shall not exceed 43 degrees Celsius or 109.4 degrees Fahrenheit " in subdivision (c)(1) of section 1572.

The Board added "The electromagnetic current or wave frequency used for treating dry eye disease or syndrome shall be between 1 MHz and 6 MHz and the medical device which delivers the electromagnetic current or wave frequency shall contain a built-in temperature sensor which displays in real-time the temperature on the surface of the skin or contain temperature presets which shut down the device if the preset temperature is exceeded. The temperature applied to the surface of the skin shall not exceed 43 degrees Celsius or 109.4 degrees Fahrenheit."

The Board modified the text and added this language to make clear that the radiofrequency technology must be contained within a frequency range with temperature controls or monitoring with an upper bound maximum temperature allowance. This protocol would not constitute surgery under the definition provided for in Business and Professions Code section 3041(b)(6) because human tissue is not cut, altered, or infiltrated. The frequency range and temperature controls were established consistent with the safe and effective protocol used in the studies cited by the Board as underlying data.

Following the modified text period, during the OAL final review period, the Board made the following non-substantive change as follows:

C. The Board replaced the word "should" with "must" in subdivision (b)(4) of Section 1572.

During the OAL final review of this regulatory proposal, it was noted that the proposed text of CCR section 1572(b)(4) inadvertently used the word "should" when the proper word is "must." (See: *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.*)

In the Board's published Initial Statement of Reasons, it is clear that this provision was intended to establish a requirement. By using "should" rather than "must," the regulation could be read as permissive rather than mandatory. To correct this drafting error, and consistent with its delegated authority, the Board's Executive Officer is making a non-substantive change to replace "should" with "must."

This revision is non-substantive because licensed California optometrists are already required to maintain, test, and inspect medical devices consistent with the standard of

care set forth in the Optometric Practice Act. The first duty of an optometrist is to make the health of the patient their first consideration. (see the Optometric Oath, published by the American Optometric Association). A physician or an optometrist that did not maintain, test, or inspect the medical devices it uses to deliver care would be violating the standard of practice, the standards of professional conduct, and the code of ethics. Therefore, adopting a discretionary standard would be a deviation from established law, as discussed in more detail below.

Specifically, Business and Professions Code section 3041.1 provides: *"An optometrist diagnosing or treating eye disease shall be held to the same standard of care to which physicians and surgeons and osteopathic physicians and surgeons are held."* The physician standard of care is well established in California case law as "the knowledge, skill and care ordinarily possessed and employed by members of the profession in good standing." (see *Flowers v. Torrance Memorial Hospital Medical Center* (1994) 8 Cal.4th 992, 998.) This is consistent with the American Medical Association's (AMA) Code of Medical Ethics, which requires physicians to adhere to standards of scientific knowledge and accepted practice (Opinion 1.1.6).

Similarly, the American Optometric Association's Standards of Professional Conduct states that Optometrists should "strive to provide care that is consistent with established clinical practice guidelines…that are based on the latest scientific knowledge and procedures…" and that "optometrists should employ only those clinical procedures and treatment regimens for which they are educated and competent to perform." The American Optometric Association's Code of Ethics requires optometrists "to advance their professional knowledge and proficiency to maintain and expand competence to benefit their patients" and "to maintain their practices in accordance with professional health care standards."

Existing law defines "professional negligence" as "a negligent act or omission by a health care provider in the rendering of professional services… within the scope of services for which the provider is licensed…." (see California Code of Civil Procedure section 340.5, Civil Code sections 3333.1 and 3333.2). A discretionary standard of device maintenance would increase the risk of patient harm, be a deviation from the standard of care, and constitute professional negligence.

Case law also supports the Board's interpretation. A physician has "a duty to use such skill, prudence, and diligence as other members of the profession commonly possess and exercise…" (see *Lattimore v. Dickey* (2015) 239 Cal.App.4th 959, 968 [191 Cal.Rptr.3d 766]) and as stated above, optometrists when diagnosing or treating eye disease, are held to the same standard of care to which physicians are held (see Business and Professions Code section 3041.1).

An optometrist, like a physician, is “required to possess and exercise, in both diagnosis and treatment, that reasonable degree of knowledge and skill which is ordinarily possessed and exercised by other members of his profession in similar circumstances.” (see *Landeros v. Flood* (1976) 17 Cal.3d 399, 408 [131 Cal.Rptr. 69, 551 P.2d 389].)

Under the law, a duty to be educated and have medical training and skill is imposed on those who practice medicine, and a physician is held liable for a lack of medical knowledge. Under the standard of care principle, negligence statutes and case law, so would an optometrist. (see *Hinson v. Clairemont Community Hospital* (1990) 218 Cal.App.3d 1110, 1119 [267 Cal.Rptr. 503] , disapproved on other grounds in *Alexander v. Superior Court* (1993) 5 Cal.4th 1218, 1228 [23 Cal.Rptr.2d 397, 859 P.2d 96].)

Further case law requires that “a hospital is obliged to maintain its premises and its instrumentalities for the comfort of its patients with such care and diligence as will reasonably assure their safety”. By analogy an optometrist would also have to maintain their instrumentalities to ensure patient safety and failure to do so would constitute negligence and unprofessional conduct under the law. (see *Valentin v. La Societe Francaise de Bienfaisance Mutuelle* (1946) 76 Cal.App.2d 1, 5 [172 P.2d 359].)

Optometrists must stay current with evolving technology and treatments, including ensuring that they properly use medical devices. In “An Optometrist’s Guide to Clinical Ethics”, published by the American Optometric Association, the optometrist is instructed that “when considering the introduction of new instrumentation into a practice, it is essential that the optometrist become knowledgeable about the conditions that the device is purported to diagnose or treat” and that once the new instrumentation, technology or device is instituted in practice “it is necessary for the optometrist to become skilled in its use”. Being skilled in the use of a device would necessarily including its proper maintenance, inspection, and testing, consistent with the manufacturers’ specifications. Otherwise, the optometrist would risk patient harm by potentially using a device that does not function as intended by the manufacturer. The process of becoming skilled “may be as simple as reading the manufacturer’s instructions or it may require taking continuing education courses.”

Additionally, federal law mirrors this standard. The Food and Drug Administration requires device manufacturers to provide *“adequate information for safe and effective use”* directed to licensed practitioners, not to the general public. (21 C.F.R. § 801.109) This professional standard is consistent with the Board’s rationale, as explained in the Initial Statement of Reasons, for requiring the optometrist to maintain, test, and inspect the device according to the manufacturer’s specifications: the requirement protects consumers by ensuring the optometrist is trained and knowledgeable in the use and maintenance of the device. Thus, compliance with manufacturer specifications for

maintenance, testing, and inspection is already inherent in the professional standard of care and adopting a discretionary standard would be contrary to existing law.

Local Mandate:

A mandate is not imposed on local agencies or school districts.

Small Business Impact:

The Board has determined that the proposed regulations would not affect small businesses. As described in the Business Impact section of the Initial Statement of Reasons, 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.

FISCAL IMPACT:

The Board has determined that there is no fiscal impact associated with this regulation.

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 is safe and effective, especially when the RF technology or device is used in combination with other proven techniques such as Intense Pulse Light therapy 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

The modified text makes clear that the RF device used is for the purpose of treating dry eye disease or syndrome, specifies a frequency range, and requires temperature monitoring or temperature presets which limit the temperature, ruling out other devices that use RF and that could potentially ablate the tissue, as these devices are considered electrosurgical units, are used in medicine, and are inappropriate to use to treat dry eye disease. The frequency range and temperate limits and controls were based on the studies cited by the Board, which showed the technology to be safe and effective.

Consideration of Alternatives: No reasonable alternative which was considered or that has otherwise been identified and brought to the attention of the Board would be more effective in carrying out the purpose for which it was proposed or would be as effective and less burdensome to affected private persons than the adopted regulations or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law. During the public comment period, the Board received comments from stakeholders that the Board considered. After considering the comments, the Board modified the text to include revisions based on these comments. The Board did not accept all the comments or alternatives, as discussed in greater detail below.

Objections or Recommendations/Responses during 45-Day Comment Period: The Board received numerous comments of which two (2) were adverse comments during the 45-day comment period on the Board's proposed adoption of section 1572. Some of the comments were accepted and others were rejected. A summary of the responses to comments can be found below.

A. September 9, 2024, letter from Stephen J. Cattolica, Executive Vice President, California Academy of Eye Physicians and Surgeons (CAEPS).

Comment Letter A Summary:

CAEPS raises concerns that the proposal "has significant flaws due to vague language, lack of specific authority and failure to conform with the statutory restrictions of optometric practice." CAEPS claims that "When RF induces neocollagenesis, it leads to the synthesis of new collagen fibers, which directly alters the tissue's architecture." CAEPS claims that RF cannot be authorized under the law because it constitutes surgery and surgery is defined as "performing any act in which human tissue is cut, altered, or otherwise infiltrated by any means." CAEPS additionally claims that "RF alters tissue through neocollagenesis" and therefore is surgery and "is excluded from the practice of optometry."

Additionally, CAEPS claims the proposal "contains substantive gaps", including by failing to "explain how the proposed educational pathway meets standards of adequacy, consistency, and rigor." CAEPS claims the proposed language authorizing RF only for a documented purpose within the scope of practice "lacks both specificity and any prescribed method of verification." CAEPS further claims the proposal does not "clearly distinguish therapeutic uses of RF from aesthetic ones." CAEPS also raises concerns that the proposal would prohibit use of RF after the optometric purpose of treatment has been achieved but does not define what is achievement or completion. CAEPS states that the proposal would require RF devices to meet state and federal requirements but does not state which code sections are to be followed and that the proposal "lacks guidelines for combining treatment modalities or evaluating their collective efficacy and safety."

Finally, CAEPS raises issues with the proposed language which would prohibit delegation of the RF technology or device, including to opticians. CAEPS states this suggests "there may be broader regulatory issues that the Board has not fully addressed."

In conclusion, CAEPS recommends the Board conduct an "audit to identify the extent and parameters of unauthorized RF procedures already being performed by its licensees, act immediately to halt such unauthorized treatments in the treatments…and report the results of its findings to the legislature…"

Response:
The Board thanks CAEPS for their comments on the proposal. However, the Board rejects the comment that the proposal has "significant flaws due to vague language, lack of specific authority and failure to conform with the statutory restrictions of optometric practice." 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 has the authority to pursue this regulation.

The Board rejects the comment that RF fails to conform with the restrictions of

optometric practice and that RF constitutes surgery under the definition of that term within Business and Professions Code section 3041(b)(6). The act of using RF does not constitute surgery because using RF to treat dry eye disease is not an act in which "human tissue is cut, altered, or otherwise infiltrated by any means." When RF is used to treat dry eye disease it is a noninvasive technology that stimulates the body's natural healing process via an electrical current and heat formation which may induce neocollagenesis. Neocollagenesis, or the process of forming collagen fibers, may result after stimuli received from the electrical current and subsequent heat formation. Collagen fibers are a protein and one component of connective tissue, which also includes elastic fibers, amorphous ground substance, and extracellular fluid, but collagen fibers by themselves do not constitute human tissue. Therefore, RF does not constitute surgery because it stimulates a natural healing process via protein formation.

The Board rejects the comment that RF technology alters human tissue. It merely applies an electromagnetic current or wave in a focused manner on the surface of the skin. In essence, it functions as a precision heat compress. While it is possible to argue that the subsequent heat formation could lightly penetrate the upper layers of skin, that interpretation would result in an absurd result. It would essentially mean that applying a warm compress, or even standing in sunshine, would constitute surgery for the purposes of Business and Professions Code Section 3041(b)(6). It would be hard to imagine what sort of device or technology the Board would be permitted to approve under Business and Professions Code Section 3041(a)(5)(G)(ii) if the application of heat without a more significant penetration of tissue constitutes surgery under Business and Professions Code Section 3041(b)(6). Therefore, looking at the statute as a whole, it is likely that the legislature used the terms "infiltrate" and "alter" in connection with the definition of surgery to refer to devices that would physically penetrate human tissue in a manner akin to cutting or removing tissue. Therefore, RF technology does not alter or infiltrate human tissue for the purposes of Business and Professions Code Section 3041(b)(6) as it simply applies precision heat to the outermost layer of human skin.

The Board rejects the comment that the proposal fails to "explain how the proposed educational pathway meets standards of adequacy, consistency, and rigor." The Board rejects the comment because the law found at BPC 3041(a)(5)(G)(ii) does not require the Board to explain how any proposed educational pathways meet standards of adequacy, consistency, or rigor. Rather, the law states that the licensee shall "successfully complete an appropriate amount of clinical training…" As stated in the Initial Statement of Reasons on page 4-5, the Board has determined that there are three pathways to demonstrate an appropriate amount of clinical training.

The Board rejects the comment that the proposed language authorizing RF only for a documented purpose within the scope of practice "lacks both specificity and any

prescribed method of verification" and rejects the comment that the proposal does not "clearly distinguish therapeutic uses of RF from aesthetic ones." Subdivision (b)(2) of section 1572 of the proposed language states that the optometrist "shall only use noninvasive radiofrequency technology or devices on patients…for the optometric purpose of treating dry eye disease or syndrome as documented in the patient's medical record." The therapeutic use of RF is for treating dry eye disease or syndrome.

For similar reasons, the Board rejects the comment that the proposal would prohibit use of RF after the optometric purpose of treatment has been achieved but does not define what is achievement or completion. The law does not require the board to define the terms "achievement" or "completion", and the proposal would require the use of RF to be documented in the patient's medical record. The prescribing optometrist conducting the treatment for the documented purpose of treating dry eye disease or syndrome would decide when it is medically appropriate to cease treatment, pursuant to the care they are providing the patient. Inappropriate use of RF would occur if the technology was used on a patient that did not have a dry eye disease or syndrome diagnosis documented in the patient's medical record.

The Board rejects the comment that the proposal states it would require RF devices to meet state and federal requirements but does not state which code sections are to be followed and rejects the comment that the proposal "lacks guidelines for combining treatment modalities or evaluating their collective efficacy and safety. The initial statement of reasons states that the proposed language contains the requirement that the device must meet state and federal requirements. The text that was noticed to the public during the 45-day comment period does not include that language. That sentence appears in the Initial Statement of Reasons, but it was decided by the Board to not include that text because that terminology is too broad and other more specific safety measures are included in the text. Specifically, the equipment must be maintained, tested and inspected according to the manufacturers' specifications.

Further, the law does not require the proposal to contain guidelines for combining treatment modalities of evaluating efficacy and safety. Optometrists, like most health care providers, commonly use multiple treatment modalities to care for their patients, which is done consistent with their individual scopes of practice and the unique health care needs of the patient.

The Board rejects the comment pertaining to the proposal which would prohibit delegation of the RF technology or device, including to opticians. CAEPS suggests "there may be broader regulatory issues that the Board has not fully addressed." The law does not authorize the Board in pursuing this authority to allow optometrists to delegate to other individuals, including opticians. Additionally, the use of RF is for the

purpose of treating an eye disease, which only licensed optometrists and ophthalmologists are trained and licensed to diagnose. Prohibiting the delegation of the technology is intended to protect consumers by ensuring they are receiving the treatment only from those educated, trained, and licensed to provide it.

Finally, the Board rejects the recommendation that it conduct an "audit to identify the extent and parameters of unauthorized RF procedures already being performed by its licensees, act immediately to halt such unauthorized treatments…and report the results of its findings to the legislature…" The Board investigates all complaints it receives alleging violations of the law involving both licensees and those engaged in unlicensed practice and takes seriously its consumer protection mandate. The Board also regularly reports complaint and enforcement statistics at quarterly board meetings, in an annual report, and via the Legislative sunset review process.

While the Board rejects these comments for the reasons stated above, the Board modified the text to define "noninvasive medical devices or radiofrequency technology" to be for the purpose of "treating dry eye disease or syndrome" and modified the text to specify the range of electromagnetic current or wave frequency that could be used, including adding a requirement that the temperature applied to the skin shall not exceed an upper bound limit, and that the medical device contain a built-in temperature sensor or contain temperature presets capable of shutting the device down if the preset temperature is exceeded.

B. September 20, 2024, email from Lucas Evensen, Associate Director, Strategic Engagement, California Medical Association (CMA).

Comment Letter B Summary:
CMA raises concerns that the proposal "lacks specific authority and fails to conform with the statutory restrictions of optometric practice."

CMA claims that "When RF technology induces neocollagenesis, it leads to the synthesis of new collagen fibers, which directly alters the tissue's architecture."

CMA claims that RF cannot be authorized under the law because it constitutes surgery and surgery is defined as "performing any act in which human tissue is cut, altered, or otherwise infiltrated by any means." CMA additionally claims that "RF alters tissue through neocollagenesis" and therefore is surgery and "is excluded from the practice of optometry."

CMA notes that there are other treatments for dry eye that do have specific statutory authority in the practice act, and they provide several examples, including IPL and intranasal stimulators.

Response:
The Board rejects the comment that the proposal "lacks specific authority and fails to conform with the statutory restrictions of optometric practice." 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 has the authority to pursue this regulation.

The Board rejects the comment that RF fails to conform with the restrictions of optometric practice and that RF constitutes surgery under the definition of that term within Business and Professions Code section 3041(b)(6). The act of using RF does not constitute surgery because using RF is not an act in which "human tissue is cut, altered, or otherwise infiltrated by any means." When RF is used to treat dry eye disease it is a noninvasive technology that stimulates the body's natural healing process via an electrical current and heat formation which may induce neocollagenesis. Neocollagenesis, or the process of forming collagen fibers, may result after stimuli received from the electrical current and subsequent heat formation. Collagen fibers are a protein and one component of connective tissue, which also includes elastic fibers, amorphous ground substance, and extracellular fluid, but collagen fibers by themselves do not constitute human tissue. Therefore, RF does not constitute surgery because it stimulates a natural healing process via protein formation.

The Board rejects the comment that RF technology alters human tissue. It merely applies an electromagnetic current or wave in a focused manner on the surface of the skin. In essence, it functions as a precision heat compress. While it is possible to argue that the subsequent heat formation could lightly penetrate the upper layers of skin, that interpretation would result in an absurd result. It would essentially mean that applying a warm compress, or even standing in sunshine, would constitute surgery for the purposes of Business and Professions Code Section 3041(b)(6). It would be hard to imagine what sort of device or technology the Board would be permitted to approve under Business and Professions Code Section 3041(a)(5)(G)(ii) if the application of heat without a more significant penetration of tissue constitutes surgery under Business and Professions Code Section 3041(b)(6). Therefore, looking at the statute as a whole, it is likely that the legislature used the terms "infiltrate" and "alter" in connection with the definition of surgery to refer to devices that would physically penetrate human tissue in a manner akin to cutting or removing tissue. Therefore, RF technology does not alter or infiltrate human tissue for the purposes of Business and Professions Code Section 3041(b)(6) as it simply applies precision heat to the outermost layer of human skin.

The Board accepts the comment that other treatments for dry eye enjoy specific statutory authorization. However, this comment is irrelevant as the Board also has the authority under BPC 3041(a)(5)(G)(ii) to approve the use of "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."

C. September 20, 2024, email from John Flanagan, Dean, Herbert Wertheim School of Optometry & Vision Science, University of California, Berkeley.

Comment Letter C Summary:
Dean Flanagan states that the Herbert Wertheim School of Optometry & Vision Science is in "full support" of the proposal to use radio frequency technology to treat dry eye disease and that the "anticipated benefits of authorizing the use…are both substantial and wide-reaching, providing clear advantages for regulatory alignment and public welfare."

Dean Flanagan notes that "California-licensed optometrists are not permitted to use RF technology, despite its proven effectiveness in treating dry eye disease" and that "expanding the treatment tools available…will result in meaningful relief for patients suffering from dry eye, significantly improving their quality of life."

Dean Flanagan states that RF technology is a "non-invasive treatment option" that "will have a significant, positive impact on the lives of those suffering from dry eye disease, while maintaining strong regulatory oversight to ensure safe and appropriate use."

Response:
The Board acknowledges and accepts the comment from Dean Flanagan regarding the benefits of authorizing RF technology for use in treating dry eye disease or syndrome.

The Board also accepts the comments that the technology is proven effective, and that regulatory oversight will ensure safe and appropriate use, as studies have shown the benefits of using RF technology to treat dry eye disease with no patient harm whatsoever.

D. September 19, 2024, email from Elizabeth Hoppe, Dean, College of Optometry, Western University of Health Sciences.

Comment Letter D Summary:
Dean Hoppe writes to "express... strong support" for the proposal and states that "authorizing this noninvasive technology will yield significant benefits for residents in California, including underserved and marginalized communities."
Dean Hoppe states that the proposal "promotes the capacity to effectively treat dry eye disease, a condition that affects millions of Californians" and notes that "despite their training in RF technology during their education" California-licensed optometrists "are unable to employ these techniques in clinical practice." Dean Hoppe states that "this restriction limits the comprehensive care that ODs can provide, denying patients access

to valuable treatment options that have proven effective…"

Dean Hoppe states that the proposal will "ensure that RF technology will be used responsibly and within the confines of optometric practice" because it "mandates appropriate clinical training and, delineates the scope of use, and protecting consumers from potential misuse.

Dean Hoppe states "that incorporating RF technology into optometric practice is not an encroachment on surgical practices, but rather an evolution of noninvasive treatments designed to enhance patient care."
Finally, Dean Hoppe notes that the proposal would "not only improve the quality-of-care patients receive, but will also align our practice with contemporary medical standards."

Response:
The Board acknowledges and accepts the comment from Dean Hoppe regarding the benefits of authorizing RF technology for use in treating dry eye disease or syndrome. The use of radiofrequency does have the potential to benefit certain patients who have darker skin tones and may not be good candidates for other dry eye disease treatments, such as Intense Pulse Light.

The Board also accepts the comments that the technology is proven effective, and that regulatory oversight will ensure safe and appropriate use, as studies have shown the benefits of using RF technology to treat dry eye disease with no patient harm.

E. September 20, 2024, email from Eric Borsting, Dean, Southern California College of Optometry, Marshall B. Ketchum University.

Comment Letter E Summary:
Dean Borsting writes to "express strong support…for the authorization of Radio Frequency (RF) technology and devices for use by California-licensed optometrists who have attained Therapeutic Pharmaceutical Agent (TPA) certification. The potential benefits to patients from this authorization are substantial and wide-reaching, positively impacting both regulatory alignment and public welfare."

Dean Borsting states that "dry eye and meibomian gland disease…impact the ocular health, vision, and quality of life of millions of Californians" and that the "conditions are difficult to manage effectively" but that "RF has show effectiveness in treating dry eye and meibomian gland disease" and that "RF is not considered surgery because it is a non-invasive procedure that uses controlled heat to stimulate tissue."

Dean Borsting writes that "RF is similar in function, mechanism of action, and application to intense pulsed light (IPL), which is an FDA-approved treatment for dry eye that is currently approved for use by California optometrists." RF and IPL are similar,

writes Dean Borsting, in that they "both…rely on precision technology and energy-based modalities without crossing the threshold into surgery." Both IPL and RF are "safe and effective in managing signs and symptoms of dry eye" even "when used separately and in conjunction."

Dean Borsting writes that "this regulation ensures that the use of RF technology remains within the scope of optometric practice and protects consumers from its potential misuse."

Response:
The Board acknowledges and accepts the comment from Dean Borsting expressing strong support for the proposal. The Board also acknowledges and accepts the comment that RF is not considered surgery because it is non-invasive.

F. September 23, 2024, email from Kristine Shultz, Executive Director, California Optometric Association.

Comment Letter F Summary:
Ms. Shultz writes to "express…strong support for the proposal to allow California optometrists to utilize radiofrequency (RF) technology in the treatment of dry eye disease."

Ms. Shultz states that authorizing California optometrists to use "RF technology…is not only consistent with modern optometric education but also aligned with the demonstrated efficacy of this noninvasive treatment in improving patient outcomes."

Ms. Shultz states that "RF technology is not a surgical procedure and would not constitute surgery as defined under the Optometric Practice Act" because "RF technology…is a noninvasive treatment that uses controlled energy to stimulate the body's natural healing process." Ms. Shultz states that RF works by producing an "electromagnetic wave" that is "transferred from an oscillatory electrical field to charged particles or dipoles (water molecules) in the target issue." The electromagnetic wave "generates vibrations of the particles, which produce friction between tissue particles and, consequently, heat is generated."

Ms. Shultz states that "RF technology is designed to treat the underlying causes of dry eye disease without the need for surgical intervention." Ms. Shultz also states that "California-licensed optometrists receive comprehensive education and training on RF technology…" and the "proposal includes stringent guidelines ensuring that only those fully trained will be authorized to perform this treatment" which "protects patients and upholds the high standards of care that optometrists provide."

Response:

The Board acknowledges and accepts the comment from Ms. Shultz expressing strong support for the proposal. The Board also acknowledges and accepts the comments from Ms. Shultz that RF technology is consistent with modern education, noninvasive, nonsurgical, and stimulates the body's natural healing process. Lastly, the Board acknowledges and accepts the comment that the proposal includes stringent guidelines outlining who can use the technology which is designed to protect patients and uphold high standards of care.

G. 124 emails of support from individuals

Comment Letter G Summary:
The Board received 124 substantially similar emailed letters of support from individuals.

Response:
The Board acknowledges and thanks these individuals for their support of the proposal.

Objections or Recommendations/Responses during 15-Day Comment Period: The Board received three (3) comments of which two (2) were adverse comments during the 15-day comment period on the Board's proposed adoption of section 1572. Some of the comments were accepted and others were rejected. A summary of the responses to comments can be found below.

A. May 2, 2025, letter from Michael T. Couris, MD, President, California Academy of Eye Physicians and Surgeons (CAEPS).

Comment Letter A Summary:
CAEPS is opposed to the regulation and claims that the proposal violates the meaning of surgery as it is defined in California Business and Professions Code Section 3041 (b)(6). CAEPS states that the modified text "proposes a specific frequency range to define radiotherapy within the optometric context" and that "varying frequencies can yield varying depth profiles, analogous to the difference between a deep incision made with a sharp instrument and superficial one produced with minimal force." CAEPS claims that the Board is "aware of and essentially admits the tissue-modifying nature of radiotherapy, as evidenced by their effort to restrict the permissible frequency range."

CAEPS further claims that the modified text requiring temperature limitations is an acknowledgement by the Board that energy is being applied to the treated area and that temperature limitations are necessary. CAEPS claims that this "supports the conclusion that energy is being used to alter tissue. It is the regulation of temperature that minimizes unintended damage while still allowing for the controlled alteration of tissue in a beneficial way – precisely aligning with the definition of surgery."

The rest of the issues raised by CAEPS are not germane to the modified text and were

dealt with in the Board's responses approved at the April 11, 2025, board meeting.

Response:
The Board thanks CAEPS for their comments on the modified proposal. The Board agrees with CAEPS that the proposal includes a specific frequency range and that varying frequencies can yield varying depth profiles. The Board also agrees with CAEPS that the proposal includes temperature limits and monitoring.

However, the Board rejects the comment that this is analogous to deeply or superficially incising tissue. The Board rejects this comment because the frequency range combined with the temperature monitoring ensures that no tissue is incised, or otherwise altered, or infiltrated, using the technology. The Board developed the frequency range and temperature limits based on a 2023 study titled "*Transcutaneous Radiofrequency-mediated Meibomian Gland Expression is an Effective Treatment for Dry Eye: A Prospective Cohort Trial*, published in The Open Ophthalmology Journal, which utilized a 1MHz frequency and a similar temperature end-point protocol. The study authors stated that "using this technique, the tissue was not ablated nor an open wound created." The study conclusion reported no burning sensations utilizing this protocol, and no skin burns and no corneal trauma among study participants over a six-month follow-up period. The study also stated that "the treatment itself could be delegated to a mid-level provider after a training session and observed by the physician to verify the technique." This is consistent with the testimony received that an ophthalmologist would likely delegate the use of RF Technology to an unlicensed medical assistant in their office.

The Board rejects the comment that the modified proposal is "precisely aligning with the definition of surgery." This comment was already addressed in the previous Board response to comments.

The modified proposal would not constitute surgery because using RF to treat dry eye disease is not an act in which "human tissue is cut, altered, or otherwise infiltrated by any means." Under the rules of statutory interpretation, courts begin with the plain language of the statute, giving words their usual and ordinary meaning (*People v. Murphy* (2001) 25 Cal.4th 136, 142, 105 Cal.Rptr.2d 387, 19 P.3d 1129.). However, the courts have also found that if interpreting the plain meaning of a word would lead to an odd or absurd result, the courts will look to the overall scope of the intention of the Legislature. (*Public Citizen v. Department of Justice,* 491 U.S. 440 (1989)). CAEPS correctly cites AB 407 (Salas) Chapter 652, Statutes of 2021 as the legislation that modified the definition of surgery within the Optometric Practice Act. However, in reading the legislative analyses the Legislature intended to expand the scope of optometrists' practice by permitting the Board to authorize the use of noninvasive devices and technology. The Legislature also did not define the words, "alter" or "infiltrate" in the statute, nor have they interpreted those words in other medical

contexts. Reading the plain meaning of the words “altered” or “infiltrate” would lead to an absurd result.

When RF is used to treat dry eye disease it is a noninvasive technology that stimulates the body’s natural healing process via an electrical current and heat formation which may induce neocollagenesis. Neocollagenesis, or the process of forming collagen fibers, may result after stimuli received from the electrical current and subsequent heat formation. Collagen fibers are a protein and one component of connective tissue, which also includes elastic fibers, amorphous ground substance, and extracellular fluid, but collagen fibers by themselves do not constitute human tissue. Therefore, RF does not constitute surgery because it stimulates a natural healing process via protein formation.

The Board rejects the comment that RF technology alters human tissue. It merely applies an electromagnetic current or wave in a focused manner on the surface of the skin. In essence, it functions as a precision heat compress. While it is possible to argue that the subsequent heat formation could lightly penetrate the upper layers of skin, that interpretation would constitute an absurd result. It would essentially mean that applying a warm compress, or even standing in sunshine, would constitute surgery for the purposes of Business and Professions Code Section 3041(b)(6). It would be hard to imagine what sort of device or technology the Board would be permitted to approve under Business and Professions Code Section 3041(a)(5)(G)(ii) if the application of heat without a more significant penetration of tissue constitutes surgery under Business and Professions Code Section 3041(b)(6). Therefore, looking at the statute as a whole, it is likely that the legislature used the terms “infiltrate” and “alter” in connection with the definition of surgery to refer to devices that would physically penetrate human tissue in a manner akin to cutting or removing tissue. Therefore, RF technology does not alter or infiltrate human tissue for the purposes of Business and Professions Code Section 3041(b)(6) as it simply applies precision heat to the outermost layer of human skin.

It is important to note that neither this commenter nor the California Medical Association, referenced below, disputes that RF technology is a rational and evidence-based method for treating dry eye disease—an area clearly within the scope of the Optometric Practice Act. They also do not dispute that optometric schools include instruction in this technology as part of their curriculum for the effective treatment of dry eye. Furthermore, they fail to contest the fact that ophthalmologists frequently delegate the use of RF technology to unlicensed medical assistants—individuals who lack surgical training—despite portraying the procedure as surgical in nature.

B. May 5, 2025, letter from Lucas Evensen, Associate Director, Strategic Engagement, California Medical Association (CMA).

Comment Letter B Summary:
CMA is opposed to the regulation because “Radiofrequency technology alters human

tissue through neocollagenesis, which directly alters the connective tissue and the architecture of other surrounding tissue" and "the use of RF technology constitutes surgery under the California Optometry Practice Act and is excluded from the practice of optometry."

CMA states that the Board "seems to be attempting to draft regulations to avoid approval of RF technology which would ablate tissue or constitute an electrosurgical unit." CMA claims that "The questions of whether RF technology ablates tissue or constitutes an electrosurgical unit distract from the relevant question. The operative question is whether the act of using RF technology *alters* human tissue by *any means*—a standard that RF technology clearly meets" and that by "framing its approval as narrow and avoiding statutory terminology, the Board appears to acknowledge that RF technology alters tissue but is seeking to circumvent through rulemaking the clear statutory limits the Legislature established in BPC 3041." CMA therefore requests the "Board not adopt the proposed regulations and withdraw this rulemaking package."

The rest of the issues raised by CMA are not germane to the modified text and were dealt with in the Board's responses approved at the April 11, 2025, board meeting.

Response:
The Board rejects the comment that the use of "RF technology constitutes surgery under the California Optometry Practice Act and is excluded from the practice of optometry."

The modified proposal would not constitute surgery because using RF to treat dry eye disease is not an act in which "human tissue is cut, altered, or otherwise infiltrated by any means." Under the rules of statutory interpretation, courts begin with the plain language of the statute, giving words their usual and ordinary meaning (*People v. Murphy* (2001) 25 Cal.4th 136, 142, 105 Cal.Rptr.2d 387, 19 P.3d 1129.). However, the courts have also found that if interpreting the plain meaning of a word would lead to an odd or absurd result, the courts will look to the overall scope of the intention of the Legislature. (*Public Citizen v. Department of Justice,* 491 U.S. 440 (1989)). Assembly Bill 407 (Salas) Chapter 652, Statutes of 2021 was the most recent legislation that modified the definition of surgery within the Optometric Practice Act. However, in reading the legislative analyses the Legislature intended to expand the scope of optometrists' practice by permitting the Board to authorize the use of noninvasive devices and technology. The Legislature also did not define the words, "alter" or "infiltrate" in the statute, nor have they interpreted those words in other medical contexts. Reading the plain meaning of the words "altered" or "infiltrate" would lead to an absurd result.

When RF is used to treat dry eye disease it is a noninvasive technology that stimulates the body's natural healing process via an electrical current and heat formation which

may induce neocollagenesis. Neocollagenesis, or the process of forming collagen fibers, may result after stimuli received from the electrical current and subsequent heat formation. Collagen fibers are a protein and one component of connective tissue, which also includes elastic fibers, amorphous ground substance, and extracellular fluid, but collagen fibers by themselves do not constitute human tissue. Therefore, RF does not constitute surgery because it stimulates a natural healing process via protein formation.

The Board rejects the comment that RF technology alters human tissue through neocollagenesis. It merely applies an electromagnetic current or wave in a focused manner on the surface of the skin. In essence, it functions as a precision heat compress. While it is possible to argue that the subsequent heat formation could lightly penetrate the upper layers of skin, that interpretation would result in an absurd result. It would essentially mean that applying a warm compress, or even standing in sunshine, would constitute surgery for the purposes of Business and Professions Code Section 3041(b)(6). It would be hard to imagine what sort of device or technology the Board would be permitted to approve under Business and Professions Code Section 3041(a)(5)(G)(ii) if the application of heat without a more significant penetration of tissue constitutes surgery under Business and Professions Code Section 3041(b)(6). Therefore, looking at the statute as a whole, it is likely that the legislature used the terms “infiltrate” and “alter” in connection with the definition of surgery to refer to devices that would physically penetrate human tissue in a manner akin to cutting or removing tissue. Therefore, RF technology does not alter or infiltrate human tissue for the purposes of Business and Professions Code Section 3041(b)(6) as it simply applies precision heat to the outermost layer of human skin.

The Board accepts the comment that it “seems to be attempting to draft regulations to avoid approval of RF technology which would ablate tissue or constitute an electrosurgical unit” because the Board is not authorized to approve technology which would ablate tissue as this would constitute surgery. The Board modified the text to make clear that the radiofrequency technology must be contained within a frequency range with temperature controls or monitoring with an upper bound maximum temperature allowance. This protocol would not constitute surgery under the definition provided for in Business and Professions Code section 3041(b)(6) because human tissue is not cut, altered, or infiltrated. However, the Board rejects the comment that by “framing its approval as narrow and avoiding statutory terminology, the Board appears to acknowledge that RF technology alters tissue but is seeking to circumvent through rulemaking the clear statutory limits the Legislature established in BPC 3041.”

To the contrary, the Board is utilizing the authority the Legislature provided for in BPC 3041(a)(5)(G)(ii) to approve the use of “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.” The Board agrees this authority is constrained by the definition of surgery which prohibits devices or

technologies in which human tissue would be cut, altered, or infiltrated by any means.

However, the use of RF technology under the Board's regulation complies with the statutory framework because the technology may only stimulate a natural process called neocollagenesis, or the process of forming collagen fibers, which may result after stimuli received from the electrical current and subsequent heat formation. Collagen fibers are a protein and one component of connective tissue, which also includes elastic fibers, amorphous ground substance, and extracellular fluid, but collagen fibers by themselves do not constitute human tissue. Therefore, RF does not constitute surgery because it stimulates a natural healing process via protein formation

C. April 25, 2025, email from Kristine Shultz, Executive Director, California Optometric Association (COA).

Comment Letter C Summary:
COA states that the "recent amendments that establish specific safety parameters for radiofrequency devices reflect a responsible, evidence-based approach that prioritizes both public safety and access to modern, effective treatments for ocular surface disease."

COA states that "the revised language…limits RF devices" to "a range that is widely regarded as therapeutic but non-ablative, meaning it does not have the capacity to cut or otherwise damage the skin." COA writes that "this important clarification…ensures that optometrists will be limited to low-risk, non-invasive RF treatments for conditions such as meibomian gland dysfunction and chronic dry eye."

COA writes that the "revised regulations require either a built-in temperature sensors that displays a real-time readout of the skin's surface temperature during treatment or preset temperature limits with automatic shut-off functions if the device exceeds the safe preset range" and "these are important safety features that give the provider precise control and guarantee of safety."

Response:
The Board acknowledges and accepts the comment from COA that the revised regulations establish safety parameters that are evidence-based and prioritize public safety and access to modern and effective treatments for dry eye disease.

The Board acknowledges and accepts the comments from COA that the modified proposal limits RF devices to ranges that are therapeutic and non-ablative. The Board also acknowledges and accepts the comment from COA that the temperature requirements represent important safety features for consumers and the treating optometrist.