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ISSUE MEMORANDUM

DATE	April 5, 2024
ТО	Committee Members, California State Board of Optometry (CSBO)
FROM	Gregory Pruden, Executive Officer
SUBJECT	Agenda Item #5 – Discussion and Possible Action on Dry Eye Syndrome, Intense Pulsed Light, & Radio Frequency Technology

Summary:

Staff presents the following information regarding Dry Eye Syndrome and technologies on the market used to treat it, including intense pulsed light (IPL) and radio frequency (RF). Some technologies, like IPL, have explicit legal authority, others, like RF, may not.

Issue:

Dry eye 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.1

Dry eye can cause:

- A scratchy feeling, like there's something in your eye.
- Stinging or burning feelings in your eye.
- Red eyes.
- Sensitivity to light.
- Blurry vision.

Anyone can get dry eye, but you might be more likely to have dry eye if you:

- Are age 50 or older.
- Are female.
- Wear contact lenses.
- Don't get enough vitamin A or omega-3 fatty acids.
- Have certain autoimmune conditions, like lupus or Sjögren syndrome.
- Spend a lot of time viewing electronic screens, such as smartphones or computers.

What's the authorized treatment for dry eye?

- 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 involving the use of IPL and/or RF are increasingly being offered to treat dry eye. IPL is a technology used to deliver pulses of light to liquefy and release oils

https://www.mayoclinic.org/diseases-conditions/dry-eyes/symptoms-causes/syc-20371863

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.

As emerging technologies are offered to treat dry eye syndrome, licensees need to be aware of potential scope of practice issues, as some technologies may not have explicit authorization under state or federal law for use by California-licensed optometrists.

IPL and RF technology, administered individually or as part of a combination regime, are often offered as a treatment for dry eye disease or 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 approval for the treatment of a disease or condition of the visual system.² 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. ³

A CBS Sacramento news article from October 2023 highlighted IPL and dry eye syndrome:

"Recently approved FDA technique proving good treatment for dry eyes"

In contrast, RF has no explicit authorization under state law for use by optometrists and staff research could only determine that there are some RF devices that have received FDA authorization for over-the-counter use for wrinkles and other aesthetic uses but could not find any RF devices that had received an FDA approved indication for the diagnosis or treatment of any condition impacting the visual system.⁴ The Board has issued no regulations authorizing the use of RF and the use of RF by California optometrists may not be authorized at this time.

How widespread RF is in the market remains unknown to staff as the services offered by optometrists are not tracked or reported. Staff could not locate any complaints regarding the use of RF technology by optometrists so it could not be determined whether consumer harm is occurring.

As emerging and innovative technologies are used to treat symptoms and conditions of the visual system, licensed optometrists and the consuming public should review and stay current on the laws and regulations governing the practice of optometry and contact the Board if they have any questions regarding technologies offered or used during their treatment.

Staff Recommendation

Staff presents different options for the Committee's consideration:

- 1) Continue to research the technology and its use for dry eye syndrome.
- 2) Pursue an outreach and education campaign regarding dry eye syndrome, IPL, and RF technology.
- 3) Pursue a statutory or regulatory change authorizing the use of RF.
- 4) Pursue a statutory or regulatory change prohibiting the use of RF.

² BPC 3041 (a)(5)(F)(xii) and BPC 3041 (a)(5)(G)(1)-(2).

³ Medical Devices; Ophthalmic Devices; Classification of the Intense Pulsed Light Device for Managing Dry Eye

⁴ BPC 3041 (a)(5)(G)(1)