

MARIAH SMITH, O.D. Board President

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ADAM SCHNEIDER, ESQ. Executive Director JEFFREY AUSTIN, O.D. Board Member

DREW JOHNSON Public Board Member

Materials for

May 30, 2024

Board Meeting



NOTICE OF PUBLIC MEETING

The Nevada State Board of Optometry will hold a Board meeting on

Thursday, May 30, 2024 beginning at 12:00 p.m. PST

Pursuant to NRS 241.023(1)(c), this meeting is being conducted by means of remote technology only. The public may attend via live stream remotely or telephonically:

https://us06web.zoom.us/j/81612476114?pwd=n5iPt2WeiJGbZVdHmWQyWRqdlH8IdG.1 Meeting ID: 816 1247 6114 Passcode: 897761 Telephone: (669) 444-9171 or (669) 900-6833

The public is invited to attend

AGENDA

NOTE: This is the tentative schedule for the meeting. The Board reserves the right to take items in a different order to accomplish business in the most efficient manner. Items on this agenda may be taken out of order, removed, combined, or delay the discussion relating to an item on the agenda at any time.

1. **Call to Order. AB 219 Compliance to be read into the record-** "in compliance with AB 219, because this meeting is being held using a remote technology system pursuant to NRS 241.023 and does not have a physical location designated for the meeting where members of the general public are permitted to attend and participate, the telephone call-in number for this meeting is 1 669 444 9171, the meeting ID is 816 1247 6114, passcode 897761."

2. Welcome, introductions.

3. **Public Comment**. No action will be taken at this meeting on any issues presented in Public Comment. Comments are limited to 3 minutes.

- 4. For Board Discussion and Possible Action. NRS 636.025(2) application to IPL
- 5. For Board Discussion and Possible Action. NAC 636.250 and R066-19 Sec. 12(3) clarification
- 6. For Board Discussion and Possible Action. NRS 636.373(4) clarification
- 7. For Board Discussion and Possible Action. NAC 636.670(4) clarification
- 8. For Board Discussion and Possible Action. 2025 legislative goals

9. For Board Discussion and Possible Action. Continuation of inquiry into Tax Commission proposed legislation re frames/lenses sales tax

10. For Board Discussion and Possible Action. Complaint 24-11 status

11. For Board Discussion and Possible Action. Complaint 24-13 status

12. **For Board Discussion and Possible Action**. Consideration and approval of response to Board of Dispensing Opticians questions re cross-over jurisdiction issues.

13. **For Board Discussion and Possible Action**. Consideration and approval of April 25, 2024 Board Meeting Minutes.

14. **Public Comment**. No action will be taken at this meeting on any issue presented in Public Comment. Comments are limited to 3 minutes.

15. For Board Discussion and Possible Action. Adjournment.

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FY 2023-2024 Regular meeting schedule

Thursday 6/27/2024 12:00p.m. (pst) Reg. Bd. Meeting- phone or Zoom

FY 2024-2025 Regular meeting schedule

Wednesday 7/31/2024 12:00p.m. (pst) Reg. Bd. Meeting- phone or Zoom Wednesday 8/28/2024 12:00p.m. (pst) Reg. Bd. Meeting- phone or Zoom

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♦ The Board is pleased to make reasonable accommodations for any member of the public who has a disability and wishes to attend the meeting. If special arrangements for the meeting are necessary, please notify the Nevada State Board of Optometry: in writing at P.O. Box 1824, Carson City, Nevada 89702; via email at <u>admin@nvoptometry.org</u>; or call 775-883-8367 as far in advance as possible.

✤ To request an advance copy of the supporting materials for this meeting, contact <u>admin@nvoptometry.org</u> or call 775-883-8367.

This Notice of Public Meeting and Agenda was posted in compliance with NRS 241.020, before 9:00 a.m. on the third working day before the meeting at the following locations:

• Nevada State Board of Optometry office, Reno, NV 89523

Nevada State Board of Optometry website: <u>https://nvoptometry.org/</u>

Nevada Public Notice website: <u>http://notice.nv.gov</u>

Materials for Item No. 4 re

- 8/2023 Letter to Dr. Bolenbaker
- 5/2024 Dr. Bolenbaker letter to the Board
- 2024-05 Optlight Instructions
- 2024-05 Role of IL-17
- Analysis of Cytokines
- Relevant law



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August 29, 2023

Dr. Jason Bolenbaker Visionary Eye Center 8175 S. Virginia St Ste B900 Reno, NV 89511 <u>drb@visionaryeyecenter.com</u> *via email only*

Dr. Bolenbaker:

During the course of its Board meeting conducted on June 22, 2023, the Nevada State Board of Optometry (NSBO) authorized its Executive Director to issue a letter regarding your inquiry about the scope of delegation to a staff member within an optometry office performing various tasks.

The Board first reminds you that changes in Nevada State Optometry laws occurred in 2019 allowing optometrists to delegate to certain staff members certain tasks so long as those staff members are under the direction and supervision of the optometrist. For purposes of this letter, "staff member" as used in your inquiry is deemed as synonymous with the definition of "assistant" as codified in NRS 636.346(4) of "a person employed by an optometrist or any medical provider or medical facility at which the optometrist provides or offers to provide his or her services as an optometrist."

Can a staff member within an optometry office perform an "assessment of fit and power of a contact lens at follow up with or without doctor supervision or presence on site"?

Directing your attention to NRS 636.346 and its subsubsections in pertinent part: (1) an assistant may fit ophthalmic lenses or spectacle lenses if the assistant acts under the direct supervision of a licensed optometrist; and (3) if an assistant conducts any activities pursuant to subsection 2, the licensed optometrist must conduct the final eye examination of the patient.

Further directing your attention to NRS 636.025(1)(f) that an act of the practice of optometry within the purview of NRS 636 includes the measurement, initial fitting, as defined in



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NRS 636.387, or adaptation of contact lenses to the human eye except under the direction, responsibility and supervision of an optometrist licensed in the State of Nevada as authorized in NRS 636.346.

Accordingly, the Board voted unanimously that so long as ordered by the optometrist, an assistant may perform a preliminary refraction so long as the optometrist checks the preliminary refraction and performs the final examination of the patient at the presentation prior to discharging the patient. Note that the Board's vote presupposes no violation of AB432 (2023), section 18, which will be codified into NRS 636, that it is unlawful for a licensee to issue or extend a prescription for an ophthalmic lens for a person if the licensee has not performed a comprehensive examination, or does not have access to the complete results of a comprehensive examination that was performed, on the person within the immediately preceding 2 years.

Within the context of the above described optometrist final examination, and in a manner consistent with AB432 (2023), section 12 which will be codified into NRS 636, the Board notes that the optometrist can perform the final examination via synchronous optometric telemedicine, i.e., optometric telemedicine in which information is exchanged via electronic communication in real time via telephone, video, a mobile application, or an online platform on an internet website. Note that the Board's vote presupposes no violation of AB432 (2023), section 19 which will be codified into NRS 636, that a licensee may engage in synchronous optometric telemedicine to provide health care services to a patient only if the licensee has completed a comprehensive examination on the patient within the immediately preceding 2 years.

Within the context of the above posed question, would a NCLE or Nevada Optician License be required or would they be covered under your license, and would it make a difference if the doctor had already seen the lens on the patient at dispense?

The Board does not have authority to determine if a given optician has appropriate licensure or not.



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Can a staff member within an optometry office perform eyelid/skin surface treatments like ZEST (aka Zocular® Eyelid System Treatment), Intense Pulsed Light (IPL), Radiofrequency or other aesthetic procedures?

Directing your attention to NRS 636.346 and its subsubsections in pertinent part: (2)(e) an assistant under the direct supervision of a licensed optometrist may use an ophthalmic device as directed by a licensed optometrist.

Further directing your attention to NRS 636.025(1)(b)-(c) and their respective statutory usages of the word "eye" but also any "appendage" of the eye. The Board classifies the eyelid inclusive of the tarsal plate, meibomian glands, and eyelashes to be appendages and/or adnexa of the eye.

Accordingly, the Board voted unanimously that so long as ordered by the optometrist, an assistant may perform the above modalities referenced in your email so long as the optometrist performs the final examination of the patient at the presentation prior to discharging the patient. Note that the Board's vote presupposes the scope of the above listed modalities being limited to the eye and appendages and/or adnexa of the eye. The Board does *not* classify, e.g., the facial cheek/buccal, as an appendage and/or adnexa of the eye.

Within the context of the above described optometrist final examination, and in a manner consistent with AB432 (2023), section 12 which will be codified into NRS 636, the Board notes that the optometrist can perform the final examination via synchronous optometric telemedicine, i.e., optometric telemedicine in which information is exchanged via electronic communication in real time via telephone, video, a mobile application, or an online platform on an internet website. Note that the Board's vote presupposes no violation of AB432 (2023), section 19 which will be codified into NRS 636, that a licensee may engage in synchronous optometric telemedicine to provide health care services to a patient only if the licensee has completed a comprehensive examination on the patient within the immediately preceding 2 years.



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Within the context of the above posed question, would said staff member need an aesthetician license?

The Board does not have authority to determine if a given staff member needs licensure issued from a separate Nevada State Board or not.

Sincerely,

/s/ Adam Schneider Adam Schneider, Esq. Executive Director Nevada State Board of Optometry Members of the Nevada Board of Optometry,

I wish to follow up on my question to the board as emailed on 5/13/2024 stating, "Also, in the course of performing intense pulsed light (IPL) for rosacea based dry eye, may an optometrist treat the whole face to more fully treat the underlying root cause?" and the response received from Director Schneider, "No. You may recall from my letter on or about 8/29/2023 that: 1) NRS 636.025(1)(b)-(c) regard "eye" and any "appendage" of the eye; 2) the Board does NOT classify, e.g., the facial cheek/buccal, as an appendage and/or adnexa of the eye; and therefore 3) any OD in this State is prohibited from performing RF or IPL or ZEST beyond the appendages and/or adnexa of the eye."

I believe optometrist should be able to treat the whole face with IPL during treatment for ocular rosacea and meibomian gland dysfunction in the state of Nevada. I also feel the board may be well within their rights to change their position on the limits to which IPL and other light-based technologies (i.e Low Level Light Therapy (LLLT) for dry eye or Red Light Therapy (RLT) for myopia control) may be applied to the body without further legislative changes.

To begin, I would like to demonstrate why it is important for an optometrist to treat the whole face with IPL while treating ocular rosacea and associated meibomian gland dysfunction. In collaboration with Dr. Melanie Denton, an optometrist in North Carolina, she provided me the findings of her conversations with Dr. Rolando Toyos, a pioneer in using IPL for the treatment of ocular rosacea, during her similar request to the state board of North Carolina as part of her successful clarification of the use of IPL technology in 2020. In her conversations with Dr. Toyos, he discussed the pathophysiology of the disease course as well as its treatment with IPL, specifically how he developed the "Toyos Protocol" so widely used in eyecare today and the same protocol used to secure FDA approval for the Lumenis OptiLight device in the treatment of dry eye. I have reached out to Dr. Toyos on this matter personally, but unfortunately was unable to speak with him prior to the scheduled board meeting.

Facial telangiectasia, as occurs in both facial and ocular rosacea, occurs as a plexus of vessels. The telangiectatic vessels are not in isolation, rather they create a vascular web that extends from the eyelids to the rest of the face. This web of vessels then contributes to the development of IL-17 and IL-6, two inflammatory mediators that increase on the ocular surface in the presence of rosacea, both "ocular" and "facial." I have attached the 2019 article from the "Journal of Cutaneous Medicine and Surgery titled "The Role of IL-17 in Papulopustular Rosacea and Future Directions" which details the multifactorial pathogenesis of Rosacea and how IL-17 is an important consideration in the disease.

Facial Rosacea increases the presence of Interleukin 17 (IL-17) and Interleukin 6 (IL-6) on the surface of the eye, which is why IPL is successful in reducing ocular inflammation as it appears to downregulate both inflammatory cytokines. This has been illustrated in a number of published clinical studies. In a 2017 study published in the American Journal of Ophthalmology, "Analysis of Cytokine Levels in Tears and Clinical Correlations After Intense Pulsed Light Treating Meibomian Gland Dysfunction" the authors show how IPL can decrease ocular surface inflammation specifically by reducing the telangiectasias and burden of the vascular web that is contributing to an overabundance of inflammatory mediators on the ocular surface.

Furthermore, Dr. Toyos reviewed his considerations when developing his protocol for treating Dry Eye with IPL. He stated that his initial testing included 3 iterations of treatment: 1. Lids only with IPL, 2. Tragus to Tragus (Ear to Ear), 3. full face IPL. He stated that treating eyelids only (Option 1) was significantly inferior to the other two protocols. In other words, treating only the lids and none of the facial telangiectasia rendered the treatment ineffective in that the magnitude of remaining telangiectatic vessels allowed the pathogenesis of ocular rosacea to continue. It is critical when treating ocular rosacea to eliminate the pathogenesis, which in this case are the telangiectatic vessels no matter how far removed from the eyelid surface they may travel. To add, the Toyos protocol used in the FDA approval of Lumenis' OptiLight device describes application of IPL from tragus to tragus, across the cheek and over the nose. I have included a copy of the protocol from Lumenis for the OptiLight demonstrating the approved procedure. Further evidence of alternative IPL treatment protocols for dry eye that include treating areas outside the eyelids and ocular adnexa include Dr. Laura Periman's and Dr. Art Epstein's protocols as presented by Dr. Corey Lappin's CE lecture hosted at https://www.youtube.com/watch?v=JCMBgf-82vM (Timestamp 33:12). Of note, Dr. Periman's procedure includes the whole face while the late Dr. Epstein's protocol also frequently included the forehead, especially for male patients. Should the board continue its stance on limiting the application of IPL treatment to the ocular adnexa while excluding other areas of the face such as the cheeks would mean Nevada optometrists are only able to apply IPL technology in an off-label fashion and not meet the current standard of care. This ignores the sound and established protocols for the treatment of dry eye with IPL.

Moving on to my belief that the board can change its stance on IPL application without further legislative action, I present the inclusive language of, "NRS 636.025 (h) Prescribing, directing the use of or using a pharmaceutical agent or device to treat an abnormality of the eye or its appendages." The inclusive language of this section confirms our ability as optometrists to use any present and future technology in the treatment of ocular disease so long as it does not violate the defined restrictions noted in, "NRS 636.025 2. The provisions of this section do not authorize an optometrist to engage in any practice which includes: (a) Any procedure using a laser, scalpel, needle or other instrument in which any human tissue is cut, burned or vaporized by incision, injection, ultrasound, laser, infusion, cryotherapy, radiation or other means; or (b)Any procedure using an instrument which requires the closure of human tissue by suture, clamp or similar device." None of the exclusive language in NRS 636.025 2 (a) and (b) restricts how or where we apply treatment with devices such as IPL, LLLT or RLT. Furthermore, NRS 636.025 (h) does not limit the route in which an agent or device is applied to the body while treating an ocular disease. Precedence has already been set in our use of treatments for ocular disease applied to the body far removed from the eye and ocular adnexa. We currently and regularly apply medications through the gastrointestinal system and nasal passages in our treatment of ocular disease. To limit our application of IPL technology solely to the eyelids is incongruent with our current ability to treat ocular disease through other parts of the body and to me violates the spirit in which the statutes of Nevada intend.

I am sensitive to the fact that treatment with devices like IPL and LLLT often overlaps with dermatological treatment of various skin conditions, so I can understand the potential concern the board may have that optometrists in Nevada can easily stray outside their described limitations of treating ocular disease. But the fact that these treatment devices may, as a side effect, concurrently improve conditions such as facial rosacea, unwanted facial hair and acne vulgaris is not reason to restrict proper use of these devices in the treatment of an ocular condition of dry eye. We do not limit our ability to prescribe medications like minocycline in dry eye just because it overlaps with identical prescriptions for acne vulgaris, nor do we limit our use of oral corticosteroids and antihistamines for severe or chronic ocular allergies just because it may subsequently treat a patient's allergic rhinitis. Many optometrists across the nation already treat dry eye using standard IPL protocols safely and within the scope of optometric practice. The eye is an integral part of the body and cannot be easily isolated during examination and treatment. Therefore, there will always be some overlap with other medical specialties in the daily care of patients with ocular diseases.

To summarize, established protocols for use of IPL in dry eye includes treatment outside the ocular adnexa and currently Nevada Revised Statutes do not limit our ability to apply treatment outside the eye and ocular adnexa in the context of treating ocular disease. I urge the board to expand their stance on IPL and other non-surgical light-based treatments to include application to areas outside the ocular adnexa should the standard protocols in the course of treating ocular disease deem it necessary to do so.

Thank you for your consideration in this matter.

Dr. Jason Bolenbaker

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Protocol for IPL treatment of DED due to MGD with OptiLight TM

Protocol for IPL treatment of DED due to MGD with OptiLight[™]

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Protocol for IPL treatment of DED due to MGD with OptiLight [™]

1. BACKGROUND

Dry Eye Disease due to Meibomian Gland Dysfunction (MGD) is one of the most frequent and less well managed diseases in ophthalmology. The condition is associated with blepharitis and inflammation of the ocular surface. Among the risk factors of this condition is facial skin Rosacea: about 80% of patients suffering from skin Rosacea have concomitant MGD. However, MGD can occur is patients without apparent symptoms of skin rosacea as well. Another well known-risk factor is the proliferation of Demodex mites on the peri-ocular skin (also associated with Rosacea).

The causal relationship between Rosacea, Demodex, blepharitis and MGD is not very well-understood. One hypothesis is that abnormal blood vessels in cutaneous rosacea secrete pro-inflammatory substances. Due to the close proximity of regions affected by rosacea (the cheeks, nose and central part of the face) and the periorbital region, these pro-inflammatory agents reach the eyelids via the orbital vasculature. The exposure of the eyelids to these inflammatory agents can trigger blepharitis and, subsequently, meibomian gland dysfunction and ocular rosacea.

However complex and unclear it is, the notable relationship between eyelid inflammation and skin inflammation around the periorbital region has prompted investigators to find ways to reduce eyelid inflammation and associated ocular complications by treating the skin around and close to the periorbital region. One of the most effective tools to do so is by applying intense pulsed light (IPL) on the skin below the lower eyelids: IPL causes thrombosis of telangiectasia (abnormal blood vessels) and, thus, removes a major source of inflammation to the eyelids. IPL may also reduce inflammation by triggering photobiomodulatory process (such as up-regulation of anti-inflammatory mediators and down-regulation of pro-inflammatory agents) and by reducing the levels of Demodex parasites on the skin. Another possible mechanism of action is boosting the activity of fibroblasts and collagen production, thereby increasing the efficiency of eyelid blinking.

2. CONDITIONS FOR USING IPL FOR TREATMENT OF DED DUE TO MGD

When considering the use of IPL for treatment of DED due to MGD, several conditions must be taken into account.

- 1) IPL treatment is most suitable for patients with Fitzpatrick skin types I to IV.
- 2) A minimum of 5 non-atrophied meibomian glands per eyelid is recommended for improvement of MGD with IPL.
- At all times during administration of IPL, the patient eyes must be protected with fully occluding eye shields.
- 4) IPL must not be applied on the lid margins or the eyelashes.
- IPL treatment may cause reactivation of a Herpes outbreak. To reduce this risk, it is advised to prescribe prophylactic antiviral therapy.

Protocol for IPL treatment of DED due to MGD with OptiLight [™]

6) Before treatment with IPL can begin, the skin reaction and patient's discomfort should be tested with one or more test spots. Patients with very sensitive skin may not be suitable for this treatment.

3. INDICATIONS

In its default configuration, OptiLight has two indications: Rosacea and MGD. However, both indications are related: since Rosacea is a strong risk factor of MGD, it is recommended to treat both indications even in cases where Rosacea is not apparent, since a substantial number of Rosacea cases are sub-clinical and may soon develop to symptomatic Rosacea.

In its upgraded configuration (IPL aesthetic upgrade), OptiLight can be used to treat a range of dermatological and aesthetic conditions, including benign pigmented epidermal lesions, benign vascular lesions, mild to moderate acne, and hair removal.

4. CONTRA-INDICATIONS

A non-exhaustive list of contra-indications includes patients with skin type VI, ocular surgery within 6 months prior the first IPL session, use of photosensitive medications (such as Isotretinoin and Doxycycline) or anti-coagulants. In the area planned for treatment, IPL should not be used in cases of active infections, neuro-paralysis, active cold sore, skin cancer or precancerous lesions. IPL should also be avoided in patients exposed to sun or artificial tanning during 3-4 weeks prior to treatment. Consult the user manual for a complete list of contra-indications

5. TREATMENT PROTOCOL FOR TREATMENT OF DED DUE TO MGD

5.1 Full treatment plan

A full IPL treatment includes 4 sessions, 2 to 4 weeks apart. After each session, a date for the next session will be set up. No follow-ups are needed between sessions.

At the beginning of each treatment subsequent to the first IPL session, the physician will inquire if any side effects related to the treatment have occurred. If so, treatment should be paused until the treated area has healed. Most side effects, if any, should fade within several days or weeks. If side effects were due to the fact that the patient's skin was tanned, treatment should only be resumed after the tan has faded. After healing, treatment can be resumed with modifications in fluence, at the physician's discretion.

After completion of the full IPL treatment, patients may need a maintenance session, usually 12 months after the last IPL treatment. We recommend to schedule an examination 6 months after the last IPL session. At that examination, the eye care professional will determine if and when to schedule the maintenance session.

Protocol for IPL treatment of DED due to MGD with OptiLight [™]

5.2 Pre-treatment instructions

Avoiding the sun:

The patient should avoid exposure to the sun for a few weeks before any IPL session.

Topical Anesthesia (optional):

Generally, IPL with the OptiLightTM can be administered without topical anesthesia, since the Sapphire lightguide is cooled.¹ However, if the treatment involves a large surface such as the full face, some patients prefer to undergo the treatment under the influence of a topical anesthetic agent, so that the procedure can proceed without discomfort. Topical anesthetics are generally applied for up to one hour prior to treatment. Immediately before treatment, the user/operator must make sure to completely remove all topical anesthetics. It is not recommended to use an anesthetic agent with vasoconstrictor effects (such as EMLA), as this will decrease the efficacy of treatment.

Cleansing:

Prior to administration of IPL, the patients face must be thoroughly cleaned. For example, a solution of 50% isopropyl + 50% distilled water may be used.

Eye protection:

The patient and all personnel present in the room must wear eye protection. For the patients, eye shields must be fully occlusive, and they must be put in place *before* coupling gel is spread over the area to be treated. Likewise, at the end of treatment, eye protection can be removed only *after* all coupling gel has been removed from the face.

Coupling gel:

A coupling gel reduces discomfort and provides a coupling medium between the lightguide and the skin surface. This coupling gel is the same type of gel you would use to perform an ultra-sound examination. However, the coupling gel must be transparent. It is recommended to use the coupling gel provided by Lumenis.

Apply a thin (1-2 mm) layer of refrigerated (43-50 °F, or 6-10 °C) coupling gel on the area to be treated.

¹ By default, the Sapphire lightguide used when treating the Rosacea indication is cooled. This cooling acts as a local anesthetics. This cooling is not relevant to the MGD indication. In this indication there is no need for cooling, as the IPL settings are much gentler.

Protocol for IPL treatment of DED due to MGD with OptiLight [™]

5.3 Treatment instructions

In each treatment session, treatment of DED due to MGD is recommended to be performed in 3 successive steps: (1) IPL treatment of Rosacea; (2) IPL treatment of MGD; (3) Meibomian gland expression.

In the Main Screen of the user interface, Select the "OptiLight" modality:



If the intention is to treat both "Rosacea" and "MGD", it is recommended to start with the "Rosacea" treatment: if not connected already, connect the large 35x15 mm Sapphire lightguide, and follow instructions as indicated on the user interface and on the instructions below. If the intention is to treat only MGD, connect the OPT handpiece (extended optical fiber) to the IPL handpiece. follow instructions as indicated on the user interface and on the instructions below.

5.3.1 IPL Settings

Except for fluence, all IPL settings (pulse structure, number of sub-pulses, sub-pulse duration and interval between sub-pulses) are already preloaded into the system. Upon selecting the patient's skin type, the fluence is automatically determined. However, the skin reaction and pain/discomfort should be tested with test spots, before treatment can begin. In case of excessive skin reaction or pain/discomfort, the fluence should be reduced by 1-2 J/cm².

Note that the IPL settings for the "Rosacea" indication are more intense than those used for the "MGD" indication. Therefore, if both indications are to be treated, it is advised to treat the Rosacea indication first, and to perform test spots for this indication. If IPL settings were acceptable for the Rosacea indication, there is no need to perform test spots for the MGD indication as well.

5.3.2 IPL treatment for Rosacea:

- If not already connected, connect the large 35 x 15 mm Sapphire lightguide to the IPL handpiece.
- Select the skin type and follow instructions. The system may ask you to change the spectral filter (Rosacea I-III or Rosacea IV-V filter)
- On the user interface, verify that the cooling option is enabled. Make sure the tip of the lightguide is indeed cooled.
- If based on your past experience or knowledge you believe the fluence is too high, decrease the fluence by 2-3 J/cm².
- Switch the system from "Standby" to "Ready".
- Do not apply pressure with the lightguide.

Protocol for IPL treatment of DED due to MGD with OptiLight [™]

 Perform a test spot: choose and inconspicuous area of similar tanning, thickness and consistency as the area to be treated- for example, the lateral side of the malar region, close to the temples, as illustrated in Figure 1.

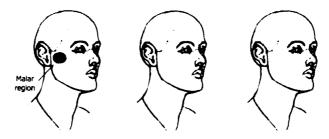


Figure 1. Area recommended for test spots.

- If the patient complaints of intolerable pain, or if the skin develops an excessive reaction,2 decrease the fluence by 1 J/cm² and repeat a 2nd test spot. Do not perform a second test spot on the same spot as the first test spot.
- For skin types I-III, before evaluating the skin reaction wait a few minutes- up to 15 minutes are recommended. For skin type IV, wait 24 to 48 hours. An excessive skin reaction is anything beyond a slight erythema of the skin (slight pinkish tine). This includes breaks in skin integrity, burns, blisters, sloughing, or bruises.
- If after 5 successive test spots and decreases of the fluence the skin reaction is still excessive, or the patient still complains of intolerable pain/discomfort, this patient is not suitable for IPL treatment, and should not be treated.
- Perform a first pass in the treatment area as indicated in Figure 2. For example, the direction can be from the right tragus to the left tragus, and the orientation of the lightguide could be vertical (in other words, when the long side of the lightguide is parallel to the nose).

² For skin types I-III, before evaluating the skin reaction wait a few minutes- up to 15 minutes are recommended. For skin type IV, wait 24 to 48 hours. An excessive skin reaction is anything beyond a slight erythema of the skin (slight pinkish tine). This includes breaks in skin integrity, burns, blisters, sloughing, or bruises.

Protocol for IPL treatment of DED due to MGD with OptiLight ™

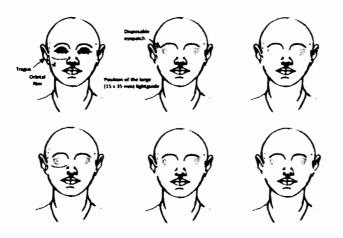


Figure 2. Treatment area for "Rosacea" treatment

- Adjacent pulses should be given with overlaps of about 1 mm.
- Usually 10-15 pulses are sufficient to cover the entire area, for a single pass.
- In subjects with skin type I-III, a second pass is recommended. In subjects with skin type IV, a second pass can be performed with caution.
- Do not apply a second pass if the skin reaction to the first pass is excessive (anything beyond slight erythema, or pain reported by the patient).
- If a second pass is performed, apply 1 to 2 mm of fresh refrigerated coupling gel to the treatment area. Do not reuse the gel from the first pass. Proceed in the same direction as the first pass (in the example given: from the right tragus to the left tragus), but in the perpendicular orientation (in the example given: when the short side of the lightguide is parallel to the nose).
- At the end of this part, switch the system to "Standby".

5.3.3 IPL treatment for MGD:

- If not already connected, connect the OPT lightguide to the IPL handpiece.
- Select the skin type and follow instructions. The system may ask you to change the spectral filter (OPT filter is used with the OPT handpiece).
- Switch the system from "Standby" to "Ready".
- Establish a Bluetooth connectivity between the OPT handpiece and the console by pressing once on the OPT trigger button. The indication that Bluetooth connectivity is established is if the wireless logo on the user interface changes from grey to blue:



Do not apply pressure with the OPT lightguide.

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- If test spots were already performed for the Rosacea treatment, there is no need to perform an additional test spot, since the MGD treatment is much gentler compared to the Rosacea treatment.
- Perform a first pass in the treatment area as indicated in Figure 3.
- Adjacent pulses should be given with overlaps of about 1 mm.
- Usually 10-12 pulses are sufficient to cover the entire area, for a single pass.
- In subjects with skin type I-III, a second pass is recommended. In subjects
 with skin type IV, a second pass can be performed with caution. See above
 how to perform a second pass: the principles are the same as for the Rosacea
 treatment.
- At the end of this part, switch the system to "Standby".

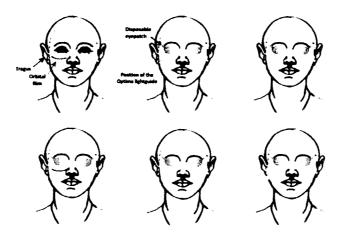


Figure 3. Treatment area for MGD treatment

5.3.4 Meibomian gland expression:

- Following IPL treatment, wipe off the coupling gel from the patient's face
- Remove the eye protection
- Prior to expression, the eye may be numbed with a topical solution, for example Proparacaine Hydrochloride 0.5%.
- Expression of the meibomian glands can be done by squeezing the meibomian glands with the aid of two sterile Q-tips (cotton tip applicators) positioned on either sides of the meibomian glands. Alternatively, a meibomian gland expressor forceps may be used.
- The Q-tips or the meibomian gland expressor forceps may be dipped in a numbing solution as well.
- Manually express the Meibomian glands on both the upper and lower eyelids. For the lower eyelid, ask the patient to look up. For the upper eyelid, ask the patient to look down

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- Apply *gentle* continuous pressure on the glands, for about 30 sec.
- Be careful not to apply too much pressure on the glands, even if the glands do not respond to pressure. Excessive pressure may damage the glands.
- Once the glands have been expressed, a drop of either topical steroid or a nonsteroidal anti-inflammatory drug (NSAID) may be given at the physician's discretion.

5.4 Post-Treatment instructions

Cold wash:

Immediately following the IPL treatment & gland expression, apply a cold wash cloth to the treated area (cold, not frozen- packs) for 5-10 minutes. Ice of chemical cold packs should not be used.

Eye shields:

If the eye shields are not disposable, the eye shields must be washed with soap and water after each patient use, followed by cleaning with a sanitizing cloth.

Exposure to Sunlight:

- Patients should be instructed to use a high factor (30–50 SPF) sun block and to protect the treated area from exposure to sunlight, for at least one month following treatment.
- The treating physician should make sure that the patient understands the need to avoid sun exposure, especially during the first 48 h after treatment.
- It is important to explain to the patients that tanning after treatment sessions may enhance melanin regeneration, which may result in unwanted hyperpigmentation.

Makeup:

- Most physicians allow their patients to apply makeup immediately after treatment. However, they advise patients to notify them, and to stop wearing makeup, if the treated area scales or cakes.
- Other physicians take a more conservative approach, advising against the use of makeup for a few days following treatment. The skin may be sensitive during this period. Removing makeup, especially if it is difficult to remove, may damage the skin and predispose the treated area to infection.

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- In case of broken or damaged skin, some physicians recommend that their patients keep the treated area covered with a dressing, to reduce the risk of trauma and infection during the first 4 or 5 days following treatment.
- If the skin remains intact immediately after IPL treatment, subjects can be instructed to continue using standard make-up and moisturizing routine when relevant. In case an unexpected skin reaction occurs, subjects must be instructed to stop using any make-up.

6. SIDE EFFECTS

The following possible side effects can occur following IPL treatments: pain/ discomfort, damage to natural skin texture, change of pigmentation, scarring, excessive edema, fragile skin, bruising, burns, pruritus and xerosis. Most of these side effects can be totally prevented if instructions are followed to the letter.

In addition to side effects on the skin, severe ocular complications can occur if eyes are not fully occluded at all times during IPL administration. Such complications include anterior uveitis, pupillary defects, iritis, anterior uveitis, posterior synechiae, and iris transillumination defects. These complications can lead to pain, photophobia and, in extreme cases, permanent damage to vision.

Review Article

The Role of IL-17 in Papulopustular Rosacea and Future Directions

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Abstract

Rosacea is a chronic, progressive, inflammatory condition phenotypically subtyped into diagnostic features, major features, and minor/secondary features. There is currently no cure for rosacea, and it carries a significant negative psychosocial burden for afflicted patients. While there are a number of treatment modalities at the disposal of the clinician, clinical experience has suggested a need for updated treatments. The pathogenesis of rosacea is multifactorial; however, this paper will focus on the pivotal role of interleukin 17 (IL-17) in the development and progression of the disease. Furthermore, this paper will explore the mechanism of action of standard rosacea treatments and their effect on different stages of the IL-17 pathway. The standard treatments for rosacea are usually effective in controlling the symptoms of the disease in its mild-to-moderate form; however, their efficacy is diminished in the setting of severe and treatment-resistant rosacea. We hypothesize that IL-17 inhibitors, currently used successfully in psoriasis and psoriatic arthritis, could perhaps be used to treat severe and treatment-resistant papulopustular rosacea in the future; however, clinical trials and case reports will be needed to dictate expanded indications of IL-17 inhibitors. Furthermore, the high cost of IL-17 inhibitors presently prevents their use in disease states other than psoriasis or psoriatic arthritis.

Keywords

rosacea, IL-17 inhibitor, metronidazole, ivermectin, azelaic acid, *Demodex folliculorum*, isotretinoin, secukinumab, ixekizumab, brodalumab

Introduction

Rosacea is a chronic, inflammatory disorder with an estimated incidence of 1.65 per 1000 person-years¹ and a prevalence of approximately 5.46%.² Rosacea is currently phenotypically subtyped into diagnostic features such as persistent centrofacial erythema, major features ranging from transient centrofacial erythema to ocular manifestations, and minor/secondary features such as burning or stinging sensations, edema, or dryness.³ A number of different pathophysiological mechanisms have been proposed for the development of rosacea; however, the exact mechanism remains to be elucidated. There are a number of treatment options that can be utilized for symptomatic control and to slow the progression of the disease. However, our current treatment modalities lose efficacy as the severity of rosacea progresses and a need for updated treatments has been identified. This paper explores the role of interleukin 17 (IL-17) in the pathophysiology of rosacea in order to determine whether IL-17 inhibitors could potentially play a role in treating severe cases of papulopustular (PPR) rosacea.

The Role of IL-17 in the Pathophysiology of Rosacea

IL-17 is a CD4+-derived proinflammatory cytokine that is produced in abundance by T helper (Th)17 cells. IL-17 can

produce cytokines, chemokines, inflammatory effectors, and antimicrobial proteins.³ Furthermore, studies have demonstrated angiogenic properties of IL-17. In vitro studies using a retroviral vector expressing mouse IL-17 increased production of proangiogenic factors in fibroblasts and tumor cells $(1 \times 10^5/\text{mL})$ cultured for 48 hours including vascular endothelial growth factor (6.87 ± 0.57; *P* < .05), keratinocytederived chemokine (25.27 ± 2.15, *P* < .05) and prostaglandin E2 (47.5 ± 3.2, *P* < .05).⁴ In vivo studies using 250 or 500 ng of IL-17 injected into rat corneas resulted in significant neovascularization in all 8 corneas tested at each dose (*P* < .05).⁴

A number of mechanisms have been proposed to contribute to the development of rosacea. Until recently, abnormal functioning of the innate immune system and neurovascular dysregulation have been at the forefront of the proposed pathophysiologies^{5,6}; however, the role of adaptive immunity, IL-17 in particular, is slowly emerging (Figure 1).

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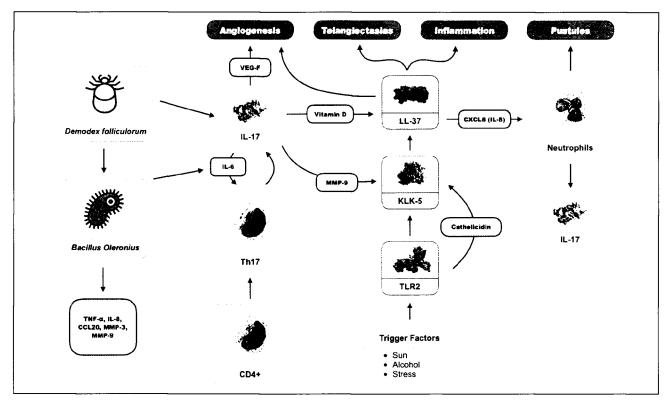


Figure 1. The role of IL-17 in the pathophysiology of rosacea.

IL, interleukin; KLK, kallikrein; MMP, matrix metalloproteinase; Th, helper T cells; TLR, toll-like receptor; TNF, tumor necrosis factor; VEG-F, vascular endothelial growth factor.

Buhl et al characterized the inflammatory infiltrate in erythematotelangiectatic, PPR, and phymatous rosacea using whole-transcriptome expression analysis, quantitative realtime reverse transcriptase PCR, and quantitative immunohistochemistry. They determined that there was a Th1 and Th17 dominance in all 3 subtypes by using immunohistochemistry to determine their signature cytokines, interferon γ and IL-17A, respectively. T-cell activity and IL-17 immunostaining were significantly higher (P < .05) in the skin of rosacea patients compared to the skin of patients with lupus and healthy controls but were the highest in PPR followed by phymatous and erythematotelangiectatic rosacea ($n \ge 5$ patients with 5 representative areas per slide).⁷ This increase was paralleled by an increased number of CD4+ cells, especially in PPR. The effective positive area of CD4+ for PPR patients was approximately 4% vs approximately <1% for healthy controls (P < .05).

Buhl et al also showed an increase in gene expression for IL-6, tumor necrosis factor (TNF), IL-20, and CCL20 (P < .05),⁷ which are involved in the induction of IL-17 and IL-22.^{7.8} IL-6 is noteworthy because it is induced by IL-17, but it also engages in a positive feedback loop and amplifies the differentiation of Th17, hence leading to a further increase in IL-17.⁹

T cells were originally thought to be the exclusive producers of IL-17; however, there is evidence that IL-17 is also secreted by innate immune cells such as macrophages, dendritic cells, natural killer cells, and neutrophilic granulocytes to name a few.^{3,10} Neutrophils are thought to be important contributors to the inflammation seen in rosacea, ^{11,12} and pustule formation is the clinical manifestation of neutrophils infiltrating perifollicular spaces.¹² Transcriptome analysis of chemokines determined that CXCL8 (previously IL-8), an important chemotactic factor for neutrophils, was upregulated in the 3 types of rosacea; however, immunohistochemistry showed evidence of neutrophils in PPR and phymatous rosacea, but not in erythematotelangiectatic rosacea.⁷ Another contributor to neutrophil attraction in rosacea patients is the enhanced presence of the mite *Demodex folliculorum*.

Demodex folliculorum is found in the skin of healthy controls, but an increased density is observed in the skin of rosacea patients.^{5,13} In 1 study with 98 volunteers, 50 of whom had rosacea, D. folliculorum densities were 5.7-fold higher in the rosacea group than the healthy control group ($4.9 \pm$ 11.2 vs 0.84 \pm 1.9; P < .0001).¹⁴ The resident bacteria of D. folliculorum, Bacillus oleronius, themselves act as chemotactic agents for neutrophils once released from the dead mites. The neutrophilic granulocytes can in turn release more IL-17. Skin samples of rosacea patients with increased densities of D. folliculorum have also been shown to express significantly more IL-8 (n = 48 in rosacea and control groups; P = .0015), IL-1β (P < .0001 for PPR [n = 32]; P < .001 for ETR [n = 18]), and TNF-α (P < .0001 for PPR).^{5.14} IL-1β plays a key role in differentiation of Th17 cells; in vivo studies using 10 patients with an NLPR3 mutation that results in excessive IL-1β production compared to 20 healthy controls showed a much higher median level of serum IL-17 in the former group (5.1 pg/mL vs 0.4 pg/mL; P = .04).¹⁵ TNF-α can indirectly induce CD4+ and IL-17 through the production of IL-1β and IL-6.¹⁶

Furthermore, 1 study showed that corneal epithelial cells produced a dose-dependent increase in gene expression of matrix metalloproteinase (MMP)-3 (61-fold increase, P = .005) and MMP-9 (301-fold increase, P = .004) upon exposure to *B. oleronius* protein.¹⁷ MMPs have been shown to play a role in the pathogenesis of rosacea,¹⁸ and are discussed further below.

It is known that rosacea begins as actinic lymphatic vasculopathy.12 UV radiation is a well-known trigger factor for rosacea and leads to the formation of reactive oxygen species (ROS), which can exacerbate the inflammatory pathway in rosacea by activating inflammasomes, proinflammatory cytokines, and inflammatory mediators.^{5,19} Other known trigger factors for rosacea include stress, spicy food, and alcohol. Trigger factors can alter the expression of Toll-like receptor 2 (TLR2), which plays an important role in pathogen recognition and activation of innate immunity.^{12,20} Yamasaki et al showed that TLR2 expression is increased in the skin of rosacea patients (n = 11) compared with healthy controls (n = 8); the relative expression of TLR2 in rosacea patients was approximately 3 times higher than the controls (P = .0431). TLR2 was also not increased in patients with other skin diseases such as psoriasis (n = 5) or atopic dermatitis (n = 7); P < .05 (data were not shown).^{5.20}

TLR2 translates into excessive production of cathelicidin, an antimicrobial peptide that induces the chemokine CXCL8, which attracts neutrophils and promotes angiogenesis.^{12,21} The active form of cathelicidin is LL-37. Patients with rosacea have been shown to have a significantly higher level of LL-37 than controls.^{5,22} Yamasaki et al used immunohistochemistry to show that mean levels of cathelicidin in patients with rosacea (n = 11) were significantly increased compared to healthy controls (n = 10): approximately 11 fmol/µg protein vs approximately 1 fmol/ μ g of protein, respectively (P = .015).²¹ Injecting LL-37 into mice models led to the development of telangiectasias, erythema, and inflammation.²³ LL-37 has both vasoactive and proinflammatory roles, and it results in the proliferation of endothelial cells and thus contributes to angiogenesis.^{5.24} LL-37 also results in neutrophil chemotaxis,²⁵ which has been implicated in the formation of pustules.¹² Th17 can lead to dysregulated or enhanced expression of LL-37⁷ through IL-17, as IL-17 promotes Vitamin-D3-induced production of cathelicidin.²⁶ LL-37 acts synergistically with IL-17 to release CXCL8, which attracts neutrophils, and IL-6, which promotes further differentiation of Th17.3

TLR2 also induces expression of kallikrein (KLK)-5, a serine protease. KLK-5 controls the enzymatic processing of cathelicidin into LL-37. KLK-5 is mediated by MMPs, and specifically, KLK-5 is cleaved from its proenzyme form by MMP-9.⁵ Studies have shown that IL-17 induces expression of MMP-9 through an extracellular signal-regulated kinase 1/2 and p38 mitogen-activated protein kinases–dependent activation of activator protein-1 and nuclear factor-kappa β (NF- $\kappa\beta$).²⁷

Ocular symptoms can occur concurrently with or independently of cutaneous features. Approximately 58%-72% of patients with rosacea develop ophthalmic findings.²⁸ Ocular rosacea results from meibomian gland dysfunction. This results in tearing, photophobia, and blurry vision. In its most severe form, ocular rosacea can result in erosions, ulceration, and corneal perforation.²⁸ An analysis of tear cytokines showed that D. folliculorum blepharitis patients (n = 15) had significantly higher levels of tear cytokines; particularly IL-17 $(95.1 \pm 36.8 \text{ pg/mL})$ compared with D. folliculorum free blepharitis patients (n = 15; 84.9 \pm 21.6 pg/mL) and a normal control group with no ocular symptoms (n = 15; 79.7 \pm 21.0) demonstrated that D. folliculorum blepharitis patients had significantly higher levels of tear cytokines; particularly IL-17 compared to each control group (P < .05), which resulted in inflammation of the lid margin and ocular surface.²⁹

Mechanisms of Action of Standard Rosacea Therapies

Standard treatments for rosacea harness their anti-inflammatory properties to provide symptom control. Common treatments for rosacea include metronidazole, ivermectin, azelaic acid, and low-dose oral antibiotics. Please refer to Figure 2 for an illustration of where these standard therapies act along the IL-17 pathway in rosacea.

Topical Therapies

Metronidazole is a standard topical, antibiotic rosacea therapy. However, it is used primarily for its anti-inflammatory rather than its antimicrobial activity. In vitro studies of metronidazole at both 5 and 50 µg/mL combined with palmitoleic acid, a free fatty acid found in human skin, showed that neutrophil-generated ROS were significantly decreased as the concentration of palmitoleic acid was increased (P < .01at a palmitoleic acid concentration of 5 µg/mL).^{30,31} This in turn can decrease the release of proinflammatory cytokines.⁵ In addition, metronidazole can reduce the density of *D. folliculorum* and impair induction of IL-17 directly and indirectly through IL-6 and CXCL8.¹² Clinically, metronidazole 0.75% can reduce erythema, papules, and pustules.³²

Ivermectin is a topical, antiparasitic, and anti-inflammatory agent. It exerts its antiparasitic action against the *D. folliculorum* mites and exerts its anti-inflammatory properties by inhibiting the NF- $\kappa\beta$ pathway, which in turn decreases the

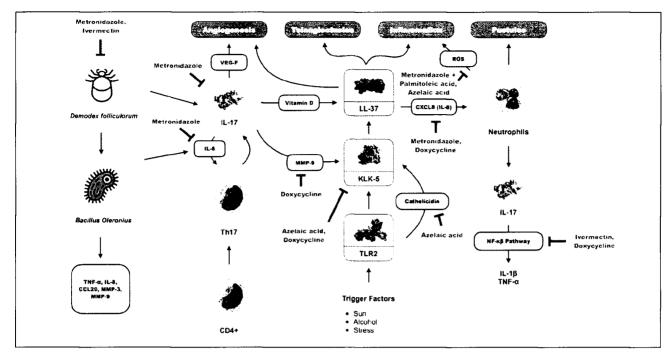


Figure 2. An illustration of where standard therapies act along the IL-17 pathway in rosacea. IL, interleukin; KLK, kallikrein; MMP, matrix metalloproteinase; Th, helper T cells; TLR, toll-like receptor; TNF, tumor necrosis factor; VEG-F, vascular endothelial growth factor.

production of IL-1 β and TNF- α .³³ Both these cytokines are induced by IL-17.³ A pilot study with 20 patients treated daily with ivermectin 1% cream for 12 weeks or greater showed that the mean density of *D. folliculorum* was significantly (*P* < .001) decreased at both week 6 (3.8/cm²) and week 12 (0.8/cm²) compared to baseline (99.9/cm²). Furthermore, the study also found that gene expression levels of IL-8, LL-37, HBD3, TLR4, and TNF- α were downregulated. LL-37 whose expression is influenced by IL-17 saw a significant reduction of 13.7-fold from baseline at week 6 (*P* = .02) and TNF- α which is induced by IL-17 decreased 2.7-fold at week 6 (*P* = .04) and 3.8-fold at week 12 (*P* = .004).³⁴ Clinically, ivermectin use translates into a decreased number of inflammatory lesions.

Azelaic acid is a topical preparation that has been shown to inhibit the expression of KLK-5 and cathelicidin, thus decreasing the production of LL-37. Furthermore, it inhibits the ROS produced by UV radiation and neutrophils. Azelaic acid also inhibits UV-induced upregulation of inflammatory cytokines such as IL-1, IL-6, and TNF- α .^{5,18} IL-1 is induced by IL-17, and IL-6 engages in a positive feedback loop, whereby it is induced by IL-17 and induces differentiation of Th17 cells.³ Clinically, azelaic acid results in less erythema and a decrease in inflammatory lesions.

Antibiotics

Antibiotics are commonly prescribed at low doses for rosacea. Options include, but are not limited to, minocycline, doxycycline, and erythromycin. A low dose of doxycycline is most commonly used for its anti-inflammatory properties. Doxycycline exerts its mechanism of action through impairing the secretion of cytokines such as IL-1 β and TNF- α , which are both induced by IL-17, and chemokines such as CXCL8 and CXCL1.¹² Doxycycline also inhibits the activity and production of MMP-9, which can be induced by IL-17, and KLK thus reducing the amount of LL-37.⁵

The above-mentioned therapies are used primarily for their anti-inflammatory effects. Furthermore, in one way or another, they all act at various stages along the IL-17 pathway. They either inhibit the downstream products of IL-17 or inhibit the cytokines responsible for the differentiation of Th17 cells.

Challenges in the Treatment of Rosacea

There is no cure for rosacea, and the aim of therapy is to control current symptoms and slow progression of the disease. Rosacea can have a significant psychosocial impact on patients' lives with patients reporting low self-esteem, low confidence, and decreased social interactions.³⁵ Problems associated with rosacea treatments are relapse upon discontinuation, and a lack of treatment options for severe and treatment-resistant PPR.

A systematic review showed that while topical ivermectin 1% was a more effective treatment option for moderatesevere PPR than metronidazole, 62.7% and 68.4% of patients relapsed 36 weeks after treatment discontinuation in the ivermectin and metronidazole groups, respectively (P = .037).³⁶

Low-dose isotretinoin has been used in treatment-resistant rosacea and when patients are intolerant to standard therapies. Isotretinoin works by downregulating TLR2,³⁷ which in turn reduces expression of cathelicidin and LL-37. While isotretinoin has been shown to reduce the number of inflammatory lesions, 1 randomized control trial showed that 58.3% of 108 patients randomized to isotretinoin 0.25 mg/kg/day relapsed within a median time of 15 weeks after discontinuing the medication. Furthermore, the relapse rates did not differ significantly based on whether the patients achieved complete or incomplete remission (P = .62).³⁸ Isotretinoin also does not reduce background erythema and telangiectasias, which can be quite bothersome for some patients.³⁸

Phymas are a more severe form of rosacea. Phymas represent hypertrophy of the sebaceous glands and rhinophyma is the most common form. Untreated, phymas can cause both functional compromise and cosmetic disfigurement. Medical treatment options include oral retinoids and antibiotics. However, medical treatment has been reported to mostly be effective early on in the disease process and does not impede the progression of rhinophyma.³⁹ Surgical options include cryosurgery, resection, scalpel excision, carbon dioxide laser, dermabrasion, and electrocautery; however, surgical treatments carry risks including but not limited to scarring, poor hemostasis, thermal spread if using a hot knife or employing electrosurgery, and depending on the surgical treatment used being expensive and time consuming.³⁹

Finally, treatments for ocular rosacea include lubricating agents, oral tetracyclines, and immunosuppressive agents such as cyclosporine. Punctual occlusion can be used for refractory eye disease.²⁸ Cyclosporine is more effective in the treatment of ocular rosacea than doxycycline. Cyclosporine inhibits a variety of T-cell activities, including suppression of Th17 cells and subsequently inhibiting the production of IL-17.40 Lam-Franco et al determined the lacrimal concentration of IL-1a and MMP-9 levels before and after antibiotic therapy with either azithromycin 500 mg/day 3 days a week or doxycycline 200 mg/day in patients with ocular rosacea. While azithromycin was successful in reducing the concentration of IL-1 α (47.0 pg/mL at baseline to 23.5 pg/mL; P =.024), a high concentration of IL-1 α was unresponsive to treatment by doxycycline. On the other hand, MMP-9 was responsive to doxycycline with a decrease from 10.28 ng/mL at baseline to 8.36 pg/mL (P = .054), but a high concentration of MMP-9 was unresponsive to azithromycin. This study concluded that baseline cytokine tear levels are markedly elevated in patients with antibiotic failure.⁴¹

There is limited high-quality evidence to support current treatments.⁴² Furthermore, patients tend to relapse after discontinuing the medications, and there are insufficient treatment options for severe and treatment-resistant PPR. Hence, clinical experience has suggested a need for updated treatments.

Future Directions

Given the contribution of IL-17 to the development of PPR and the fact that current therapies already target the IL-17 pathway, perhaps IL-17 inhibitors can be used as a potential treatment for severe and treatment-resistant PPR. There is currently 1 clinical trial in Phase 1b at Stanford University that is studying the use of secukinumab in moderate-to-severe PPR; however, preliminary results are not yet available from this study.⁴³ IL-17 inhibitors have been used successfully in psoriasis; however, their high cost represents a barrier to their use in other conditions.

There are 3 IL-17 inhibitors currently on the market secukinumab (Cosentyx-Novartis), ixekizumab (Taltz-Lilly), and brodalumab (Siliq-Bausch Medical). Cosentyx has been on the market the longest, having been first approved by the Food and Drug Administration in January 2015. Taltz was approved next in March 2016, followed by Siliq in February 2017. Secukinumab is a recombinant human monoclonal IgG1/ κ antibody that specifically binds to IL-17A.⁴⁴ Ixekizumab has a similar mechanism of action but is a humanized IgG4 monoclonal antibody.⁴⁵ Brodalumab, on the other hand, is a human monoclonal IgG2 antibody that binds to IL-17RA, which is a protein expressed on the cell surface receptor utilized by multiple IL-17 cytokines.⁴⁶ Brodalumab can thus block the action of IL-17A, IL-17F, IL-17C, IL-17A/F heterodimer, and IL-25.⁴⁶

All 3 agents have a similar side effect profile; however, brodalumab has a black box warning for suicidal ideation and behavior, including completed suicides.⁴⁶ The best option for a patient has to be tailored to their individual needs; however, brodalumab represents an attractive treatment option for severe rosacea as it blocks the action of a number of IL-17 cytokines. Secukinumab, on the other hand, has been studied for longer and may be the safest of the 3 to administer if IL-17 inhibitors are used in the future to treat severe and treatment-resistant cases of PPR.

Conclusion

IL-17 plays a pivotal role in the development and progression of PPR, and current therapies already target different parts of the IL-17 pathway. Further studies and careful observation of patients with both psoriasis and rosacea on IL-17 inhibitors will dictate whether the indications for IL-17 inhibitors can be expanded to include treatment of severe and treatment-resistant PPR when traditional routes fail.

Declaration of Conflicting Interests

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References

- 1. Spoendlin J, Voegel JJ, Jick SS, Meier CR. A study on the epidemiology of rosacea in the U.K. *Br J Dermatol*. 2012;167(3):598-605.
- Gether L, Overgaard LK, Egeberg A, Thyssen JP. Incidence and prevalence of rosacea: a systematic review and meta-analysis. *Br J Dermatol.* 2018;179:282-289.
- Onishi RM, Gaffen SL. Interleukin-17 and its target genes: mechanisms of interleukin-17 function in disease. *Immunology*. 2010;129:311-321.
- Numasaki M, Fukushi J, Ono M, et al. Interleukin-17 promotes angiogenesis and tumor growth. *Blood*. 2003;101:2620-2627.
- Woo YR, Lim JH, Cho DH, Park HJ. Rosacea: molecular mechanisms and management of a chronic cutaneous inflammatory condition. *Int J Mol Sci.* 2016;17:1-23.
- Steinhoff M, Schmelz M, Schauber J. Facial erythema of rosacea - aetiology, different pathophysiologies and treatment options. *Acta Derm Venereol.* 2016;96:579-586.
- Buhl T, Sulk M, Nowak P, et al. Molecular and morphological characterization of inflammatory infiltrate in rosacea reveals activation of Th1/Th17 pathways. *J Invest Dermatol.* 2015;135:2198-2208.
- Lyakh L, Trinchieri G, Provezza L, Carra G, Gerosa F. Regulation of interleukin-12/interleukin-23 production and the T-helper 17 response in humans. *Immunol Rev.* 2008;226: 112-131.
- Ogura H, Murakami M, Okuyama Y, et al. Interleukin-17 promotes autoimmunity by triggering a positive-feedback loop via interleukin-6 induction. *Immunity*. 2008;29:628-636.
- Keijsers RRMC, Hendriks AGM, van Erp PEJ, et al. In vivo induction of cutaneous inflammation results in the accumulation of extracellular trap-forming neutrophils expressing RORgammat and IL-17. J Invest Dermatol. 2014;134: 1276-1284.
- Jones DA. Rosacea, reactive oxygen species, and azelaic acid. J Clin Aesthet Dermatol. 2009;2:26-30.
- Gerber PA, Buhren BA, Steinhoff M, Homey B. Rosacea: the cytokine and chemokine network. *J Investig Dermatol Symp Proc.* 2011;15:40-47.
- 13. Bonnar E, Eustace P, Powell FC. The demodex mite population in rosacea. J Am Acad Dermatol. 1993;28:443-448.
- Casas C, Paul C, Lahfa M, et al. Quantification of demodex folliculorum by PCR in rosacea and its relationship to skin innate immune activation. *Exp Dermatol.* 2012;21:906-910.

- Lasigliè D, Traggiai E, Federici S, et al. Role of IL-1 beta in the development of human T(H)17 cells: lesson from NLPR3 mutated patients. *PLoS One*. 2011;6:e20014.
- 16. Zheng Y, Sun L, Jiang T, Zhang D, He D, Nie H. TNF α promotes Th17 cell differentiation through IL-6 and IL-1 β produced by monocytes in rheumatoid arthritis. *J Immunol Res.* 2014;385352.
- 17. O'Reilly N, Gallagher C, Reddy Katikireddy K, Clynes M, O'Sullivan F, Kavanagh K. Demodex-associated Bacillus proteins induce an aberrant wound healing response in a corneal epithelial cell line: possible implications for corneal ulcer formation in ocular rosacea. *Invest Ophthalmol Vis Sci.* 2012;53:3250-3259.
- Coda AB, Hata T, Miller J, et al. Cathelicidin, kallikrein 5, and serine protease activity is inhibited during treatment of rosacea with azelaic acid 15% gel. J Am Acad Dermatol. 2013;69: 570-577.
- Vemuri RC, Gundamaraju R, Sekaran SD, Manikam R. Major pathophysiological correlations of rosacea: a complete clinical appraisal. *Int J Med Sci.* 2015;12:387-396.
- Yamasaki K, Kanada K, Macleod DT, et al. TLR2 expression is increased in rosacea and stimulates enhanced serine protease production by keratinocytes. *J Invest Dermatol*. 2011;131: 688-697.
- Yamasaki K, Di Nardo A, Bardan A, et al. Increased serine protease activity and cathelicidin promotes skin inflammation in rosacea. *Nat Med.* 2007;13:975-980.
- 22. Zheng Y, Niyonsaba F, Ushio H, et al. Cathelicidin LL-37 induces the generation of reactive oxygen species and release of human alpha-defensins from neutrophils. *Br J Dermatol.* 2007;157:1124-1131.
- Kim M, Kim KE, Jung HY, et al. Recombinant erythroid differentiation regulator 1 inhibits both inflammation and angiogenesis in a mouse model of rosacea. *Exp Dermatol.* 2015;24:680-685.
- Schwab VD, Sulk M, Seeliger S, et al. Neurovascular and neuroiminune aspects in the pathophysiology of rosacea. *J Investig Dermatol Symp Proc.* 2011;15:53-62.
- Yamasaki K, Gallo RL. Rosacea as a disease of cathelicidins and skin innate immunity. J Investig Dermatol Symp Proc. 2011;15:12-15.
- Peric M, Koglin S, Kim SM, et al. IL-17A enhances vitamin D(3)-induced expression of cathelicidin antimicrobial peptide in human keratinocytes. *J Immunol.* 2008;181:8504-8512.
- Sakurai T, Yoshiga D, Ariyoshi W, et al. Essential role of mitogen-activated protein kinases in IL-17A-induced MMP-3 expression in human synovial sarcoma cells. *BMC Res Notes*. 2016;9:68.
- Wladis EJ, Adam AP. Treatment of ocular rosacea. Surv Ophthalmol. 2018;63:340-346.
- Kim JT, Lee SH, Chun YS, Kim JC. Tear cytokines and chemokines in patients with demodex blepharitis. *Cytokine*. 2011;53:94-99.
- Miyachi Y. Potential antioxidant mechanism of action for metronidazole: implications for rosacea management. Adv Ther. 2001;18:237-243.
- Akamatsu H, Oguchi M, Nishijima S, et al. The inhibition of free radical generation by human neutrophils through the synergistic effects of metronidazole with palmitoleic acid: a possi-

ble mechanism of action of metronidazole in rosacea and acne. *Arch Dermatol Res.* 1990;282:449-454.

- 32. Rivero AL, Whitfeld M. An update on the treatment of rosacea. *Aust Prescr.* 2018;41:20-24.
- 33. Stein L, Kircik L, Fowler J, et al. Efficacy and safety of ivermectin 1% cream in treatment of papulopustular rosacea: results of two randomized, double-blind, vehicle-controlled pivotal studies. J Drugs Dermatol. 2014;13:316-323.
- Schaller M, Gonser L, Belge K, et al. Dual anti-inflammatory and anti-parasitic action of topical ivermectin 1% in papulopustular rosacea. J Eur Acad Dermatol Venereol. 2017;31: 1907-1911.
- Huynh TT. Burden of disease: the psychosocial impact of rosacea on a patient's quality of life. Am Health Drug Benefits. 2013;6:348-354.
- Ebbelaar CCF, Venema AW, Van Dijk MR. Topical ivermectin in the treatment of papulopustular rosacea: a systematic review of evidence and clinical guideline recommendations. *Dermatol and Ther.* 2018;8:379-387.
- Dispenza MC, Wolpert EB, Gilliland KL, et al. Systemic isotretinoin therapy normalizes exaggerated TLR-2-mediated innate immune responses in acne patients. *J Invest Dermatol.* 2012;132:2198-2205.
- Sbidian E, Vicaut É, Chidiack H, et al. A Randomized-controlled trial of oral low-dose isotretinoin for difficult-to-treat papulopustular rosacea. *J Invest Dermatol.* 2016;136:1124-1129.

- Krausz AE, Goldberg DJ, Ciocon DH, Tinklepaugh AJ. Procedural management of rhinophyma: a comprehensive review. J Cosmet Dermatol. 2018;17:960-967.
- 40. Wang K, Shi L, Yu Z, et al. Cyclosporine a suppresses the activation of the Th17 cells in patients with primary Sjogren's syndrome. *Iran J Allergy Asthma Immunol.* 2015;14:198-207.
- 41. Lam-Franco L, Perfecto-Avalos Y, Patino-Ramirez BE, Rodriguez Garcia A. IL-1alpha and MMP-9 tear levels of patients with active ocular rosacea before and after treatment with systemic azithromycin or doxycycline. *Ophthalmic Res.* 2018;60:109-114.
- van Zuuren EJ, Fedorowicz Z, Carter B, van der Linden MM, Charland L. Interventions for rosacea. *Cochrane Database of Syst Rev.* 2015;4:CD003262.
- 43. Chang A. Open Label Study to Assess the Effect of Secukinumab in Moderate to Severe Papulopustular Rosacea. https://clinicaltrials.gov/ct2/show/NCT03079531.
- Inc. NPC. PRODUCT MONOGRAPH PrCOSENTYX® (Secukinumab) 2018.
- 45. Inc. ELC. PRODUCT MONOGRAPH INCLUDING PATIENT MEDICATION INFORMATION PrTALTZ[™] ixekizumab. 2017.
- LP VC. PRODUCT MONOGRAPH INCLUDING PATIENT MEDICATION INFORMATION PrSILIQ[™] brodalumab. 2018.

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Analysis of Cytokine Levels in Tears and Clinical Correlations After Intense Pulsed Light Treating Meibomian Gland Dysfunction

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• PURPOSE: To investigate the change from baseline of inflammatory markers in tears of dry eye disease (DED) subjects owing to meibomian gland dysfunction (MGD) after intense pulsed light (IPL) treatment and meibomian gland expression (MGE) compared to sham treatment, and the correlations with ocular surface parameters.

• DESIGN: Randomized, double-masked, controlled study.

• METHODS: Those randomized into the active treatment arm received 3 consecutive treatments $(14 \sim 16 \text{ J/cm}^2)$ approximately 4 weeks apart in the periocular region. Control eyes received 3 treatments in the same intervals of 0 J/cm². Tear samples in all eyes were collected and analyzed at baseline, week 12, and/or week 4 for interleukin (IL)-17A, IL-6, and prostaglandin E2 (PGE2). The correlations between cytokines and ocular surface parameters were analyzed before and after IPL treatment. • RESULTS: All of the inflammatory markers declined in value compared to baselines. IL-17A and IL-6 showed statistically significant decreases compared to sham treatment at each measured time point. PGE2 showed statistically significant decreases compared to sham at week 12. Results showed that the expressions of IL-17A and IL-6 correlated well with ocular surface parameters of the lower eyelid before IPL. The changed values of IL-6 and PGE2 in tears correlated with the changed values of partial ocular surface parameters after IPL treatment in study eyes, respectively.

• CONCLUSIONS: The study results suggest that IPL can significantly reduce inflammatory markers in tears of patients suffering with DED owing to MGD after IPL treatment. These findings indicate that IL-17A and IL-6 play roles in the pathogenesis of DED owing to MGD, and the reduction of the inflammatory factors is consistent with the improvement of partial clinical symptoms and signs. (Am J Ophthalmol 2017;183:81–90. © 2017

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RY EYE DISEASE (DED) ATTRIBUTABLE TO MEIBOmian gland dysfunction (MGD) represents a common and growing public health issue, particularly in older adults. MGD is a common cause of evaporative dry eye, affecting almost 70% of the population in some parts of the world, especially in Asia.¹ Meibomian glands are the largest sebaceous glands in the human body. Meibomian glands synthesize and secrete a mixture of lipids, termed meibomian oil or meibum,^{2,3} which is delivered as a clear liquid via orifices located directly in front of the mucocutaneous junction. MGD produces an abnormal meibum that becomes more stagnant than the usual clear liquid secretions.^{4,5} MGD and associated evaporative tear loss is followed by increasing inflammation on the surface of the eye and bacterial overgrowth, as abnormal lipids can provide a rich substrate for the resident bacterial microbiota. The subsequent release of toxic bacterial products, such as lipases. and the production and release of proinflammatory cytokines are pathogenic. This malfunction leads to worsening of abnormal meibum, discomfort, and further derangements of the ocular surface and tear film. Although there are different pathogenic mechanisms responsible for DED owing to MGD, evidence increasingly suggests that all forms of MGD are characterized by varying ocular surface inflammation.^{6,7} Many investigators have reported that the chronic inflammatory status in patients with MGD is associated with high concentrations of tear cytokines.^{8–12} Currently approved topical medications for dry eye, such as cyclosporine and lifitegrast, target inflammation on the ocular surface.^{13,14}

Intense pulsed light (IPL) therapy uses light energy to affect the skin surface, and is widely used in dermatology to treat a variety of conditions, including facial rosacea, port wine stains, seborrheic keratosis, and hypertrophic scar.¹⁵ In addition, the IPL device emits energy in a band from a base of the visible spectrum (580 nm) to near-infrared (1200 nm).¹⁶ Concurrent ocular surface health improvements have been observed serendipitously in

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patients undergoing IPL for the dermatologic manifestations of rosacea, leading to interest in evaluating IPL as a potential therapy for DED owing to MGD. There has been a growing number of physicians across the world that use IPL to treat MGD and dry eye.^{17,18} Recently, researchers demonstrated that IPL with multiple sculpted pulses showed therapeutic potential for DED owing to MGD, improving tear film quality and reducing symptoms of dry eye.^{19,20}

There are several related speculative mechanisms whereby IPL treatment is believed to improve signs and symptoms of DED owing to MGD. First, IPL produces heat that is transferred to the thin periocular skin, which allows the softening of meibum, aids expression, and melts pathologically dysfunctional secretions.¹⁷ Second, the IPL device emits energy that is preferentially absorbed by chromophores in hemoglobin, closing abnormal vasculature in the eyelid margin and adjacent conjunctiva and preventing abnormal vessels from local release of inflammatory factors.^{16,21} Third, IPL therapy may exert an effect in relief of inflammatory and neurogenic pain,²² which is highly related to the improvement of clinical symptoms of DED owing to MGD. Lastly, the IPL treatment can immediately reduce bacteria loads of the eyelid margin and the surrounding adnexa and the associated inflammation caused by them.²³ Despite the many anecdotal case reports outlining efficacy of IPL treatments in dry eye,¹⁷ research quantifying the reduction in specific inflammatory markers during and after IPL treatment is still sparse.

There is mounting evidence that inflammation plays a key role in the pathogenesis of the ocular surface disease that develops in dry eye.²⁴ Interleukin (IL)-17A is a proinflammatory cytokine produced by T-helper cells and the most commonly investigated member of the IL-17 family.⁹ There is an important role for IL-17 in dry eye inflammation processes.²⁵ IL-17 and IL-6 have both been studied as a possible connection between inflammation and ocular surface parameters in DED.^{11,12,25} Further, prostaglandin E2 (PGE2) levels were shown to be higher in tears of MGD patients than in the normal controls.²⁶ In this study, we compared the levels of all 3 inflammatory markers-IL-17A, IL-6, and PGE2-in tears of subjects suffering with DED owing to MGD before, during, and after MGE combined with either IPL or sham treatments so as to evaluate the efficacy of IPL in reducing tear film cytokines. Additionally, we analyzed inflammatory factor levels in tears and clinical correlations after IPL treating DED owing to MGD.

METHODS

• **SUBJECTS:** This randomized, double-masked, controlled clinical trial was conducted in compliance with the principles of the Declaration of Helsinki for the protection of

human subjects in medical research and was approved by the Human Research and Ethics Committee of Peking University First Hospital before the study began. All participants signed written informed consent forms before enrollment. The study was registered at http://www.chictr.org.cn (Study no ChiCTR-INR-16010256).

Subjects were recruited from the outpatient department of the Department of Ophthalmology of Peking University First Hospital from February 2016 to March 2016, and the study was conducted in April 2016. The eyes of subjects were randomized into study or control arms. The inclusion criteria^{17,27-29} for this study were (1) adult patients over the age of 18; (2) evidence of meibomian gland obstruction (based on a meibomian gland secretion score of ≤ 12 for 15 glands of the lower lid); (3) Standard Patient Evaluation of Eye Dryness (SPEED) ≥ 6 in both eyes; (4) Fitzpatrick skin type 1-4. Meibomian gland secretion score was measured using the meibomian gland evaluator (Tear Science Inc., Morrisville, North Carolina, USA). The procedure was performed following Lane protocol,²⁷; 15 glands, in both upper and lower eyelids, were evaluated. For each of these glands, the secretion was graded as follows: 0 = no secretion; 1 = inspissated/toothpaste consistency; 2 = cloudy liquid secretion; and 3 = clear liquid secretion. The scores were then summed to a single meibomian gland yield secretion score (MGYSS). The SPEED questionnaire was used to evaluate the severity and frequency of dry eye symptoms.²⁸ Exclusion criteria included (1) patients with any intraocular inflammatory condition, ocular surgery, or trauma in the past 6 months; (2) patients with present ocular infection or allergy; (3) patients with any eyelid structural abnormality; (4) patients with any systemic disease that could lead to DED; (5) if subjects were unable to stop using medication that may lead to DED; (6) patients currently being treated with punctual plugs; (7) patients who tanned in the past 4 weeks; (8) patients with skin cancer or pigment lesion in the treatment zone; (9) subjects who were pregnant/ nursing; (10) any systemic or local conditions that researcher considered inappropriate for the trial. Qualifying subjects stopped all topical or oral dry eye medications, artificial tears, and interventions 2 weeks before the baseline examination.

Eighty-eight eyes of 44 patients with DED owing to MGD (12 male and 32 female) were enrolled into this prospective study, with a mean age of 46.3 ± 16.9 years (range 23–86 years).

• INTERVENTION PROCEDURE: The study and control eyes of subjects were randomized according to the random number table by the dermatologist (P.T.), who completed the IPL treatments with the M22 system (Lumenis, Tel Aviv, Israel). Before treatment, the subjects received topical tetracaine/lidocaine cream (compound lidocaine cream; Ziguang Pharmaceutical Co, Ltd, Beijing, China) to periocular treatment areas for 30 minutes (surface anesthesia) and topical ophthalmic oxybuprocaine hydrochloride eye drops (Benoxil; Santen Pharmaceutical Co, Ltd, Osaka, Japan) into the conjunctival sac 5 minutes before treatment. The study eyes received IPL treatment $(14 \sim 16 \text{ J/cm}^2)$ depending on the Fitzpatrick skin type per the Toyos protocol, followed by MGE on both the upper and lower eyelids using the Arita meibomian gland compressor (Katena Products, Inc, Denville, New Jersey, USA) with no heat. Control eyes received sham IPL treatment (0 J/cm^2), followed by the same MGE. Handheld flashlights were used to simulate light flicker during IPL therapy in the treatment of the control eyes. IPL treatment was administered to the periocular tissues in 6 treatment areas from the nasal to the temporal side on each eyelid, for a total of 3 treatments approximately every 4 weeks.¹⁹ Patients received a total of 12 overlapping IPL pulses in the periocular areas (8 mm \times 15 mm each) on the upper and lower eyelids (Figure 1). Subjects received 1 full pass with overlapping flashes to ensure treatment of the entire area. All treatment areas were identical within different subjects. Prior to light treatment, protective metal shields were placed over the cornea and sclera. During the follow-up period of IPL treatment, all subjects used polyethylene glycol eye drops 3 times a day (Systane ULTRA, Alcon Company, Fort Worth, Texas, USA).

• OCULAR SURFACE PARAMETERS: The primary outcome measure was meibomian gland assessment (MGA), measured using the meibomian gland evaluator. Evaluation indicators were the number of meibomian glands yielding liquid secretion (MGYLS) and the number of meibomian glands yielding clear secretion (MGYCS). The scores were then then summed to a single-score MGYSS according to the above grading standards, termed u-MGYLS/MGYCS/MGYSS for the upper lid and d-MGYLS/MGYCS/MGYSS for the lower lid.²⁷

SPEED questionnaire and ocular surface disease index (OSDI) were used to evaluate the severity and frequency of dry eye symptoms. Tear breakup time (TBUT) was measured using moist fluorescein sodium strips (Jingming New Technological Development Co, Ltd, Tianjin, China). After the fluorescein was instilled into the conjunctival sac, the patient was asked to blink several times. Then the tear film was observed under the cobalt blue filter during biomicroscopy. The average TBUT of 3 repeated measurements was recorded for each eye. Following the TBUT measurement, the corneal fluorescent staining (CFS) was measured. The cornea was divided into 4 quadrants. Each quadrant was graded on a scale of 0 to 3^{30} (0 = no punctate staining, 1 = 1-30 instances of punctatestaining, 2 =punctate staining >30 but no infused lesions, 3 = infused lesions or ulcer). Total CFS of 4 quadrants ranged from 0 to 12.

• TEAR SAMPLE COLLECTION AND ANALYSIS: Tear samples were collected by instilling 60 μ L of phosphate-

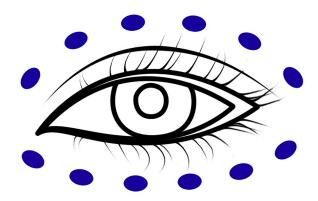


FIGURE 1. Intense pulsed light treatment zone included 6 overlapping periocular areas (8 mm \times 15 mm each) on each eyelid.

buffered saline into the inferior fornix without topical anesthetic, followed by movement of the eyes to mix the tear fluid content.³¹ A total of approximately 30 μ L of unstimulated tear fluid and buffer were collected from the inferior tear meniscus of each eye using a glass capillary micropipette at the lateral canthus. Samples were placed into a 200- μ L Eppendorf tube and immediately transported in an insulated cooler to a -80 C freezer, where they remained frozen until further examination.

Tear cytokines IL-17A and IL-6 concentrations were measured using a multiplex immunobead assay (BDTM Cytometric Bead Array Human Soluble Protein Flex Set; BD Biosciences, San Jose, California, USA) and flow cytometry (BD LSRFortessa; BD Biosciences). The measurements were performed according to protocol.³² Briefly, 10 µL tear fluid was thawed and added to a 50-µL mixture containing each capture antibody-bead reagent and 50 µL detector antibody-phycoerythrin reagent. The mixture was subsequently incubated for 3 hours at room temperature and washed to remove unbound detector antibody-phycoerythrin reagent before flow cytometry. Data were acquired and analyzed using BD Cytometric Bead Array software to calculate the cytokine concentration based on the standard curves and a 5-parameter logistic curve-fitting model with FCAP Array software v3. Flow cytometry was performed using the BD LSRFortessa system (BD Bioscience). The lower limits of detection were the following: IL-17A, 0.3 pg/mL (Human IL-17A Flexset, 560383; BD Biosciences); IL-6, 1.6 pg/mL (Human IL-6 Flexset, 558276; BD Biosciences). The lowest cytokine concentration in the linear portion of the standard curve was used for statistical comparison of tear samples with concentrations of less than this level.

Tear concentrations of PGE2 were measured using a PGE2 ELISA kit (ab133021; Abcam Inc, Cambridge, Massachusetts, USA) according to the manufacturer's instructions. The diluted tear samples (100 μ L) was placed in a 96-well goat anti-mouse IgG-coated plate and incubated for 2 hours. After incubation, the plate was washed using the provided washing buffer, and the color was developed

by adding PNPP (200 μ L) substrate after 45 minutes. The amount of PGE2 was acquired and calculated using Gen5 2.04.11 software, which calculates the cytokine concentration based on the standard curves, and a 4-parameter logistic curve-fitting model with ELISACalc. ELISA was performed using the BioTekEpoch (1311227; BioTek Instruments, Inc, Winooski, Vermont, USA). According to the manufacturer, the assay's lower limit of detection was 13.4 pg/mL.

We collected tear samples of both eyes at baseline prior to treatment, on week 4, and on week 12 for each subject. Then, we selected the baseline, week 4, and week 12 points to analyze the levels of cytokines IL-17A and IL-6 in the tear samples; the baseline and week 12 points were selected for analysis of the PGE2 concentration.

• STATISTICAL ANALYSIS: Data are expressed as mean \pm standard error of the mean (SEM). Analysis between 2 different time points (week 4 and week 12) for single variable data was performed using a paired-samples test with SPSS 17.0 for Windows software (SPSS Inc, Armonk, New York, USA). To compare the change in cytokine concentration in tears of study eyes with control eyes at individual time points, a paired-samples test was used. Correlations between the expressions of cytokines and ocular surface parameters, and between their changed values after IPL treatment, were analyzed by Spearman correlation coefficient, respectively. For all tests, P < .05 was considered to be statistically significant.

RESULTS

• INTENSE PULSED LIGHT DOWNREGULATES THE LEVEL OF INTERLEUKIN 17A IN TEARS OF PATIENTS WITH DRY EYE DISEASE OWING TO MEIBOMIAN GLAND DYSFUNC-TION: The changed values of cytokine IL-17A level in tears on week 4 and week 12 after IPL treatment in the study eyes were -173.49 ± 32.26 and -211.75 ± 33.78 pg/mL, respectively (n = 44, mean \pm SEM). The IL-17A levels of the control eyes were -64.64 ± 24.12 and -89.61 ± 22.21 pg/mL, respectively. All values represent a decrease from the pretreatment baselines. As shown in Figure 2, IL-17A was more significantly reduced in the IPL treatment arm than in the control after both week 4 and week 12 of IPL treatment (both P < .001). The value of IL-17A was most significantly decreased at the final study time point after 3 IPL treatments at week 12 compared to week 4 of IPL treatment in the treatment arm (Figure 2, P < .001). However, in the control eyes, no significant differences were found between the measured values of IL-17A at week 4 and week 12 of IPL treatment (Figure 2, P = .068).

• INTENSE PULSED LIGHT DOWNREGULATES THE LEVEL OF INTERLEUKIN 6 IN TEARS OF PATIENTS WITH DRY

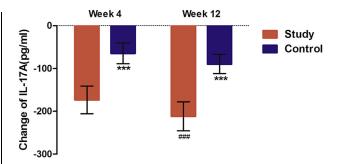


FIGURE 2. Intense pulsed light (IPL) downregulates the level of interleukin (IL)-17A in tears of patients with dry eye disease owing to meibomian gland dysfunction (MGD). IL-17A change to baseline. Baseline corrected change of the level of IL-17A (week 4 minus baseline; week 12 minus baseline). The mean changed value of tear IL-17A level (pg/mL) after week 4 and week 12 of IPL treatment in the study eyes and the control eyes (mean \pm SEM, n = 44) is shown. ***P < .001 compared to the study eyes at the same time point including week 4 and week 12. ###P < .001 compared to week 4 in the study eyes. Bars designate the means with 95% confidence intervals. Week 4: difference value between pretreatment and week 4 after IPL treatment; Week 12: difference value between pretreatment and week 12 after IPL treatment.

EYE DISEASE OWING TO MEIBOMIAN GLAND DYSFUNC-TION: The changed values of cytokine IL-6 level in tears at week 4 and week 12 after IPL treatment in the study eyes were -308.35 ± 58.59 and -405.62 ± 65.61 pg/mL, respectively (n = 44, mean \pm SEM). The IL-6 levels of the control eyes were -50.61 ± 22.08 and -143.46 ± 25.99 pg/mL (in the order designated above). These numbers represented a decrease from the pretreatment baselines. Compared to the control eyes, the value of IL-6 was significantly more decreased in the study eyes after week 4 and week 12 of IPL treatment (Figure 3, both P < .01). Like IL-17A, IL-6 levels were most significantly lowered after week 12 compared to week 4 (Figure 3, P < .01).

• INTENSE PULSED LIGHT DOWNREGULATES THE LEVEL OF PROSTAGLANDIN E2 IN TEARS OF PATIENTS WITH DRY EYE DISEASE OWING TO MEIBOMIAN GLAND DYSFUNCTION: The changed concentration of PGE2 in tears at week 12 after IPL treatment in the study eyes was -1.64 ± 0.14 ng/mL (n = 44, mean \pm SEM). The PGE2 level of the control eyes at the same time point was -0.73 ± 0.13 ng/mL (n = 44, mean \pm SEM). Both numbers represent a decrease from the pretreatment baselines. Compared to the control eyes, the mean concentration of PGE2 was more significantly decreased in the study eyes after week 12 of IPL treatment (Figure 4, P < .001).

• CORRELATIONS BETWEEN CYTOKINES AND OCULAR SURFACE PARAMETERS IN PATIENTS WITH DRY EYE DIS-EASE OWING TO MGD BEFORE INTENSE PULSED LIGHT

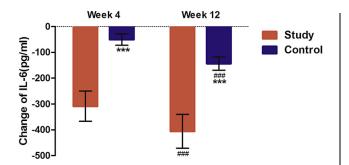


FIGURE 3. Intense pulsed light (IPL) downregulates the level of interleukin (IL)-6 in tears of patients with dry eye disease owing to meibomian gland dysfunction. IL-6 change to baseline. Baseline corrected change of the level of IL-6 (week 4 minus baseline; week 12 minus baseline). The mean changed value of IL-6 (pg/mL) after week 4 and week 12 of IPL treatment in the study eyes and the control eyes (mean \pm SEM, n = 44) is shown. ***P < .001 compared to the study eyes at the same time point including week 4 and week 12. ###P < .001 compared to week 4 in both eyes. Values are expressed as picograms (means \pm SEM pg/mL). Bars designate the means with 95% confidence intervals. Week 4: difference value between pretreatment and week 12 after IPL treatment; Week 12: difference value between pretreatment and week 12 after IPL treatment.

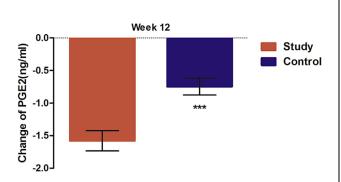


FIGURE 4. Intense pulsed light (IPL) downregulates the level of prostaglandin E2 (PGE2) in tears of patients with dry eye disease owing to meibomian gland dysfunction. PGE2 change to baseline. Baseline corrected change of the level of PGE2 (week 12 minus baseline). The mean changed value of PGE2 (ng/mL) after week 12 (in the IPL treatment endpoint) of IPL treatment in the study eyes and the control eyes (mean \pm SEM, n = 44) is shown. ***P < .001 compared to the study eyes in the IPL treatment endpoint. Values are expressed as nanograms (means \pm SEM, ng/mL). Bars designate the means with 95% confidence intervals. Week 12: difference value between pretreatment and week 12 after IPL treatment.

TREATMENT: The correlations between the expressions of IL-17A, IL-6, and PGE2 and ocular surface parameters of 44 subjects were evaluated in protein levels. One eye was randomly selected for statistical analysis. The correlation analysis between the expression of IL-17A and IL-6 in protein levels and some ocular surface parameters (SPEED,

OSDI, BUT, and CFS) showed no statistical significance (all P > .05). The correlation analysis between the expression of PGE2 in protein levels and any ocular surface parameter showed no statistical significance (all P > .05). On the other hand, the levels of IL-17A in tears correlated well with d-MGYLS (R = -0.680, P < .001; Figure 5, Top left), d-MGYCS (R = -0.692, P < .001; Figure 5, Top center), and d-MGYSS (R = -0.692, P < .001; Figure 5, Top right) at the pretreatment baselines. The levels of IL-6 in tears correlated well with d-MGYLS (R = -0.839, P < .001; Figure 5, Bottom left), d-MGYCS (R = -0.446, P = .002; Figure 5, Bottom center), and d-MGYSS (R = -0.845, P < .001, Figure 5, Bottom center), and the pretreatment baselines.

• CORRELATIONS BETWEEN THE CHANGED VALUES OF CYTOKINES AND THE CHANGED VALUES OF OCULAR SUR-FACE PARAMETERS AFTER INTENSE PULSED LIGHT TREATING PATIENTS WITH DRY EYE DISEASE OWING TO MEIBOMIAN GLAND DYSFUNCTION: Baseline corrected change of the levels of cytokines and ocular surface parameters (week 12 minus baseline) represented a decrease from the pretreatment baselines. The correlations between the changed values of IL-17A, IL-6, PGE2, and ocular surface parameters of 44 subjects were evaluated in protein levels. The correlation analysis between the changed values of IL-17A, IL-6, and PGE2 in protein levels and the changed values of any ocular surface parameter showed no statistical significance (all P > .05) in control eyes. On the other hand, the changed value of IL-6 in tears correlated with the changed value of d-MGYCS (R = -0.411, P = .006; Figure 6, Left) after IPL treatment in study eyes. The changed level of PGE2 in tears correlated with that of CFS (R = 0.311, P = .040; Figure 6, Right) after IPL treatment in study eyes.

DISCUSSION

MEIBOMIAN GLAND DYSFUNCTION IS A HIGHLY PREVALENT and growing ocular surface condition with potential to create long-term damage to the ocular surface. Current therapies for DED with or without MGD remain nonpermanent and many patients experience side effects or incomplete resolution, prompting researchers to continue exploration of more effective therapeutic approaches. IPL therapy, which has been used extensively in dermatology to treat chronic skin conditions including rosacea, is a relatively new treatment in ophthalmology for patients with evaporative DED.¹⁵ Although there are very few studies published on the use of IPL in patients to reduce the signs and symptoms of DED owing to MGD, IPL therapy has promising results for these patients. Previous reports outline statistically significant improvements in symptoms and clinical examination findings of dry eye owing to MGD.¹⁸ It is helpful to continue to build knowledge in

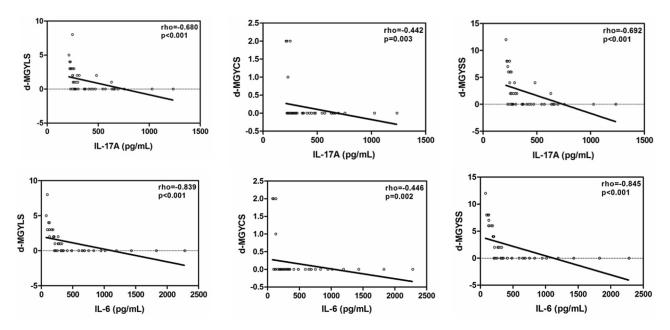


FIGURE 5. Correlations between cytokines (interleukin [IL]-17A and IL-6) and ocular surface parameters in patients with dry eye disease owing to meibomian gland dysfunction before intense pulsed light treatment. Correlation between levels of IL-17A and IL-6 in tears and ocular surface parameters including (at lower lid) number of meibomian glands yielding liquid secretion (d-MGYLS; Top left, Bottom left), number of meibomian glands yielding clear secretion (d-MGYCS; Top center, Bottom center), and single meibomian gland yield secretion score (d-MGYSS; Top right, Bottom right). The R and P values were determined with Spearman correlation coefficient.

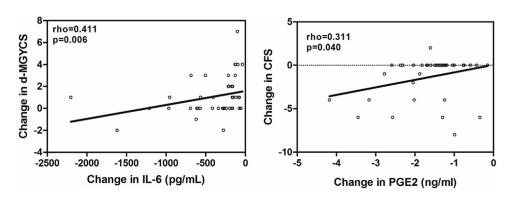


FIGURE 6. Correlations between the changed values of cytokines (interleukin [IL]-6 and prostaglandin E2 [PGE2]) and the changed values of ocular surface parameters after intense pulsed light (IPL) treating patients with dry eye disease owing to meibomian gland disease. (Left) Correlations between the changed values of IL-6 and the changed values of number of meibomian glands yielding clear secretion of the lower eyelid (d-MGYCS). (Right) Correlations between the changed values of PGE2 and the changed values of corneal fluorescent staining (CFS). The R and P values were determined with Spearman correlation coefficient.

this area by reporting the change in common ocular surface inflammatory markers owing to MGE alone and also combined with IPL.

Our study showed that IL-17A and IL-6 were significantly decreased in tears from patients with DED owing to MGD after IPL treatment in the study eyes. IL-17A is the most commonly studied member of the IL-17 family, which consists of 6 related proteins, from IL-17A to IL-17F. Th-17 cells are the major source of IL-17A and F, while other cell populations express IL-17A to a lesser extent. As a result, assessment of IL-17A indicates that Th-17 cells are more likely to be the source cells than other cell populations.⁹ Several reports previously highlighted increased tear inflammatory cytokines such as IL-17 and IL-6 in patients with DED owing to MGD.^{9,11,12,24}

Normal meibum contains antimicrobial properties that keep the lid margin clear from overgrowth.¹⁷ Abnormal blood vessel growth from chronic inflammation (telangiectasias) surround the meibomian glands and leak inflammatory mediators that cause malfunction of the glands.³³ This dysfunction leads to formation of an abnormal meibum. Eyelid margin telangiectasias are often seen clinically in patients with DED owing to MGD and ocular rosacea. The pathophysiology of rosacea involves thinning of connective tissues, allowing passive dilation of blood vessels (erythema and telangiectasias) and extravasation of inflammatory mediators (causing papules and pustules).¹⁸ IPL allows for selective ablation of these superficial vessels by targeting chromophores in hemoglobin, which not only reduces telangiectasias and erythema but also presumably decreases inflammatory marker access to the meibomian glands.²³ In this research, both IL-17A and IL-6 cytokines were found to be decreased in tears from patients with DED owing to MGD after IPL treatment. Potentially, IPL near the lid should cause closing of the abnormal blood vessels secreting inflammatory mediators, reducing the amount of cytokines IL-17A and IL-6 found in the tears, and also decreasing bacterial overgrowth by disrupting bacterial cell walls with targeted wavelengths of light. Based on this evidence, our data suggest that the decrease of tear IL-17A and IL-6 may correlate with the reduction of signs and symptoms of patients seen in other studies.¹⁷

In our study, the levels of both IL-17A and IL-6 in tears correlated well with d-MGYLS, d-MGYCS, and d-MGYSS at the pretreatment baselines. But, the correlation analysis between the expression of IL-17A and IL-6 in protein levels and SPEED/OSDI showed no statistical significance. Associations between DED signs and symptoms are low and inconsistent, which is consistent with the systematic literature review of the available evidence on associations between clinical signs and symptoms in DED.³⁴ The results of the study found that the indicators of the lower eyelid and inflammation were more related. This suggests that the lower eyelid may be more sensitive to inflammation, compared with the upper eyelid index. The MGA of the lower eyelid as an observation indicator in patients with DED owing to MGD is more meaningful and, combined with the upper eyelid, can be used as screening indicators.

There are some related speculative mechanisms whereby the inflammatory factors in tears are more related to the lower eyelid indexes in patients with DED owing to MGD. First, there are about 25–40 glands (average 31), the length of the central tarsal gland is about 5.5 mm, and the capacity is 26 μ L in the upper eyelid tarsal gland, whereas there are about 20–30 glands (average 26), the length of the central tarsal gland is about 2 mm, and the capacity is 13 μ L in the lower eyelid tarsal gland. The secretion lipid capacity of the upper eyelid is 2 times that of the lower eyelid. Meibomian glands are anatomically different between upper and lower eyelids and may differ functionally, given that upper evelids move more prominently than do the lower eyelids during blinking.³⁵ Second, Eom and associates³⁶ mentioned that gravity may lead to meibum stagnancy in the ducts and orifices, with the result that meibum is more difficult and discontinuous to secrete in the lower eyelid than in the upper eyelid. In our study, we noticed that gland secretion

function in the lower eyelids was damaged more seriously than in the upper eyelids $(2.3 \pm 3.2 \text{ vs } 9.3 \pm 7.5 \text{ at the base-}$ line of the study) in study eyes, which is consistent with previous studies.^{37,38} It is presumed that the content of inflammatory factors in tears may be more related to the indexes of the lower eyelid. Third, the upper meniscus filled out fully, and the excess tears were distributed to the lower tear meniscus. Also, tear meniscus height and area of the lower eyelid are greater and wider than the upper eyelid.^{39,40} Coupled with the role of gravity, the lower eyelid may contact the inflammatory factors in the tears for a longer time and in a wider area, and thus lower eyelid damage is more serious. In other words, inflammatory factors can affect the function of the lower eyelid, resulting in the content of inflammatory factors in tears and lower eyelid indexes being more relevant. It is further explained that lower eyelid damage is more serious in patients with DED owing to MGD. So MGA of the lower eyelid as a measure of DED owing to MGD indicators is more meaningful.

The changed value of IL-6 in tears correlated with the changed values of d-MGYCS after IPL treatment in study eyes. This change suggests that the improvement of d-MGYCS is likely to result in a change in the concentration of IL-6 after IPL treatment. The improvement of the lower eyelid gland clear secretion is particularly associated with the level of IL-6. IPL treatment is more relevant to the change in IL-6. In our study, we noticed that the lowered rate of IL-6 changes was greater than that of IL-17A (-84% vs -52% at the end of the study) in study eyes. IL-6 may be associated with an improvement in eyelid gland signs after IPL treatment. This may be because the decline in IL-17A is not large enough and the sample size of the study is too small.

Reductions in the levels of IL-6 and IL-17A were seen at each study time point in both arms of the study. Chauhan and associates showed that blockade of IL-17 significantly reduced the severity and progression of DED in vivo, which was paralleled by a reduction in the expansion of Th17 cells.⁴¹ Assessment of IL-17A indicates that Th-17 cells are more likely to be the source cells than the other cell populations above.⁹ IL-6 also plays a critical role in Th17 cell differentiation.⁴² Further research is needed to determine which marker may be most critical and whether Th17 cells are also changed when DED owing to MGD is treated with IPL.

The data showed that levels of PGE2 were lowered in both the control and the study arms and were lowest in the study group receiving IPL. The changed level of PGE2 in tears correlated with that of CFS after IPL treatment in study eyes. PGE2 is a prostaglandin with a significant role in inflammation.^{43,44} A small amount of PGE2 is likely to be sufficient to elicit and maintain the inflammatory pain state. PGE2 is a key mediator of pain in inflammation,⁴⁴ and its reduction may be responsible for improvement of symptoms in patients receiving IPL for dry eye. Commonly detectable signs of DED owing to MGD, including tear film instability, evaporative dry eye, and eyelid inflammation, are caused by modified and deficient meibum lipids.⁴⁵ Lipid synthesis processes of the meibomian glands are known to be affected by hormonal (mostly androgen), vascular, and neuronal influences.⁴⁶ PGE2 may be produced by damaged ocular surface cells, induced by microbes present on the surface, or a result of acute and chronic inflammation on the surface of the eve and within abnormal meibomian glands.⁴⁷ The elevated PGE2 in DED patients may aggravate ocular surface inflammation by inducing other inflammatory mediators. The elevated PGE2 may stimulate tear production to overcome surface dryness as well as to elicit irritation symptoms. Reduction in PGE2 levels was also found in the tears of all study patients, but was lowest in the active comparator group receiving IPL. The mechanism by which PGE2 levels are reduced by MGE and IPL is unclear but may be related to reduction in bacterial loads, improvement in meibum quality, decrease in skin inflammation, closure of telangiectasias, and photomodulation of meibomian glands. Further study is warranted to determine the role of PGE2 as a marker in DED owing to MGD.

It is interesting that the lowered levels of IL-17A, IL-6, and PGE2 were seen in the control group at all time points. MGE is known to improve symptoms of dry eye disease.⁴⁸ MGE could increase the meibum secretions, reduce the inflammation reaction of meibomian glands, and then lower the level of the molecules in tear samples. The study results also indicate that IPL treatment combined with MGE is more effective than expression alone. Expression would be expected to initially increase the levels of ocular surface inflammation as abnormal gland secretions are expressed onto the surface and then would be expected to decrease as abnormal secretions make way for healthier oils.

The improved outcomes in inflammatory markers with IPL treatment are likely owing to several mechanisms of action. The wavelength of light used in IPL for patients with DED owing to MGD is partially infrared, which can penetrate skin to the meibomian glands, generating enough heat to melt the solid secretions in the dysfunctional glands.⁴⁹ The M22 model uses the cooling sapphire crystal tip to cool the skin, allowing higher-temperature pulses without epidermal burning.⁵⁰ Secondly, optimized pulse technology (OPT) is a feature on the fifth-generation M22 unit that may confer outcome advantages. The OPT can eliminate energy peak at the beginning of the pulse and increase energy at the end of the pulse, so that the entire energy output can safely and effectively heat the target

tissue to the therapeutic temperature. Homogeneous "squared off" energy distribution provides more reproducible treatments for patients, which is also a feature not in other technologies. Thirdly, the IPL is known to close abnormal telangiectasia in skin rosacea, including ocular rosacea, preventing the continued leakage of cytokines that can perpetuate inflammation. Lastly, and possibly most importantly, the specific wavelengths of light provided by the IPL may also stimulate mitochondria of meibomian glands to function normally through a process known as photomodulation.⁵¹ This is the first published work outlining the study of these inflammatory markers over a typical clinical treatment course.

There are several limitations in this study. The volume of tear samples taken was not enough to analyze more than these 3 inflammatory markers. Many hundreds of inflammatory markers are present in acute and chronic dry eye, and some of these markers may prove to be even more important as markers in this disease. Another limitation is the female preponderance (73%) in our enrolled patients, although it reflects the sex divisions seen in clinical practice. The subjects were also asked to provide a subjective assessment of their eyes one to the other, which could introduce some variability. Lastly, it is possible that the subjects could discern whether and how much light/ thermal energy was imparted to them, as there is no practical way to present IPL as a true sham treatment. In future studies, clinicians could potentially test larger volumes of tear samples at more time points and enlarge the sample size to optimize the power of the study.

In conclusion, this research demonstrates the reduction of 3 important ocular surface inflammatory factors-IL-17A, IL-6, and PGE2-indicating that IPL combined with MGE is more effective than MGE alone in reducing inflammation of patients with DED owing to MGD. The expressions of IL-17A and IL-6 in protein levels are consistent with ocular surface parameters of the lower eyelid before IPL treatment. Also, the reduction of the inflammatory factors is consistent with the improvement of partial clinical symptoms and signs (d-MGYCS and CFS). These findings indicate that IL-17A and IL-6 play roles in the pathogenesis of DED owing to MGD, and the IL-6 and PGE2 in tears have potential to be a sign of symptom improvement for IPL treatment in patients with DED owing to MGD. In addition, these data present the possibility of an important new approach for treatment of DED owing to MGD. More studies are required to elucidate other issues related to DED, IPL, and its treatment, including the best inflammatory marker to follow, ideal treatment energies, and number of treatments.

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REFERENCES

- 1. Schaumberg DA, Nichols JJ, Papas EB, et al. The international workshop on meibomian gland dysfunction: report of the subcommittee on the epidemiology of, and associated risk factors for, MGD. *Invest Ophthalmol Vis Sci* 2011;52:1994–2005.
- 2. Nicolaides N, Kaitaranta JK, Rawdah TN, et al. Meibomian gland studies: comparison of steer and human lipids. *Invest Ophthalmol Vis Sci* 1981;20:522–536.
- 3. Ong BL, Larke JR. Meibomian gland dysfunction: some clinical, biochemical and physical observations. *Ophthalmic Physiol Opt* 1990;10:144–148.
- Korb DR, Blackie CA. Meibomian gland therapeutic expression: quantifying the applied pressure and the limitation of resulting pain. *Eye Contact Lens* 2011;37:298–301.
- 5. Olson MC, Korb DR, Greiner JV. Increase in tear film lipid layer thickness following treatment with warm compresses in patients with meibomian gland dysfunction. *Eye Contact Lens* 2003;29:96–99.
- 6. Pflugfelder SC. Anti-inflammatory therapy of dry eye. Ocul Surf 2003;1:31–36.
- 7. Wei Y, Asbell PA. The core mechanism of dry eye disease is inflammation. *Eye Contact Lens* 2014;40:248–256.
- Lee H, Chung B, Kim KS, Seo KY, Choi BJ, Kim TI. Effects of topical loteprednol etabonate on tear cytokines and clinical outcomes in moderate and severe meibomian gland dysfunction: randomized clinical trial. *Am J Ophthalmol* 2014;158: 1172–1183.e1.
- 9. Kang MH, Kim MK, Lee HJ, et al. Interleukin-17 in various ocular surface inflammatory diseases. *J Korean Med Sci* 2011; 26:938–944.
- Frey AG, Nandal A, Park JH, et al. Iron chaperones PCBP1 and PCBP2 mediate the metallation of the dinuclear iron enzyme deoxyhypusine hydroxylase. *Proc Natl Acad Sci U S* A 2012;111:8031–8036.
- 11. Acera A, Rocha G, Vecino E, et al. Inflammatory markers in the tears of patients with ocular surface disease. *Ophthalmic Res* 2008;40:315–321.
- 12. Pflugfelder SC. Tear cytokine profiles in dysfunctional tear syndrome. Am J Ophthalmol 2009;147:198–205.e1.
- Prabhasawat P, Tesavibul N, Mahawong W. A randomized double-masked study of 0.05% cyclosporine ophthalmic emulsion in the treatment of meibomian gland dysfunction. *Cornea* 2012;31:1386–1393.
- 14. Holland EJ, Luchs J, Karpecki PM, et al. Liftegrast for the treatment of dry eye disease: results of a phase III, randomized, double-masked, placebo-controlled trial (OPUS-3). *Ophthalmology* 2017;124:53–60.
- Piccolo D, Di Marcantonio D, Crisman G, et al. Unconventional use of intense pulsed light. *Biomed Res Int* 2014;2014: 618206.
- 16. Schroeter CA, Haaf-von Below S, Neumann HAM. Effective treatment of rosacea using intense pulsed light systems. *Dermatol Surg* 2005;31:1285–1289.
- Toyos R, McGill W, Briscoe D. Intense pulsed light treatment for dry eye disease due to meibomian gland dysfunction; a 3-year retrospective study. *Photomed Laser Surg* 2015;33:41–46.
- Vora GK, Gupta PK. Intense pulsed light therapy for the treatment of evaporative dry eye disease. Curr Opin Ophthalmol 2015;26:314–318.

- 19. Craig JP, Chen Y, Turnbull PRK. Prospective trial of intense pulsed light for the treatment of meibomian gland dysfunction. *Invest Ophthalmol Vis Sci* 2015;56:1965–1970.
- 20. Gupta PK, Vora GK, Matossian C, et al. Outcomes of intense pulsed light therapy for treatment of evaporative dry eye disease. *Can J Ophthalmol* 2016;51:249–253.
- **21.** de Godoy CHL, Silva PF, de Araujo DS, et al. Evaluation of effect of low-level laser therapy on adolescents with temporomandibular disorder: study protocol for a randomized controlled trial. *Trials* 2013;14:229.
- 22. Irvine J, Chong SL, Amirjani N, Chan KM. Double-blind randomized controlled trial of low-level laser therapy in carpal tunnel syndrome. *Muscle Nerve* 2004;30:182–187.
- 23. Farrell HPP, Garvey M, Cormican M, et al. Investigation of critical inter-related factors affecting the efficacy of pulsed light for inactivating clinically relevant bacterial pathogens. *J Appl Microbiol* 2010;108:1494–1508.
- 24. Pflugfelder SC. Antiinflammatory therapy for dry eye. Am J Ophthalmol 2004;137:337–342.
- Lee SY, Han SJ, Nam SM, et al. Analysis of tear cytokines and clinical correlations in Sjögren syndrome dry eye patients and non-Sjögren syndrome dry eye patients. *Am J Ophthalmol* 2013;156:247–253.e1.
- **26.** Shim J, Park C, Lee HS, et al. Change in prostaglandin expression levels and synthesizing activities in dry eye disease. *Ophthalmology* 2012;119:2211–2219.
- 27. Lane SS, DuBiner HB, Epstein RJ, et al. A new system, the LipiFlow, for the treatment of meibomian gland dysfunction. *Cornea* 2012;31:396–404.
- 28. Ngo W, Situ P, Keir N, et al. Psychometric properties and validation of the Standard Patient Evaluation of Eye Dryness questionnaire. *Cornea* 2013;32:1204–1210.
- 29. Blackie CA, Coleman CA, Holland EJ. The sustained effect (12 months) of a single-dose vectored thermal pulsation procedure for meibomian gland dysfunction and evaporative dry eye. *Clin Ophthalmol* 2016;10:1385–1396.
- Anon. Corneal Disease Group of Ophthalmological Society CMA. Experts' consensus about clinical diagnosis and treatment of dry eye (2013). Chin J Ophthalmol 2013;49(1):73–75.
- **31.** Argüeso P, Balaram M, Spurr-Michaud S, et al. Decreased levels of the goblet cell mucin MUC5AC in tears of patients with Sjögren syndrome. *Invest Ophthalmol Vis Sci* 2002;43: 1004–1011.
- **32.** Cook EB, Stahl JL, Lowe L, et al. Simultaneous measurement of six cytokines in a single sample of human tears using microparticle-based flow cytometry: allergics vs. non-allergics. *J Immunol Methods* 2001;254:109–118.
- **33.** Geerling G, Tauber J, Baudouin C, et al. The international workshop on meibomian gland dysfunction: report of the subcommittee on management and treatment of meibomian gland dysfunction. *Invest Ophthalmol Vis Sci* 2011;52: 2050–2064.
- 34. Bartlett JD, Keith MS, Sudharshan L, Snedecor SJ. Associations between signs and symptoms of dry eye disease: a systematic review. *Clin Ophthalmol* 2015;9: 1719–1730.
- **35.** Knop E, Knop N, Millar T, et al. The international workshop on meibomian gland dysfunction: report of the subcommittee on anatomy, physiology, and pathophysiology of the meibomian gland. *Invest Ophthalmol Vis Sci* 2011; 52:1938–1978.

- **36.** Eom Y, Choi K-E, Kang S-Y, et al. Comparison of meibomian gland loss and expressed meibum grade between the upper and lower eyelids in patients with obstructive meibomian gland dysfunction. *Cornea* 2014;33:448–452.
- **37.** Pult H, Riede-Pult BH, Nichols JJ. Relation between upper and lower lids' meibomian gland morphology, tear film, and dry eye. *Optom Vis Sci* 2012;89:E310–E315.
- Srinivasan S, Menzies K, Sorbara L, Jones L. Infrared imaging of meibomian gland structure using a novel keratograph. Optom Vis Sci 2012;89:788–794.
- **39.** Shen M, Li J, Wang J, et al. Upper and lower tear menisci in the diagnosis of dry eye. *Invest Ophthalmol Vis Sci* 2009;50: 2722–2726.
- **40.** Wang J, Simmons P, Aquavella J, et al. Dynamic distribution of artificial tears on the ocular surface. *Arch Ophthalmol* 2008; 126:619–625.
- 41. Chauhan SK, El Annan J, Ecoiffier T, et al. Autoimmunity in dry eye is due to resistance of Th17 to Treg suppression. J Immunol 2009;182:1247–1252.
- 42. Lin P, Suhler EB, Rosenbaum JT. The future of uveitis treatment. Ophthalmology 2014;121:365–376.
- **43.** Iyer JP, Srivastava PK, Dev R, et al. Prostaglandin E(2) synthase inhibition as a therapeutic target. *Expert Opin Ther Targets* 2009;13:849–865.

- 44. Ek M, Engblom D, Saha S, et al. Inflammatory response: pathway across the blood-brain barrier. *Nature* 2001;410: 430–431.
- 45. Goto E, Endo K, Suzuki A, et al. Tear evaporation dynamics in normal subjects and subjects with obstructive meibomian gland dysfunction. *Invest Ophthalmol Vis Sci* 2003;44:533–539.
- McCulley JP, Shine WE. The lipid layer of tears: dependent on meibomian gland function. *Exp Eye Res* 2004;78:361–365.
- 47. Johnson ME. The association between symptoms of discomfort and signs in dry eye. Ocul Surf 2009;7:199–211.
- Korb DR, Greiner JV. Increase in tear film lipid layer thickness following treatment of meibomian gland dysfunction. Adv Exp Med Biol 1994;350:293–298.
- **49.** Terada O, Chiba K, Senoo T, Obara Y. [Ocular surface temperature of meibomia gland dysfunction patients and the melting point of meibomian gland secretions]. *Nihon Ganka Gakkai Zasshi* 2004;108:690–693.
- 50. Raulin C, Greve B, Grema H. IPL technology: a review. Lasers Surg Med 2003;32:78–87.
- 51. Wong W-R, Shyu W-L, Tsai J-W, et al. Intense pulsed light effects on the expression of extracellular matrix proteins and transforming growth factor beta-1 in skin dermal fibroblasts cultured within contracted collagen lattices. *Dermatol Surg* 2009;35:816–825.

Item 4 Relevant law:

NRS 636.025 Acts constituting practice in optometry; unauthorized acts.

1. The acts set forth in this section, or any of them, whether done severally, collectively or in combination with other acts that are not set forth in this section constitute practice in optometry within the purview of this chapter:

(a) Advertisement or representation as an optometrist.

(b) Adapting, or prescribing or dispensing, without prescription by a practitioner of optometry or medicine licensed in this State, any ophthalmic lens, frame or mounting, or any part thereof, for correction, relief or remedy of any abnormal condition or insufficiency of **the eye or any appendage** or visual process. The provisions of this paragraph do not prevent an optical mechanic from doing the mere mechanical work of replacement or duplication of the ophthalmic lens or prevent a licensed dispensing optician from engaging in the practice of ophthalmic dispensing.

(c) The examination, evaluation, diagnosis and treatment of the human eye and its appendages, the measurement of the powers or range of human vision by any means, including, without limitation, the use of an autorefractor or other automated testing device, unless performed under the direct responsibility of a licensed optometrist as authorized in <u>NRS 636.346</u>, the determination of the accommodative and refractive states of the eye or the scope of its function in general, or the diagnosis or determination of any visual, muscular, neurological, interpretative or anatomic anomalies or deficiencies of the eye or its appendages or visual processes.

(d) Prescribing, directing the use of or using any optical device in connection with ocular exercises, orthoptics, vision rehabilitation, vision therapy or visual training.

(e) The prescribing of contact lenses.

(f) The measurement, initial fitting, as defined in <u>NRS 636.387</u>, or adaptation of contact lenses to the human eye except under the direction, responsibility and supervision of an optometrist licensed in the State of Nevada as authorized in <u>NRS 636.346</u>.

(g) The topical use of pharmaceutical agents to determine any visual, muscular, neurological, interpretative or anatomic anomalies or deficiencies of the eye or its appendages or visual processes.

(h) Prescribing, directing the use of or using a pharmaceutical agent or device to treat an abnormality of the eye or its appendages.

(i) Removing a foreign object from the surface or epithelium of the eye.

- (j) Removing eyelashes with forceps.
- (k) Closing the lacrimal punctum of the eye.

(l) The ordering or performing of laboratory tests or imaging to assist in the diagnosis of an abnormality of the eye or its appendages.

2. The provisions of this section do not authorize an optometrist to engage in any practice which includes:

(a) Any procedure using a laser, scalpel, needle or other instrument in which any human tissue is cut, burned or vaporized by incision, injection, ultrasound, laser, infusion, cryotherapy, radiation or other means; or

(b) Any procedure using an instrument which requires the closure of human tissue by suture, clamp or similar device.

[2:208:1955]—(NRS A 1961, 758; 1979, 952; 1995, 1033; 1999, 1914; 2019, 3638)

"Device" is not defined in NRS/NAC 636, but is used in two other definitions-

NRS 636.021 "Ophthalmic lens" defined. "Ophthalmic lens" means a refractive or nonrefractive **device** for the correction or relief of or remedy for an abnormal condition or inefficiency of the eye or visual process. The term includes a spectacle lens, a contact lens and a protective lens.

NAC 636.055 "Ophthalmic products" defined. "Ophthalmic products" means any materials used for the correction or relief of or remedy for any abnormal condition or inefficiency of the eye or visual process. The term includes, but is not limited to, spectacle frames, spectacle lenses, contact lenses, devices and pharmaceutical agents.

Materials for Item No. 5 re

- 8/2023 Letter re: patient scheduling
- Letter from Kopolow and Girisgen
- Relevant law

NEVADA STATE BOARD OF OPTOMETRY



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August 29, 2023

Robert Horner, O.D. 7888 S. Hat Creek Ct. Sparks, NV 89436 <u>robertkhorner@yahoo.com</u> *via email only*

Dr. Horner:

During the course of its Board meeting conducted on June 22, 2023, the Nevada State Board of Optometry authorized its Executive Director to issue a letter regarding your inquiry about optical retailers providing certain administrative services to an optometric practice.

Your request stems from a corporate officer of Walmart in or about March 2023 stating to you that it is illegal in Nevada for Walmart staff to schedule your practice's patients. When you asked the corporate officer for the Nevada law to support the position, she was unable and/or refused to provide you with one.

For the Board's consideration, you represented that you have been paying Walmart employees to provide administrative services, separate and distinct from the contract to lease the space and equipment from Walmart as the practice's landlord. You represented that such administrative services consist of the optical department performing confirmation calls and scheduling patients when you and your staff are not present, e.g., during your closed hours and vacation. You further represented that the administrative service does not have any other access to your patient records and thereby access to private health information (PHI), and instead your practice has its own computer system and own scheduling books separate from Walmart.

Under the facts and circumstances that you presented to the Board, the Board voted unanimously that an optometrist may contract with an outside/non-licensee entity, be it an optical retailer or another third-party entity, to fill-in patient names on a schedule prepared by the optometrist. Your hiring of Walmart personnel, or another third-party entity, to schedule your practice's appointments in your practice's appointment book at your behest is not in violation of Nevada State Optometry laws. Within Nevada State Optometry laws, there is no prohibition of an optometrist hiring a third-party entity to provide such administrative services, i.e., scheduling appointments, confirmation calling, insurance billing, and billing.

The Board's vote is predicated upon the facts and circumstances that you presented to the Board including your representations that the optical staff does not have access to your practice's medical records, that

NEVADA STATE BOARD OF OPTOMETRY



MARIAH SMITH, O.D. Board President

STEPHANIE LEE, O.D. Board Member Post Office Box 1824 Carson City, Nevada 89702 Telephone: (775) 883-8367 Facsimile: (775) 305-0105 E-Mail: <u>admin@nvoptometry.org</u>

ADAM SCHNEIDER, ESQ. Executive Director JEFFREY AUSTIN, O.D. Board Member

DREW JOHNSON Public Board Member

your schedule and medical records are kept separate from the administrative service, that such scheduling occurs under your *complete control*, that there is no directive from Walmart dictating to you and your practice how many patients must be seen in a business day, that Walmart does not have control over *any* of your scheduling, and instead that the administrative service that you contact with Walmart to provide has the ability to only fill in the blanks for your patient schedule.

Such practices would be consistent with R066-19 Section 12(3) that an optometrist may form a business relationship with a person who is not licensed to practice optometry to perform duties concerning the operation of the business limited to duties concerning, e.g., the operation of the business and may include, without limitation, performing services related to business development, business administration, and medical billing.

The Board's vote, and consequently this letter conveying the results of the Board's vote, is not to be construed as an abrogation of, e.g.: 1) NRS 636.372(4) which prohibits an optometrist from entering into a lease unless, during the term of the lease, the optometrist maintains exclusive access to, and control and ownership of, the medical records of each patient of the optometrist; 2) NAC 636.240(1) which prohibits a licensee and a person who is not licensed pursuant NRS 636 from entering into a lease with terms that authorizes the person who is not licensed to exercise control over the operation of the licensee's practice; and 3) the intent of R066-19 Section 12(4) which requires an optometry, to maintain organizational and financial independence from the person who is not licensed to practice optometry, to maintain organizational and financial independence from the person who is not licensee to practice optometry and ensure that the person who is not licensed to practice optometry is not involved in clinical decisions and scheduling of patients, i.e., the mere administrative function of a non-licensee person or entity when contracted by the doctor and at the doctor's behest, to fill in the blanks of a doctor's schedule is not the actual scheduling of patients as used in the relevant sections of NRS 636 or NAC 636.

Sincerely,

/s/ Adam Schneider Adam Schneider, Esq. Executive Director Nevada State Board of Optometry To: Adam Schneider-Executive Director, Nevada State Board of Optometry

From: H. Kenneth Kopolow, O.D. and Steve Girisgen, O.D.

May 22, 2024

Our concern is that NAC 636.250 and NAC 636. xxx (uncodified below) contain potentially conflicting language, which may result in ambiguity in the event a non-licensed business entity engages in questionable practices while in a business relationship with a licensee. In our opinion, the uncodified verbiage works well for a licensee seeking to outsource various business tasks to an independent 3rd party provider of such services but becomes far more susceptible to abuse when the non-licensed business associate exists to live "symbiotically" as (essentially) a retail arm of the optometric practice. Outsourcing duties such as billing, payroll, accounting/bookkeeping services, etc., may work well for a licensee. However, if the entity to which the licensee outsources has a monetary stake in the performance of the licensee, a difficult-to-regulate conflict of interest arises between a licensee regulated by the Board of Optometry and a "business partner" who is not. The problem is further compounded when the boundaries between clinical care and "business decisions" are ill-defined, as so many aspects of operating an eye care center are interdependent and cannot be differentiated into one category or another.

636.250 states a licensee must "maintain a partition or wall in such a manner as to ensure a clear separation between his or her office and the business of the person who is not licensed; and (b) Maintain a separate reception area, cash drawer, scheduling system, staff, computerized system and physical space from those of the business of the person who is not licensed. 2. A licensee shall not: (a) Use legal representation paid for or arranged by a person who is not licensed pursuant to the provisions of chapter 636 of NRS in any proceeding before the Board concerning the business relationship between the licensee and other person..." The uncodified passage allows for the non-licensed business operator to engage in activities such as banking, payroll, representation in regulatory matters not relating to health care, and numerous other activities that may directly or indirectly impact the clinical care delivered by the licensee. The very premise of a business arrangement where the "business associate" has the freedom to make payroll, banking, legal representation, etc., decisions on behalf of the independent optometrist is to consolidate operations for efficiency and improved profitability. In the case of an equity entity, paying an optometrist for the purpose of becoming a business associate with significant control over the combined newly formed enterprise runs contrary to longstanding statutes that ensure a clear separation between the 2 business associates. For example, if payroll services are being provided to the licensee, as well as to the non-licensee, a substantial risk of economization of scale exists, resulting in the possible co-mingling of funds, especially if the entity providing such payroll services are owned by the non-licensed business associate or an affiliate thereof.

Other examples of conflicting interests:

• It is fundamental to the arrangement that a mutually beneficial relationship exists between a licensee and a non-licensee, and the potential exists for billing to be combined for economic savings. As you know, insurance companies pay claims in the form of bulk payments, leaving it up to the Parties to separate potentially co-mingled funds. We are concerned as to how such activities could be regulated.

• An argument could be made that all business decisions directly or indirectly impact the clinical care provided by the side-by-side establishment. For example, payroll decisions impact manpower, staff training, and scope of care, yet would be under the control of a non-licensed person or entity.

 \cdot A website for the non-licensee that offers a link or phone number to the licensee's scheduling department could be a violation of anti-kickback laws.

As currently written, we believe the yet-to-be-codified draft poses potential threats to Nevada optometrists and their patients. Based on our prior communications, we understand the Board voted on this verbiage to address a particular licensee's request, but if left unaddressed, we believe non-licensed potential business "partners" are likely to exploit the ambiguities, resulting in unintended consequences.

We respectfully request the Board re-visit the verbiage of this legislation and consider addressing our concerns.

Best regards,

H. Kenneth Kopolow, O.D. Steve Girisgen, O.D.

Reference Statutes:

NAC 636.250 Separation between office of optometry and other businesses required. (NRS 636.125, 636.300) 1. A licensee who locates his or her office in a part of a building where a person who is not licensed pursuant to the provisions of chapter 636 of NRS conducts business shall: (a) Construct and maintain a partition or wall in such a manner as to ensure a clear separation between his or her office and the business of the person who is not licensed; and (b) Maintain a separate reception area, cash drawer, scheduling system, staff, computerized system and physical space from those of the business of the person who is not licensed. 2. A licensee shall not: (a) Use legal representation paid for or arranged by a person who is not licensed pursuant to the provisions of chapter 636 of NRS in any proceeding before the Board concerning the business relationship between the licensee and other person; or (b) Except as otherwise authorized by NRS 636.347, serve as an employee or independent contractor of any person who is not licensed to practice optometry.

NAC 636.xxx Business relationships between optometrists and non-optometrists. 1. If an optometrist forms an association or other business relationship with a physician pursuant to NRS 636.373, the optometrist must: (a) Comply with any applicable requirements of the Internal Revenue Service; (b) Maintain financial and organizational independence from any person who is not licensed to practice optometry, other than the physician; and (c) Ensure that any advertising, marketing and promotional materials accurately portray the position of the optometrist within the association or business relationship, including, without limitation, whether the practice of the optometrist is included within any assumed or fictitious name used by the association or other business relationship. 2. An optometrist shall not employ or be employed by a physician. 3. An optometrist may form an association or other business relationship with a person, other than a physician, who is not licensed to practice optometry to perform duties concerning the operation of the business and may include, without limitation, performing services related to payroll, human resources, real estate, regulatory matters not related to health care, banking, accounting, administration of benefits, marketing, merchandising, occupancy, accounts payable, accounts receivable, supply chain management, business development, business administration, labor, compliance with applicable laws and regulations, purchasing and medical

billing. 4. An optometrist who forms an association or other business relationship with a person who is not licensed to practice optometry pursuant to subsection 3 shall: (a) Comply with any applicable requirements of the Internal Revenue Service; (b) Maintain organizational and financial independence from the person who is not licensed to practice optometry and ensure that the person who is not licensed to practice optometry is not involved in: (1) Clinical decisions; (2) Scheduling of patients; (3) Any decision concerning scope of practice or use of facilities, equipment or drugs; or (4) Any other decision concerning the provision of care to a patient or the outcome of any treatment or other service provided to a patient; and...

Item 5 Relevant law:

NAC 636.250 requires a licensee and non-optometrist business to maintain its own scheduling and computer system, have no influence on the licensee's staff, maintain clear separation of physical space, etc.

R066-19 Sec. 12(3) regards business relationships between optometrists and non-optometrists.

Paragraph 3 states "An optometrist may form an association or other business relationship with a person, other than a physician, who is not licensed to practice optometry to perform duties concerning the operation of the business. Such duties must be limited to duties concerning the operation of the business and may include, without limitation, performing services related to payroll, human resources, real estate, regulatory matters not related to health care, banking, accounting, administration of benefits, marketing, merchandising, occupancy, accounts payable, accounts receivable, supply chain management, business development, business administration, labor, compliance with applicable laws and regulations, purchasing and medical billing."

Paragraph 4 lists what cannot be performed, i.e., "clinical decisions, scheduling of patients, any decision concerning scope of practice or use of facilities, equipment or drugs; or any other decision concerning the provision of care to a patient or the outcome of any treatment or other service provided to a patient, and ensure that any advertising, marketing and promotional materials accurately portray the position of the optometrist within the association or business relationship . . ."

Item 5 Relevant law:

NAC 636.250 requires a licensee and non-optometrist business to maintain its own scheduling and computer system, have no influence on the licensee's staff, maintain clear separation of physical space, etc.

R066-19 Sec. 12(3) regards business relationships between optometrists and non-optometrists.

Paragraph 3 states "An optometrist may form an association or other business relationship with a person, other than a physician, who is not licensed to practice optometry to perform duties concerning the operation of the business. Such duties must be limited to duties concerning the operation of the business and may include, without limitation, performing services related to payroll, human resources, real estate, regulatory matters not related to health care, banking, accounting, administration of benefits, marketing, merchandising, occupancy, accounts payable, accounts receivable, supply chain management, business development, business administration, labor, compliance with applicable laws and regulations, purchasing and medical billing."

Paragraph 4 lists what cannot be performed, i.e., "clinical decisions, scheduling of patients, any decision concerning scope of practice or use of facilities, equipment or drugs; or any other decision concerning the provision of care to a patient or the outcome of any treatment or other service provided to a patient, and ensure that any advertising, marketing and promotional materials accurately portray the position of the optometrist within the association or business relationship . . ."

Materials for Item No. 6 re

- email from Dr. Tonya Hubbard
- Relevant law

| From: | Nevada State Board of Optometry |
|----------|---|
| То: | <u>admin</u> |
| Subject: | New contact form from Tonya Hubbard, OD |
| Date: | Friday, May 17, 2024 1:25:49 PM |

Name

Tonya Hubbard, OD

Email

hubbardtonya@hotail.com

Your Subject

VSP Ventures leadership

Message

I would like to know from the NV Board Optometry purview - if there is no replacement for Dr. Michitsch as the OD name/leader of VSP Ventures in Nevada - what happens to the doctors under employment of VSP Ventures? It does not seem they could continue to practice under their contract. If you have any clarification please let me know.

Item 6 Relevant law:

NRS 636.300(1) (unprofessional conduct for association as an optometrist with any corporation violating NRS 636);

NRS 636.300(2) (unprofessional conduct for accepting employment, directly or indirectly, from a person not licensed to practice optometry to assist the person in such practice or enable the person to engage therein);

NRS 636.301(2) (division of fees or any understanding or arrangement designed to influence the independent judgment or practice of the optometrist with any person who is not an optometrist);

NAC 636.250(2)(b) (prohibition of licensee as an employee or independent contractor of any person who is not licensed to practice optometry);

R066-19, Section 12(3) (in an association or business with a non-licensee, limitation of non-licensee's duties concerning the operation of the business);

R066-19, Section 12(4) (in an association or business with a non-licensee, maintain organizational and financial independence from the non-licensee with no influence upon clinical decisions, scheduling of patients, any decision concerning scope of practice or other decision concerning the provision of patient care).

NRS 636.373(3) ("A person shall not directly or indirectly supervise an optometrist within the scope of his or her practice of optometry unless the person is licensed to practice optometry pursuant to this chapter")

NRS 636.373(4) ("A person, including an officer, employee or agent of any commercial or mercantile establishment, shall not directly or indirectly control, dictate or influence the professional judgment of the practice of optometry by a licensed optometrist, unless the person is licensed to practice optometry pursuant to this chapter.")

Materials for Item No. 7 re

• Relevant law

Item 7 Relevant law

NRS 636 and NAC 636 (no prohibition per se of filling an international OD's or OMD's contact lens Rx)

NAC 636.670(4) (contact lenses parameters include base curve or equivalent, diameter, refractive power, brand and type, and actual materials desired with percentage of water content and thickness¹ and whether the Rx is for daily wear or stated maximum number of 24-hour periods);

NAC 636.680(4) (brand name and type of lens dispensed must be identical to the brand name and type of lens of prescribed)

¹ R101-24 re NAC 636.670(4)(b)(2) (the actual materials desired with their percentage of water content and thickness)

Materials for Item No. 8 re

• ARBO Survey results

Nevada Board Query: Does your State have restrictions that only optometrists can own an optometry office? 6/6/23

| | Does your State have restrictions that only optometrists can own an | Do you have any restrictions that an optometrist can't be employed by | |
|----------|--|---|--|
| State | optometry office? | an optician or ophthalmologist, or private equity? | |
| | | We do have a statute that prohibits "fee splitting" between the OD and the owner | |
| | | (if not an OD/MD, etc). The legal definition of fee splitting is argued about, but | |
| | | the idea is that the OD does not directly split any portion of his/her fees for | |
| AL | In Alabama, anyone can own an optometry practice. | professional services with the owner of the practice. | |
| АК | | | |
| AR | No, we allow co-ownership with Ophthalmology | Yes, our optometrists may only be employed by themselves, other optometrists or ophthalmologists. | |
| | Arizona has specific requirements for practice designations and ownership. See A.R.S. 32-1753: 32-1753. Practice designations; definition. A. A licens | | |
| | | partner with other health professionals. 3. A professional limited liability company | |
| | | the ownership interest. 4. A professional corporation in which health professionals | |
| | collectively possess at least fifty-one percent of the ownership interest. 5. An e | | |
| | subsection. B. A licensee must practice only under the name under which the l | - | |
| A.7 | is considered a health care profession under 32-3101. | nber of the health professions as defined in section 32-3101. A Dispensing Optician | |
| AZ CA | | | |
| | | | |
| CO CT | | | |
| СТ | | | |
| DE | | | |
| DC | | | |
| FL | | | |
| GA | | | |
| ні | Hawaii Revised Statutes and Hawaii Administrative Rules are silent on both questions. | | |
| ID | | No | |
| IL | | | |
| IN | | | |
| IA | | | |
| KS | | | |
| КҮ | | | |
| LA | | | |
| MA | | | |
| MD | | | |
| ME | | | |

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| | | |
| MN | | |
| МО | | |
| MS | | |
| МТ | | |
| | optometrist can form a simple partnership or PLLC only with another OD or | Yes, an optometrist can only be employed by another OD or an OMD or visa versa. |
| ND | | |
| NE | | |
| | You can view the laws and rules that govern this profession from the links provided. RSA- New Hampshire Statutes - Table of Contents (state.nh.us) https://www.gencourt.state.nh.us/rsa/html/NHTOC/NHTOC-XXX-327.htm RULE- Opt 100-600 (state.nh.us) https://gencourt.state.nh.us/rules/state_agencies/opt100-600.html | |
| NJ | | |
| NM | | |
| NV | | |
| | In New York State, an unlicensed individual may own a business that offers optometric services in accordance with section 7106 of Education Law and part 29.8 of the Rules of the Board of Regents, both of which may be found on | Section 7106(2) of Education Law allows for corporate practice of the optometry profession. Therefore, an optician and optometrist can co-own a practice. They cannot form a professional corporation (PC), however, they can establish a business corporation. Section 7106(2) can be found on our web site at https://www.op.nysed.gov/professions/optometry/laws-rules-regulations/article-143 |
| он | | |
| ОК | | |
| OR | See attact | ned response. |
| PA | | |
| RI | | |
| SC | | |
| | | |
| SD | | |
| TN | - | |
| тх | See attached rules | |

| WY | doctor or doctor of osteopathy intends to be physically present in the office. | | |
|----|--|---|--|
| | | ge (added by our state Medical Society) that reads: A licensee who enters into a y shall conspicuously post in each office the regularly scheduled hours the medical | |
| wv | See attached response. | | |
| wı | Here are some state laws in Wisconsin that address the question: Wis. Stat. 449.03 Enforcement. (1) No rule made by the examining board shall expand the practice of optometry or affect the practice of dispensing opticians, nor shall the examining board enact rules which forbid the employment of an optometrist or declare such employment unprofessional conduct, or prohibit the operation of an optometric department by optometrists in a mercantile establishment [Under sub. (1), the board is prohibited from enacting rules that affect the practice of dispensing opticians or forbidding the employment by them of optometrists or declaring such employment unprofessional conduct. Feinberg v. Hasler, 63 Wis. 2d 268, 217 N.W.2d 334 (1974). Wis. Stat 449.08 Unprofessional conduct. (1) Unprofessional conduct includes without limitation because of enumeration: (d) Splitting or dividing any fee for optometric service with any person, except an associate licensed optometrist Wis Admin Code OPT 5.02 (11) Splitting or dividing any fee for optometric service with any person, except an associate licensed optometrist | | |
| WA | No. We do no regulate optometrists and if they own a business nor who they are employed by. | Νο | |
| VA | | | |
| VT | | | |
| UT | Utah Code 58-16a-701 Form of Practice states: (1) An optometrist licensed under this chapter may engage in practice as an optometrist or in the practice of optometry only as an individual licensee. However, as an individual licensee he may be: (a) an individual operating as a business proprietor; (b) an employee of another person or corporation; (c) a partner in a lawfully organized partnership; (d) a lawfully formed professional corporation; (e) a lawfully organized limited liability company; (f) a lawfully organized business corporation; or (g) any other form of organization recognized by the state and which is not prohibited by division rule made in collaboration with the board. (2) Regardless of the form in which a licensee engages in the practice of optometry, the licensee may only permit the practice of optometry in that form of practice to be conducted by an individual: (a) licensed in Utah as an optometrist under Section 58-16a-301; and (b) who is able to lawfully and competently engage in the practice of optometry. | | |

Here's our rules regarding owning an optometric practice in Oregon:

852-020-0045

Requirements for Business Entity Organization

The following provisions apply to Oregon optometry practices, as defined in ORS 683.010, organizing or operating as a business entity and are in addition to the provisions for a professional corporation, limited liability company and partnership outlined in ORS Chapters 58, 63, 67, and 70.

(1) Definitions. As used in these administrative rules, unless the context requires otherwise:

(a) "Business entity" means:

(A) A professional corporation organized under ORS Chapter 58, predecessor law or comparable law of another jurisdiction;

(B) A limited liability company organized under ORS Chapter 63 or comparable law of another jurisdiction;

(C) A partnership organized in Oregon after January 1, 1998, or that is registered as a limited liability partnership, or that has elected to be governed by ORS Chapter 67 or comparable law of another jurisdiction; or

(D) A limited partnership organized under ORS Chapter 70, predecessor law or comparable law of another jurisdiction.

(b) "Majority ownership interest" means more than 50 percent of:

(A) The issued voting stock of a professional corporation;

(B) The members of a limited liability company; or

(C) Participation in the profits of a partnership.

(c) "Organizational document" means:

(A) The articles of incorporation of a professional corporation, or comparable document of another jurisdiction;

(B) The articles of organization of a limited liability company, or comparable document of another jurisdiction;

(C) The partnership agreement and, for a limited liability partnership, its registration, or comparable document(s) of another jurisdiction; or

(D) A certificate of limited partnership, or comparable document of another jurisdiction.

(d) "Owner" means a voting shareholder of a professional corporation, member of a limited liability company, or partner of a partnership.

(e) "Principal" means a person who is a director of a professional corporation, manager of a limited liability company, or general partner of a limited partnership.

(2) Requirements for business entities organized to practice optometry:

(a) The majority ownership interest must be held by optometric physicians licensed in this state to practice optometry:

(A) A majority of the principals must be optometric physicians who are licensed in this state to practice optometry;

(B) All officers except the secretary and treasurer, if any, must be optometric physicians who are licensed in this state to practice optometry. Any two or more offices may be held by the same person;

(b) A professional corporation may be a shareholder of a professional corporation organized for the purpose of practicing optometry solely for the purpose of effecting a reorganization as defined in the Internal Revenue Code;

(c) The Oregon Board of Optometry has the discretion to allow business entities to apply for a waiver of the majority ownership requirement provided full disclosure of business ownership is provided to the Board, a plan and timetable is presented for a transition to meet the requirements of this rule, and the Board finds that the health and welfare of the patient is the first priority of the optometric physicians and business entity; and

(d) Upon a finding that a holder or owner of an optometric practice has failed to comply with the provisions of this rule or the regulations prescribed by the Board pursuant to the practice of optometry, the Oregon Board of Optometry may consider the failure to comply with this rule as a violation of this rule which may subject a holder or owner to discipline pursuant to ORS 683.140.

(3) Licensee will report ownership in any Oregon optometry business per 852-050-0016 in the Board's online licensing system.

Shelley Hanson Shelley.g.Hanson@obo.oregon.gov Executive Director Oregon Board of Optometry 1500 Liberty St SE, Ste 210 Salem, OR 97302 971-701-1194 Melissa: 971-701-1603 Fax 503.914.5142 //Oregon.gov/obo—licensee self-service portal access is on the home page Any information provided in this email may be confidential under ORS 676.175 and is not to be distributed.

From: Lisa Fennell <lfennell@arbo.org> Sent: Tuesday, June 6, 2023 10:53 AM To: Lisa Fennell <lfennell@arbo.org> Subject: ARBO Member Query

ARBO Member Board Executives:

The Nevada Board of Optometry would like to know the following:

- Does your State have restrictions that only optometrists can own an optometry office?
- Do you have any restrictions that an optometrist can't be employed by an optician or ophthalmologist, or private equity?

Please send your response to me and I'll compile them for the NV Board.

Thanks, Lisa

Gisa Fennell

Executive Director Association of Regulatory Boards of Optometry

Note New Address: 3440 Toringdon Way Suite 205 PMB #20533 Charlotte, NC 28277

Main Phone: 704-970-2710 Direct Phone: 704-970-2755 www.arbo.org Texas statutes don't talk about ownership as much as control of optometry.

See https://statutes.capitol.texas.gov/Docs/OC/htm/OC.351.htm#351.408

Sec. 351.408. CONTROL OF OPTOMETRY. (a) This section and Sections 351.602(c)(2), 351.603(b), 351.604(3), and 351.605 shall be liberally construed to prevent manufacturers, wholesalers, and retailers of ophthalmic goods from controlling or attempting to control the professional judgment, manner of practice, or practice of an optometrist or therapeutic optometrist.

(b) In this section, "control or attempt to control the professional judgment, manner of practice, or practice of an optometrist or therapeutic optometrist" includes:

(1) setting or attempting to influence the professional fees or office hours of an optometrist or therapeutic optometrist;

(2) restricting or attempting to restrict an optometrist's or therapeutic optometrist's freedom to see a patient by appointment;

(3) terminating or threatening to terminate an agreement, including a lease, or other relationship in an attempt to control the professional judgment, manner of practice, or practice of an optometrist or therapeutic optometrist;

(4) providing, hiring, or sharing employees, business services, or similar items to or with an optometrist or therapeutic optometrist; and

(5) making or guaranteeing a loan to an optometrist or therapeutic optometrist in excess of the value of the collateral securing the loan.

(c) A manufacturer, wholesaler, or retailer of ophthalmic goods may not directly or indirectly:

(1) control or attempt to control the professional judgment, manner of practice, or practice of an optometrist or therapeutic optometrist;

(2) employ or contract for the services of an optometrist or therapeutic optometrist if part of the optometrist's or therapeutic optometrist's duties involves the practice of optometry or therapeutic optometry; or

(3) pay an optometrist or therapeutic optometrist for a service not provided.

(d) This section does not apply to a manufacturer, wholesaler, or retailer of ophthalmic goods who is an optometrist, therapeutic optometrist, or licensed physician or a legal entity wholly owned and controlled by at least one optometrist, therapeutic optometrist, or licensed physician, unless the optometrist, therapeutic optometrist, or legal entity has offices at more than three locations.

And https://statutes.capitol.texas.gov/Docs/OC/htm/OC.351.htm#351.363

Sec. 351.363. MERCANTILE ESTABLISHMENT. (a) To safeguard the visual welfare of the public and the doctor-patient relationship, assign professional responsibility, establish standards of professional surroundings, more nearly secure to the patient the optometrist's or therapeutic optometrist's undivided loyalty and service, and carry out the prohibitions of this chapter against placing an optometric or therapeutic optometric license in the service or at the disposal of an unlicensed person, this section applies to an optometrist or therapeutic optometrist who leases space from and practices optometry or therapeutic optometry on the premises of a mercantile establishment.

(b) The optometric practice must be owned by an optometrist or therapeutic optometrist. Every phase of the practice and the leased space of the optometric practice must be controlled exclusively by an

optometrist or therapeutic optometrist.

(c) The prescription files and business records of the optometric practice are the sole property of the optometrist or therapeutic optometrist and may not be involved with a mercantile establishment or unlicensed person.

(d) The lessor of the optometric practice space may inspect business records that are essential to the successful initiation or continuation of a lease of space based on a percentage of gross receipts.

(e) The leased space of the optometric practice must be definite and apart from space used by other occupants of the premises. Solid, opaque partitions or walls from floor to ceiling must separate the optometric practice space from space used by other occupants. Railings, curtains, or other similar arrangements do not satisfy the requirements of this subsection.

(f) The leased space must have a patient's entrance opening on a public thoroughfare, such as a public street, hall, lobby, or corridor. An aisle of a mercantile establishment does not satisfy the requirement of this subsection. An entrance is not considered a patient's entrance unless actually used as an entrance by the optometrist's or therapeutic optometrist's patients.

| From: | wvbdopt@frontier.com |
|--------------|----------------------------------|
| То: | Lisa Fennell |
| Subject: | RE: ARBO Member Query |
| Date: | Tuesday, June 6, 2023 6:03:43 PM |
| Attachments: | 30-8 Business Entitu 230606.pdf |

That can be a little convoluted. Only licensees may own an optometric business entity, formerly known as an optometric corporation. The idea behind it is that an optometrist must be free to exercise his or her professional judgment and not be controlled by someone else. We had a policy that forbids an optometrist to be an employee of an ophthalmologist for the same reason.

At one time WalMart had provisions in optometrist contracts several years ago that set office hours, length of appointments, and access to optometrist records. It was a controversy over 10 years ago. Our attorney negotiated with Wal-Mart's attorney for a while. They made a couple of concessions, but the talks broke down. The Board ended the discussion by informing Walmart of Federal tax guidelines regarding the definition of a contractor vs. an employee. There were provisions in Wal-Mart's optometrist contracts that would have defined an optometrist as an employee. That would have increased Wal-Mart's tax liability.

A few years later the employment issue came up again. We had a different attorney. She had a different interpretation. She said that a license is a property right. An optometrist is free to choose to sacrifice his or her rights to another in a contract. The Board changed its policy on optometrists being an employee of an ophthalmologist for the reason listed above. There is now a policy that allows an optometrist to work for an ophthalmologist. The Board has not sought an attorney's opinion on this issue for at least 5-7 years.

Best wishes,

Pamela Carper

Executive Director WV Board of Optometry 179 Summers Street, #231 Charleston, WV 25301 Phone: 304-558-5901 Fax: 304-558-5908 E-mail: wvbdopt@frontier.com Website: https://www.wvbo.org

From: Lisa Fennell <lfennell@arbo.org> Sent: Tuesday, June 6, 2023 1:53 PM To: Lisa Fennell <lfennell@arbo.org> Subject: ARBO Member Query

ARBO Member Board Executives:

The Nevada Board of Optometry would like to know the following:

- Does your State have restrictions that only optometrists can own an optometry office?
- Do you have any restrictions that an optometrist can't be employed by an optician or ophthalmologist, or private equity?

Please send your response to me and I'll compile them for the NV Board.

Thanks, Lisa

Qisa Fennell

Executive Director Association of Regulatory Boards of Optometry

Note New Address:

3440 Toringdon Way Suite 205 PMB #20533 Charlotte, NC 28277

Main Phone: 704-970-2710 Direct Phone: 704-970-2755 www.arbo.org

ARTICLE 8. OPTOMETRISTS.

§30-8-1. Unlawful acts.

(a) It is unlawful for any person to practice or offer to practice optometry in this state without a license or permit issued under the provisions of this article, or advertise or use any title or description tending to convey the impression that they are an optometrist unless the person has been duly licensed or permitted under the provisions of this article.

(b) A business entity may not render any service or engage in any activity which, if rendered or engaged in by an individual, would constitute the practice of optometry, except through a licensee or permittee.

(c) A licensee may not practice optometry as an employee of any commercial or mercantile establishment.

(d) A licensee may not practice optometry on premises not separate from premises whereon eyeglasses, lenses, eyeglass frames or any other merchandise or products are sold by any other person. For the purposes of this section, any room or suite of rooms in which optometry is practiced shall be considered separate premises if it has a separate and direct entrance from a street or public hallway or corridor within a building, which corridor is partitioned off by partitions from floor to ceiling.

(e) A person who is not licensed under this article as an optometrist may not characterize himself or herself as an "optometrist" or "doctor of optometry" nor may a person use the designation "OD".

§30-8-2. Applicable law.

The practice of optometry and the Board of Optometry are subject to the provisions of article one of this chapter, the provisions of this article and the board's rules.

§30-8-2a.

Repealed.

Acts, 2010 Reg. Sess., Ch. 152.

§30-8-2b.

Repealed.

Acts, 2010 Reg. Sess., Ch. 152.

§30-8-3. Definitions.

As used in this article:

(a) "Appendages" means the eyelids, the eyebrows, the conjunctiva and the lacrimal apparatus.

(b) "Applicant" means any person making application for a license, certificate or temporary permit under the provisions of this article.

(c) "Board" means the West Virginia Board of Optometry.

(d) "Business entity" means any firm, partnership, association, company, corporation, limited partnership, limited liability company or other entity owned by licensees that practices optometry.

(e) "Certificate" means a prescription certificate issued under section fifteen of this article.

(f) "Certificate holder" means a person authorized to prescribe certain drugs under section fifteen of this article.

(g) "Examination, diagnosis and treatment" means a method compatible with accredited optometric education and professional competence pursuant to this article.

(h) "License" means a license to practice optometry.

(i) "Licensee" means an optometrist licensed under the provisions of this article.

(j) "Ophthalmologist" means a physician specializing in ophthalmology licenced in West Virginia to practice medicine and surgery under article thereof this chapter or osteopathy under article fourteen of this chapter.

(k) "Permittee" means a person holding a temporary permit.

(1) "Practice of optometry" means the examining, diagnosing and treating of any visual defect or abnormal condition of the human eye or its appendages within the scope established in this article or associated rules.

(m) "Temporary permit" or "permit" means a permit issued to a person who has graduated from an approved school, has taken the examination prescribed by the board, and is awaiting the results of the examination.

§30-8-3a.

Repealed.

Acts, 2010 Reg. Sess., Ch. 152.

§30-8-3b.

Repealed.

Acts, 2010 Reg. Sess., Ch. 152.

§30-8-4. Board of Optometry.

(a) The West Virginia Board of Optometry is continued. The members of the board in office on July 1, 2010, shall, unless sooner removed, continue to serve until their respective terms expire and until their successors have been appointed and qualified.

(b) The board shall consist of the following members appointed by the Governor, by and with the advice and consent of the Senate:

(1) Five licensed optometrists; and

(2) Two citizen members, who are not licensed under the provisions of this article and who do not perform any services related to the practice of the profession regulated under the provisions of this article.

(c) Each licensed member of the board, at the time of his or her appointment, must have held a professional license in this state for a period of not less than three years immediately preceding the appointment.

(d) Each member of the board must be a resident of this state during the appointment term.

(e) The term shall be three years. A member may not serve more than two consecutive full terms. A member may continue to serve until a successor has been appointed and has qualified.

(f) A vacancy on the board shall be filled by appointment by the Governor for the unexpired term of the member whose office is vacant and the appointment shall be made within sixty days of the vacancy.

(g) The Governor may remove any member from the board for neglect of duty, incompetency or official misconduct.

(h) A member of the board immediately and automatically forfeits membership to the board if his or her license to practice is suspended or revoked, is convicted of a felony under the laws of any jurisdiction, or becomes a nonresident of this state.

(i) The board shall elect annually a president and a secretary-treasurer from its members who serve at the will of the board.

(j) Each member of the board is entitled to compensation and expense reimbursement in accordance with article one of this chapter.

(k) A majority of the members of the board constitutes a quorum.

(1) The board shall hold at least two meetings a year. Other meetings may be held at the call of the president or upon the written request of two members at the time and place as designated in the call or request.

(m) Prior to commencing his or her duties as a member of the board, each member shall take and subscribe to the oath required by section five, article four of the Constitution of this state.

§30-8-5. Powers and duties of the board.

(a) The board has all the powers and duties set forth in this article, by rule, in article one of this chapter and elsewhere in law.

(b) The board shall:

(1) Hold meetings, conduct hearings and administer examinations;

(2) Establish requirements for licenses, certificates and permits;

(3) Establish procedures for submitting, approving and rejecting applications for licenses, certificates and permits;

(4) Determine the qualifications of any applicant for licenses, certificates and permits;

(5) Prepare, conduct, administer and grade examinations for licenses;

(6) Determine the passing grade for the examinations;

(7) Maintain records of the examinations by the board or a third party administer, including the number of persons taking the examinations and the pass and fail rate;

(8) Hire, discharge, establish the job requirements and fix the compensation of the executive secretary;

(9) Maintain an office and hire, discharge, establish the job requirements and fix the compensation of employees, investigators and contracted employees necessary to enforce the provisions of this article;

(10) Investigate alleged violations of the provisions of this article, legislative rules, orders and final decisions of the board;

(11) Conduct disciplinary hearings of persons regulated by the board;

(12) Determine disciplinary action and issue orders;

(13) Institute appropriate legal action for the enforcement of the provisions of this article;

(14) Maintain an accurate registry of names and addresses of all licensees regulated by the board;

(15) Keep accurate and complete records of its proceedings, and certify the same as may be necessary and appropriate;

(16) Establish the continuing education requirements for licensees;

(17) Issue, renew, combine, deny, suspend, revoke or reinstate licenses, certificates and permits;

(18) Establish a fee schedule;

(19) Propose rules in accordance with the provisions of article three, chapter twenty-nine-a of this code to implement the provisions of this article; and

(20) Take all other actions necessary and proper to effectuate the purposes of this article.

(c) The board may:

(1) Contract with third parties to administer the examinations required under the provisions of this article;

(2) Sue and be sued in its official name as an agency of this state; and

(3) Confer with the Attorney General or his or her assistant in connection with legal matters and questions.

§30-8-5a.

Repealed.

Acts, 2010 Reg. Sess., Ch. 152.

§30-8-6. Rulemaking.

(a) The board shall propose rules for legislative approval, in accordance with the provisions of article three, chapter twenty-nine-a of this code, to implement the provisions of this article, including:

(1) Standards and requirements for licenses, certificates and permits;

(2) Procedures for examinations and reexaminations;

(3) Requirements for third parties to prepare and/or administer examinations and reexaminations;

(4) Educational and experience requirements;

(5) The passing grade on the examinations;

(6) Standards for approval of courses and curriculum;

(7) Procedures for the issuance and renewal of licenses, certificates and permits;

(8) A fee schedule;

(9) A prescription drug formulary classifying those categories of oral drugs rational to the diagnosis and treatment of visual defects or abnormal conditions of the human eye and its appendages, which may be prescribed by licensees from Schedules III, IV and V of the Uniform Controlled Substances Act. The drug formulary may also include oral antibiotics, oral nonsteroidal anti-inflammatory drugs and oral carbonic anhydrase inhibitors;

(10) Requirements for prescribing and dispensing contact lenses that contain and deliver

pharmaceutical agents that have been approved by the Food and Drug Administration as a drug;

(11) Continuing education requirements for licensees;

(12) The procedures for denying, suspending, revoking, reinstating or limiting the practice of licensees, certificate holders and permittees;

(13) Requirements for inactive or revoked licenses, certificates or permits;

(14) Requirements for an expanded scope of practice for those procedures that are taught at fifty percent of all accredited optometry schools; and

(15) Any other rules necessary to effectuate the provisions of this article.

(b) All of the board's rules in effect on July 1, 2010, shall remain in effect until they are amended or repealed, and references to provisions of former enactments of this article are interpreted to mean provisions of this article.

(c) The board shall promulgate procedural and interpretive rules in accordance with section eight, article three, chapter twenty-nine-a of this code.

§30-8-7. Fees; special revenue account; administrative fines.

(a) All fees and other moneys, except administrative fines, received by the board shall be deposited in a separate special revenue fund in the State Treasury designated the "West Virginia Board of Optometry Fund", which is continued. The fund is used by the board for the administration of this article. Except as may be provided in article one of this chapter, the board retains the amount in the special revenue account from year to year. No compensation or expense incurred under this article is a charge against the General Revenue Fund.

(b) Any amount received as fines, imposed pursuant to this article, shall be deposited into the General Revenue Fund of the State Treasury.

§30-8-8. License to practice optometry.

(a) To be eligible for a license to engage in the practice of optometry, the applicant must:

- (1) Be at least twenty-one years of age;
- (2) Be of good moral character;

(3) Graduate from a school approved by the Accreditation Council on Optometric Education or successor organization;

(4) Pass an examination prescribed by the board;

(5) Complete an interview with the board;

(6) Not be addicted to the use of alcohol, drugs or other controlled substances;

(7) Not have been convicted of a felony in any jurisdiction within ten years preceding the date of application for license, which conviction has not been reversed; and

(8) Not have been convicted of a misdemeanor or felony in any jurisdiction if the offense for which he or she was convicted related to the practice of optometry, which conviction has not been reversed.

(b) A registration to practice issued by the board prior to July 1, 2010, shall for all purposes be considered a license issued under this article: Provided, That a person holding a registration issued prior to July 1, 2010, must renew pursuant to the provisions of this article.

§30-8-9. Scope of practice.

(a) A licensee may:

(1) Examine, diagnose and treat diseases and conditions of the human eye and its appendage within the scope established in this article or associated rules;

(2) Administer or prescribe any drug for topical application to the anterior segment of the human eye for use in the examination, diagnosis or treatment of diseases and conditions of the human eye and its appendages: Provided, That the licensee has first obtained a certificate;

(3)(A) Administer or prescribe any drug from the drug formulary, as established by the board pursuant to section six of this article, for use in the examination, diagnosis or treatment of diseases and conditions of the human eye and its appendages: Provided, That the licensee has first obtained a certificate;

(B) New drugs and new drug indications may be added to the drug formulary by approval of the board;

(4) Administer epinephrine by injection to treat emergency cases of anaphylaxis or anaphylactic shock;

(5) Prescribe and dispense contact lenses that contain and deliver pharmaceutical agents and that have been approved by the Food and Drug Administration as a drug;

(6) Prescribe, fit, apply, replace, duplicate or alter lenses, prisms, contact lenses, orthoptics, vision training, vision rehabilitation;

(7) Perform the following procedures:

(A) Remove a foreign body from the ocular surface and adnexa utilizing a nonintrusive method;

(B) Remove a foreign body, external eye, conjunctival, superficial, using topical anesthesia;

(C) Remove embedded foreign bodies or concretions from conjunctiva, using topical anesthesia, not involving sclera;

(D) Remove corneal foreign body not through to the second layer of the cornea using topical anesthesia;

(E) Epilation of lashes by forceps;

(F) Closure of punctum by plug; and

(G) Dilation of the lacrimal puncta with or without irrigation;

(8) Furnish or provide any prosthetic device to correct or relieve any defects or abnormal conditions of the human eye and its appendages;

(9) Order laboratory tests rational to the examination, diagnosis, and treatment of a disease or condition of the human eye and its appendages;

(10) Use a diagnostic laser; and

(11) A licensee is also permitted to perform those procedures authorized by the board prior to January 1, 2010.

(b) A licensee may not:

(1) Perform surgery except as provided in this article or by legislative rule;

(2) Use a therapeutic laser;

(3) Use Schedule II controlled substances. However, an oral pharmaceutical certified licensee may prescribe hydrocodone and hydrocodone containing drugs for a duration of no more than three days;

(4) Treat systemic disease; or

(5) Present to the public that he or she is a specialist in surgery of the eye.

§30-8-10. Exceptions from licensure.

The following persons are exempt from licensure under this article:

(1) Persons licensed to practice medicine and surgery under article three of this chapter or osteopathy under article fourteen of this chapter; and

(2) Persons and business entities who sell or manufacture ocular devices in a permanently established place of business, who neither practice nor attempt to practice optometry.

§30-8-11. Issuance of license; renewal of license; renewal fee.

(a) A licensee shall annually or biennially on or before July 1, renew his or her license by completing a form prescribed by the board, paying the renewal fee and submitting any other information required by the board.

(b) The board shall charge a fee for renewal of a license, and a late fee for any renewal not paid by the due date.

(c) The board shall require as a condition of renewal of a license that each licensee complete

continuing education.

(d) The board may deny an application for renewal for any reason which would justify the denial of an original application for a license.

§30-8-12. Temporary permits.

(a) Upon proper application and the payment of a fee, the board may issue, without examination, a temporary permit to engage in the practice of optometry in this state.

(b) If the permittee receives a passing score on the examination, a temporary permit expires thirty days after the permittee receives the results of the examination.

(c) If the permittee receives a failing score on the examination, the temporary permit expires immediately.

(d) An applicant under this subsection may only be issued one temporary permit. Upon the expiration of a temporary permit, a person may not practice as an optometrist until he or she is fully licensed under the provisions of this article. In no event may a permittee practice on a temporary permit beyond a period of ninety consecutive days.

(e) A temporary permittee under this section shall work under the supervision of a licensee, with the scope of such supervision to be defined by the board by legislative rule.

§30-8-13. License from another jurisdiction; license to practice in this state.

(a) The board may issue a license to practice to an applicant of good moral character who holds a valid license or other authorization to practice optometry from another jurisdiction, if the applicant demonstrates that he or she:

(1) Holds a license or other authorization to practice optometry in another state which requirements are substantially equivalent to those required in this state;

(2) Does not have charges pending against his or her license or other authorization to practice, and has never had a license or other authorization to practice revoked;

(3) Has not previously failed an examination for professional licensure in this state;

- (4) Has paid the applicable fee;
- (5) Has passed the examination prescribed by the board; and
- (6) Has fulfilled any other requirement specified by the board.

(b) In its discretion, the board may interview and examine an applicant for licensing under this section. The board may enter into agreements for reciprocal licensing with other jurisdictions having substantially similar requirements for licensure.

§30-8-14. Prescriptive authority.

(a) A licensee may prescribe: (1) Topical pharmaceutical agents; (2) oral pharmaceutical

agents that are included in the drug formulary established by the board pursuant to section six of this article or new drugs or new drug indications added by a decision of the board; and (3) contact lenses that contain and deliver pharmaceutical agents that have been approved by the Food and Drug Administration as a drug.

- (b) An applicant must:
- (1) Submit a completed application;
- (2) Pay the appropriate fee;
- (3) Show proof of current liability insurance coverage;
- (4) Complete the board required training;
- (5) Pass an examination; and
- (6) Complete any other criteria the board may establish by rule.

§30-8-15. Administration of injectable pharmaceutical agents.

(a) A licensee may not administer pharmaceutical agents by injection, other than epinephrine to treat emergency cases of anaphylaxis or anaphylactic shock, unless the provisions of this section, along with any legislative rule promulgated pursuant to this section, have been met.

(b) Additional pharmaceutical agents by injection may be included in the rules for legislative approval in accordance with the provisions of article three, chapter twenty-nine-a of this code. These rules shall provide, at a minimum, for the following:

(1) Establishment of a course, or provide a list of approved courses, in administration of pharmaceutical agents by injection;

(2) Definitive treatment guidelines which shall include, but not be limited to, appropriate observation for an adverse reaction of an individual following the administration of a pharmaceutical agent by injection;

(3) A requirement that a licensee shall have completed a board approved injectable administration course and completed an American Red Cross or American Heart Association basic life-support training, and maintain certification in the same;

(4) Continuing education requirements for this area of practice;

(5) Reporting requirements for licensees administering pharmaceutical agents by injection to report to the primary care physician or other licensed health care provider as identified by the person receiving the pharmaceutical agent by injection;

(6) Reporting requirements for licensees administering pharmaceutical agents by injection to report to the appropriate entities;

(7) That a licensee may not delegate the authority to administer pharmaceutical agents by injection to any other person; and

(8) Any other provisions necessary to implement the provisions of this section.

(c) In no event may a licensee be granted authority under this section to administer a pharmaceutical agent by injection directly into the globe of the eye.

§30-8-16. Special volunteer license; civil immunity for voluntary services rendered to indigents.

(a) There is established a special volunteer license for optometrists who are retired or are retiring from the active practice of optometry and wish to donate their expertise for the care and treatment of indigent and needy patients in the clinical setting of clinics organized, in whole or in part, for the delivery of health care services without charge.

(b) The special volunteer license shall be issued by the board to optometrists licensed or otherwise eligible for licensure under this article without the payment of an application fee, license fee or renewal fee, and shall be issued for the remainder of the licensing period, and renewed consistent with the boards other licensing requirements.

(c) The board shall develop application forms for the special volunteer license provided in this section which shall contain the optometrist's acknowledgment that:

(1) The optometrist's practice under the special volunteer license will be exclusively devoted to providing optometrical care to needy and indigent persons in West Virginia;

(2) The optometrist will not receive any payment or compensation, either direct or indirect, or have the expectation of any payment or compensation but may donate to the clinic the proceeds of any reimbursement, for any optometrical services rendered under the special volunteer license;

(3) The optometrist will supply any supporting documentation that the board may reasonably require; and

(4) The optometrist agrees to continue to participate in continuing education as required by the board for a special volunteer license.

(d) Any person engaged in the active practice of optometry in this state whose license is in good standing may donate their expertise for the care and treatment of indigent and needy patients pursuant to an arrangement with a clinic organized, in whole or in part, for the delivery of health care services without charge to the patient. Services rendered pursuant to an arrangement may be performed in either the office of the optometrist or the clinical setting.

(e) Any optometrist who renders any optometrical service to indigent and needy patients of a clinic organized, in whole or in part, for the delivery of health care services without charge, under a special volunteer license authorized under this section or pursuant to an arrangement with a clinic as authorized pursuant to subsection (d) of this section without payment or compensation or the expectation or promise of payment or compensation is immune from liability for any civil action arising out of any act or omission resulting from the rendering of the optometrical service at the clinic unless the act or omission was the result of the optometrist's gross negligence or willful misconduct. In order for the immunity under this subsection to apply, before the rendering of any services by the optometrist at the clinic, there must be a written agreement between the optometrist and the clinic stating that the optometrist

will provide voluntary uncompensated optometrical services under the control of the clinic to patients of the clinic before the rendering of any services by the optometrist at the clinic: Provided, That any clinic entering into such written agreement is required to maintain liability coverage of not less than \$1 million per occurrence

(f) Notwithstanding the provisions of subsection (d) of this section, a clinic organized, in whole or in part, for the delivery of health care services without charge is not relieved from imputed liability for the negligent acts of an optometrist rendering voluntary optometrical services at or for the clinic under a special volunteer license under this section or who renders such care and treatment pursuant to an arrangement with a clinic as authorized pursuant to subsection (d) of this section.

(g) For purposes of this section, "otherwise eligible for licensure" means the satisfaction of all the requirements for licensure in this article except the fee requirements.

(h) Nothing in this section may be construed as requiring the board to issue a special volunteer license to any optometrist whose license is or has been subject to any disciplinary action or to any optometrist who has surrendered a license or caused such license to lapse, expire and become invalid in lieu of having a complaint initiated or other action taken against his or her license, or who has elected to place a license in inactive status in lieu of having a complaint initiated or other action taken against his or her license.

(i) Any policy or contract of liability insurance providing coverage for liability sold, issued or delivered in this state to any optometrist covered under the provisions of this article shall be read so as to contain a provision or endorsement whereby the company issuing such policy waives or agrees not to assert as a defense on behalf of the policyholder or any beneficiary thereof, to any claim covered by the terms of such policy within the policy limits, the immunity from liability of the insured by reason of the care and treatment of needy and indigent patients by an optometrist who holds a special volunteer license or who renders such care and treatment pursuant to an arrangement with a clinic as authorized pursuant to subsection (d) of this section.

§30-8-17. Optometric business entities.

(a) Only licensees may own a business entity that practices optometry.

(b) A licensee may be employed by the business entity.

(c) A business entity shall cease to engage in the practice of optometry when it is not wholly owned by licensees: Provided, That the personal representative of a deceased shareholder shall have a period, not to exceed eighteen months from the date of such shareholder's death, to dispose of such shares.

§30-8-18. Complaints; investigations; due process procedure; grounds for disciplinary action.

(a) The board may upon its own motion based on credible information or based upon the quarterly report from the Board of Pharmacy as required by §60A-9-1 et seq. of this code shall upon the written complaint of any person cause an investigation to be made to determine whether grounds exist for disciplinary action under this article or the legislative rules of the

board.

(b) Upon initiation or receipt of the complaint, the board shall provide a copy of the complaint to the licensee, certificate holder, or permittee.

(c) After reviewing any information obtained through an investigation, the board shall determine if probable cause exists that the licensee or permittee has violated §30-8-18(g) of this code or rules promulgated pursuant to this article.

(d) Upon a finding that probable cause exists that the licensee or permittee has violated §30-8-18(g) of this code or rules promulgated pursuant to this article, the board may enter into a consent decree or hold a hearing for the suspension or revocation of the license, certificate, or permit or the imposition of sanctions against the licensee, certificate holder, or permittee. Any hearing shall be held in accordance with the provisions of this article, and the provisions of §29A-5-1 and §29A-6-1 et seq. of this code.

(e) Any member of the board or the executive secretary of the board may issue subpoenas and subpoenas duces tecum on behalf of the board to obtain testimony and documents to aid in the investigation of allegations against any person regulated by the article.

(f) Any member of the board or its executive secretary may sign a consent decree or other legal document on behalf of the board.

(g) The board may, after notice and opportunity for hearing, deny or refuse to renew, suspend, or revoke the license, certificate, or permit of, impose probationary conditions upon or take disciplinary action against, any licensee, certificate holder, or permittee for any of the following reasons once a violation has been proven by a preponderance of the evidence:

(1) Obtaining a license, certificate, or permit by fraud, misrepresentation or concealment of material facts;

(2) Being convicted of a felony or other crime involving moral turpitude;

(3) Being guilty of unprofessional conduct which placed the public at risk;

(4) Intentional violation of a lawful order;

(5) Having had an authorization to practice optometry revoked, suspended, other disciplinary action taken, by the proper authorities of another jurisdiction;

(6) Having had an application to practice optometry denied by the proper authorities of another jurisdiction;

(7) Exceeded the scope of practice of optometry;

(8) Aiding or abetting unlicensed practice;

(9) Engaging in an act while acting in a professional capacity which has endangered or is likely to endanger the health, welfare, or safety of the public; or

(10) False and deceptive advertising; this includes, but is not limited to, the following:

(A) Advertising "free examination of eyes", or words of similar import and meaning; or

(B) Advertising frames or mountings for glasses, contact lenses, or other optical devices which does not accurately describe the same in all its component parts.

(h) For the purposes of §30-8-18(g) of this code disciplinary action may include:

(1) Reprimand;

(2) Probation;

(3) Administrative fine, not to exceed \$1,000 per day per violation;

(4) Mandatory attendance at continuing education seminars or other training;

(5) Practicing under supervision or other restriction;

(6) Requiring the licensee or certificate holders to report to the board for periodic interviews for a specified period of time; or

(7) Other corrective action considered by the board to be necessary to protect the public, including advising other parties whose legitimate interests may be at risk.

§30-8-19. Procedures for hearing; right of appeal.

(a) Hearings shall be governed by the provisions of section eight, article one of this chapter.

(b) The board may conduct the hearing or elect to have an administrative law judge conduct the hearing.

(c) If the hearing is conducted by an administrative law judge, at the conclusion of a hearing he or she shall prepare a proposed written order containing findings of fact and conclusions of law. The proposed order may contain proposed disciplinary actions if the board so directs. The board may accept, reject or modify the decision of the administrative law judge.

(d) Any member or the executive secretary of the board has the authority to administer oaths, examine any person under oath and issue subpoenas and subpoenas duces tecum.

(e) If, after a hearing, the board determines the licensee, certificate holder or permittee has violated the provisions of this article or the board's legislative rules, a formal written decision shall be prepared which contains findings of fact, conclusions of law and a specific description of the disciplinary actions imposed.

§30-8-20. Judicial review.

Any licensee, certificate holder or permittee adversely affected by a decision of the board entered after a hearing may obtain judicial review of the decision in accordance with section four, article five, chapter twenty-nine-a of this code, and may appeal any ruling resulting from judicial review in accordance with article six, chapter twenty-nine-a of this code.

§30-8-21. Criminal proceedings; penalties.

(a) When, as a result of an investigation under this article or otherwise, the board has reason to believe that a licensee, certificate holder or permittee has committed a criminal offense under this article, the board may bring its information to the attention of an appropriate law-enforcement official.

(b) A person violating section one of this article is guilty of a misdemeanor and, upon conviction thereof, shall be fined not less than \$1,000 nor more than \$5,000 or confined in jail not more than six months, or both fined and confined.

§30-8-22. Single act evidence of practice.

In any action brought or in any proceeding initiated under this article, evidence of the commission of a single act prohibited by this article is sufficient to justify a penalty, injunction, restraining order or conviction without evidence of a general course of conduct.

Materials for Item No. 9 re

- Relevant law
- Taxation letter from Dr. Stephanie Lee

Item 9 Relevant law

NRS 372.055 "Retailer" defined.

3. A licensed optometrist . . . is a consumer of, and shall not be considered, a retailer within the provisions of this chapter, with respect to the ophthalmic materials used or furnished by him in the performance of his professional services in the diagnosis, treatment or correction of conditions of the human eye, including the adaptation of lenses or frames for the aid thereof.

(Prior existing) NAC 372.320(2)

2. The tax applies to the entire charge made by a dispensing optician for eyeglasses and related products furnished in filling a prescription of an ... optometrist.

(Presently existing) NAC 372.320 Oculists, optometrists and dispensing opticians. (NRS 360.090, 372.055, 372.725)

1. Oculists and optometrists are the consumers of ophthalmic materials including eyeglasses, frames and lenses used or furnished in the performance of their professional services in the diagnosis, treatment or correction of conditions of the human eye. The tax applies to the sale of the materials to oculists and optometrists.

2. The tax applies to the entire charge made by a dispensing optician for eyeglasses and related products furnished in filling a prescription.

(Proposed via R043-24I) NAC 372.320

2. The tax applies to the entire charge made by a dispensing optician for eyeglasses and related products furnished in filling a prescription, *whether the dispensing optician is licensed or not*.

NAC 360.190 (any person may petition for an advisory opinion concerning matters within the jurisdiction of the Department [of Taxation] or [Nevada Tax] Commission. . . . All petitions must be in writing, be addressed to the Director and set forth at least the following: (a) A statement that an advisory opinion is requested; (b) A succinct statement of all the facts and circumstances necessary to dispose of the petition; (c) A clear, simple statement of the issue or question to be resolved; (d) A statement of all statutes, rules, agency decisions or other authorities which the petitioner believes may be relevant in disposing of the petition; and (e) A statement with supporting arguments and authorities of the petitioner's opinion of a proper disposition of the petition.") May 13, 2024

Dear Sirs:

I am writing to you in concern with the recent interpretation of NAC 372.320:

NAC 372.320 Oculists, optometrists and dispensing opticians. (NRS 360.090, 372.055, 372.725)

1. Oculists and optometrists are the consumers of ophthalmic materials including eyeglasses, frames and lenses used or furnished in the performance of their professional services in the diagnosis, treatment or correction of conditions of the human eye. The tax applies to the sale of the materials to oculists and optometrists.

2. The tax applies to the entire charge made by a dispensing optician for eyeglasses and related products furnished in filling a prescription.

[Tax Comm'n, Combined Sales and Use Tax Ruling No. 10, eff. 3-1-68]

Definitions;

Oculist_Ophthalmologist.or.Optometrists; a.person.skilled.in.testing.for.defects.of.vision.in.order.to.prescribe. corrective.glasses;

Dispensing.Optician_a person qualified and licensed to fit and supply eyeglasses

I have been in the optometric industry since 1985 here in Las Vegas. I started as an assistant/optician in 1985. I graduated from Optometry school in 1992 with my doctorate. I have worked in multiple settings, including the HMO (Sierra Health Services), Commercial/ Retail (Lenscrafters and Walmart), and eventually in a group private practice. I feel the need to express my concern over the recent interpretation of NAC 372.320.

There is a clear delineation of professions between an Oculist, Optometrist and a dispensing optician. Each of the professions are separate in their education, training and licensing. We work together in referring to each other for our expertise for the benefit of the patients and the public. This has worked in our state for decades, and I see that from NAC 372.320 which went into effect on 3-1-1968.

Oculists and Optometrists are medical professionals and have been deemed consumers of ophthalmic materials as clearly indicated in NRS 372.055 section 3. We use these related materials to help diagnose, treat or correct conditions of the human eye. We create customized prescriptions for our patients. We do that within our licensed practices with the aid of our clinical staff. These employees are under our supervision, direction and control. Our staff cannot create anything without the optometrists being responsible. So our optical staff are not licensed

opticians, they are staff trained by optometrists to work in fulfilling the prescriptions we, optometrists, create.

Dispensing opticians are a separate licensing as they exist with the Nevada State Board of Dispensing Opticians. These opticians are licensed by the state to provide the ability to fill or create a prescription lens or glasses under their own will, without the guidance or supervision of an Optometrist or Ophthalmologist. These professionals have been trained and educated in their field such as a pharmacist is in their expertise. These professionals can operate their own businesses or work for other corporations, such as Lenscrafters, Pearle Vision, or Walmarts.

The Nevada legislators of our past had the wisdom to understand the differences in our professions and as such created NAC 372.320.

Section 1, explains that Oculists and Optometrists are consumers of the materials so we have a Use tax that applies to materials oculist and optometrists use.

Section 2, explains the tax that is applied to the entire sales made by a dispensing optician.

It is for this reasoning that my concern was raised by the recent interpretation of NAC 372.320. There should not be a sales tax applied to prescriptions created in Oculists or Optometrists offices.

Thank you for your consideration,

Stephanie Lee, OD

Materials for Item No. 11 re

- Letter of concern (redacted)
- Letter from Nutile Law (redacted)

NEVADA STATE BOARD OF OPTOMETRY



MARIAH SMITH, O.D. Board President

JULIE C. ALAMO-LEON, O.D. Board Member Post Office Box 1824 Carson City, Nevada 89702 Telephone: (775) 883-8367 Facsimile: (775) 305-0105 E-Mail: <u>admin@nvoptometry.org</u>

> ADAM SCHNEIDER, ESQ. Executive Director

JEFFREY AUSTIN, O.D. Board Member

DREW JOHNSON Public Board Member

May 13, 2024

via email only

Re: NSBO Complaint# 24-13

Dear Dr. - the below are draft Minutes of the Board's April 25, 2024 meeting. This draft will be presented to the Board for approval at its next meeting on May 30, 2024 and are provided herein as a courtesy update to you on the status of Complaint 24-13:

Action Item 16. Complaint 24-13. Director Schneider read a statement in the record:

NRS 636.310)(3) authorizes the Executive Director to notify the Board of an investigation for further consideration by the Board if deemed necessary by the Board after an investigation.

This public complaint submitted on or about April 15, 2024 is being presented in a double-blind manner, i.e., the Board is not being told during the course of this agenda item who the complainant is or who the subject licensee is.

The materials associated with this agenda item are redacted to eliminate any identification of party identities, gender, locality, whether the practice is commercial or private, or whether the licensee is new to Nevada or not.

I am requesting the Board not ask any questions of me about such information as this is immaterial to the Board's evaluation of the allegations, the licensee's response and the licensee's submitted documents in support of the response. As I have made the licensee aware telephonically on April 22nd and in writing on April 16, the purpose of this double-blind presentation is to afford the licensee due process and avoid any undue influence upon the Board by mere virtue of who the complainant may or may not be or who the licensee may or may not be, and in order to balance the statutory directives of protecting the public while balancing the licensee's due process rights. The allegations regard an advertisement for free examinations at the licensee's then-future primary practice location. It is the licensee's then-future location because the licensee has since retracted the location as the primary location in light of the business's advertisement.

Both the optical business and the licensee separately state that the licensee did not know about advertisement and the optical business has stated that all responsibility lies with it and not the licensee.

The licensee acknowledges her knowledge that advertisements for free services are illegal within Nevada optometry laws. The licensee has since confirmed that not only has the original post been taken down, but the posts which the optical business controls have been taken down and no longer exists on social media according to her and her counsel.

I will now ask the Board to deliberate and discuss what it wants to do next in this matter. Options available to the Board include closure of the investigation, issuance of a letter of concern then closing the investigation, authorization of the Executive Director to issue additional subpoenas and/or request a supplemental response from the licensee, or request that the Attorney General's office pursue a formal complaint against the licensee and prosecute the matter as provided under NRS 636.325. If the Board votes for authorizing a formal complaint, which the Executive Director is not advocating for one way or another, it will be up to the Attorney General's Office to apply laws to facts and decide what specific charges should be included in the formal complaint.

Dr. Smith noted the licensee made a good faith effort in complying with the investigation. The issue is if the optical business is advertising for the optometrist to perform free examinations, this suggests that the optometrist would be paid by the optical business. The materials produced thus far do not answer those questions. Dr. Smith commented that under the circumstances there may be a contract between the licensee and the optical business. Colloquy and agreement for a letter of concern and to request the contract, particularly when the licensee may be associating with the optical business in the future. Such concerns include is the licensee an actual independent contractor, how the licensee had planned on being paid, and this investigation remains open. Dr. Smith moved for a letter of concern and to request a copy of the executed contract be provided presuming the licensee executed one, and no formal hearing at this point in time. Dr. Austin seconded. Motion passed unanimously. DAG Weiss noted disciplinary action for a contract that never occurred and was essentially only an idea would be difficult to be actionable.

Pursuant to the above, please consider this to be that letter of concern and the Board's request for your executed contract or written agreement with as we have already discussed telephonically on April 25, 2024. Please supply to <u>director@nvoptometry.org</u> by end of business May 20, 2024. In light of the Board's next meeting being May 30, 2024, this deadline will not be extended/continued. The contract will be presented to the Board in a double-blind manner on May 30, 2024, i.e., the Board is not being told your identity or 's identity. Moreover, the materials associated with the presentation will be redacted to eliminate any identification of party identities, gender, locality, whether the practice is commercial or private, or whether the licensee is new to Nevada or not, etc. The Board will assess and determine next steps, if any.

Respectfully,

/s/ Adam Schneider Adam Schneider, Esq. Executive Director



Maria Nutile, Esq.* Bridget Kelly, Esq. **

* licensed in NV, AZ and CO ** licensed in NV and AZ

May 20, 2024

VIA EMAIL director@nvoptometry.org

Adam Schneider, Esq. Executive Director Nevada State Board of Optometry P.O. Box 1824 Carson City, NV 89702

Re: NSBO Complaint #24-13 **.** 0.D.

Dear Mr. Schneider:

This firm represents Dr. ("Licensee"). In that regard, we write in response to your letter of concern dated May 13, 2024 ("Letter") relating continuing concerns of the Nevada State Board of Optometry ("Board") as to Licensee's association with the business of a nonlicensee ("Business"). Specifically, the Board questions how the Licensee *would have been* compensated *if* Licensee had performed the free eye exams advertised (without Licensee's knowledge or consent) by the Business. The Board has also requested a copy of the contract between Licensee and the Business, under the belief that the potential for Licensee's future association with the Business remains open.

As detailed below, Licensee assures the Board there is no current association between Licensee and the Business whatsoever, nor will there be in the future. In light of that, and the fact that the contract between Licensee and the Business was rescinded prior to its effective date, Licensee respectfully declines to provide a copy of the contract at this time.

Licensee's practice goals and ideals have been focused on providing optometry services to underserved populations. Licensee had previously started a mobile practice to bring much-needed services to those unable to travel for examinations and fittings, such as seniors and prisoners. After much effort, Licensee was was forced to give up that practice due to closed payor contract panels and the resulting financial hardship. In seeking alternate practice opportunities (and income), Licensee had initially believed the Business would be a good fit because their focus would be underserviced, financially challenged populations. Unfortunately, Licensee had not sought legal

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A. Schneider, Esq. May 20, 2024 Page 2

counsel with regard to the Business opportunity, due to limited financial resources after closing the mobile practice.

Licensee was greatly dismayed to learn that the Business had advertised free eye exams at the future practice location without Licensee's knowledge. It quickly became clear to Licensee that the Business structure had not been vetted. Licensee immediately cancelled/rescinded the contract with the Business (due to be effective on May 1, 2024) on or about April 16, 2024. Licensee has decided to move on and cut all ties with the Business, and has no intention of renewing negotiations with them in the future. Licensee has been pursuing other opportunities, and as of this writing is considering a firm independent contractor offer from a licensee-owned optometry practice, while Licensee continues working with the prison system.

With regard to the Board's request for a copy of the Licensee's executed contract or written agreement with the Business, Licensee respectfully declines that request at this time. As discussed above, the contract was rescinded before it started. Licensee never provided any professional services in association with the Business, and is actively pursuing other endeavors. We would prefer not to waste the Board's valuable time to review a contract which has no legal force or effect.

Should you have any questions, I may be reached at 702.307.4871.

Sincerely,

NUTILE LAW

Bridget Kelly

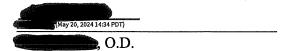
Bridget Kelly, Esq.

cc: Maria Nutile, Esq.

A. Schneider, Esq. May 20, 2024 Page 3

Response to Letter of Concern, NSBO Complaint #24-13

Read and approved by:



Materials for Item No. 12 re

• Draft letter to Opticians Board

NEVADA STATE BOARD OF OPTOMETRY



MARIAH SMITH, O.D. Board President

JULIE C. ALAMO-LEON, O.D. Board Member Post Office Box 1824 Carson City, Nevada 89702 Telephone: (775) 883-8367 Facsimile: (775) 305-0105 E-Mail: <u>admin@nvoptometry.org</u>

ADAM SCHNEIDER, ESQ. Executive Director JEFFREY AUSTIN, O.D. Board Member

DREW JOHNSON Public Board Member

May 30, 2024

NV Board of Dispensing Opticians 4790 Caughlin Pkwy. #241 Reno, NV 89519 <u>Info@nvopticians.org</u> *via email only*

Dear Nevada Board of Dispensing Opticians:

This Board is in receipt of your questions and multiple subparts generally regarding optometric telehealth and non-optometrists' employment of optometrists. This Board has conferred and offers the following responses. As an opening salvo to these questions:

1) AB 432(19) needs to be read in whole, and not in individual parts;

2) nothing in AB 432 abrogates already existing NRS 636 or already existing NAC 636 inclusive of R066-19;

3) the idiom of "better to ask for forgiveness than permission" does not apply to this Board when a licensee engages in unprofessional conduct or violates Nevada optometry laws. A licensee's adherence to Nevada optometry law is always expected and a condition of maintaining their license. Violations arising to the level of unprofessional conduct as defined in NRS 636 will be investigated and pursued; and

4) the questions' scenarios tend to be too vague to answer with true specificity. The Board nonetheless will attempt to answer these in furtherance of a good faith collaboration between our Boards. This is particularly true when our Boards may potentially encounter the same issues of telemedicine misuse and abuse, and improper non-separation of optometry clinics from non-optometry businesses. a. Section 19(9)(a) prohibits issuing prescriptions unless the optometrist performs a synchronous manifest refraction, but are there any requirements that the optometrist see patients in person at some point, or is a synchronous eye exam seen as comparable to an in-person comprehensive eye exam?

It first needs to be emphasized that AB 432(19)(9) regards practicing to the standard of care. Section 19(9)(a) prohibits the licensee from violating the standard of care as if the presentation was an in-person examination. Section 19(9)(b) prohibits conditioning the provision of optometric telemedicine with a standard of care below that required in 19(9)(a).

The question mentions a synchronous manifest refraction. "Manifest" does not exist within the text of 19(9), but "refraction" in the form of "auto-refraction" does in 19(9)(a)(3). Licensees should not think or presume that manifest refractions are somehow unnecessary when engaging in synchronous optometric telemedicine examinations to obtain a proper vision prescription under the standard of care. A comprehensive eye examination has to be done in person, and synchronous telehealth would be for non-comprehensive exams where the doctor has seen the patient in the past two years and has access to the records of a comprehensive exam in the prior two years. An example would be obtaining an update on a contact lens fit to then order the contacts. Note that a Nevada Administrative Code ("NAC") for 19(9)(a) has been proposed through the workshop process, which LCB is processing as "R101-24." This proposed NAC states that the issuance of a prescription for an ophthalmic lens cannot occur without the licensee performing a synchronous manifest refraction.

The question does not specify if the licensee has completed a comprehensive exam on the patient within the immediately preceding 2 years. Section 19(2) prohibits a licensee's synchronous optometric telemedicine upon a patient unless the same licensee completed a comprehensive examination upon the patient in-person within the immediately preceding 2 years. R101-24 includes an NAC for 19(2) that no synchronous optometric telemedicine can be conducted unless the licensee has access to the patient's records and contemporaneously reviews such records.

Note that asynchronous optometric telemedicine as described in Section 19(4) is not allowed in this context of an *examination*, when asynchronous is only for purposes of a *consult*. An example of the latter is when an OD is requested by a different provider to look at a retinal photo, and which is not allowed to make a diagnosis or treatment plan.

The question does not specify if the presentation is for a new patient or for a comprehensive exam. 19(2) places strictures on licensees from practicing optometric telemedicine to examine patients without satisfying certain requirements first. 19(3) bears in mind 19(2), and then only allows synchronous optometric telemedicine for *non-comprehensive* examinations of *new* patients if the licensee has access to all of the information from a comprehensive exam in the immediately preceding 2 years of an optometrist (herein "OD") or an ophthalmologist (herein "OMD").

Because 19(3) only mentions non-comprehensive examinations via synchronous optometric telemedicine, 19(3) does not allow for comprehensive examinations via synchronous

optometric telemedicine. R101-24 includes an NAC for 19(3) that "access" includes the act of reviewing such information prior to or contemporaneous with the examination, and that nothing in 19(3) is meant to prevent a licensee from providing care to a patient whom is already an existing patient within the licensee's practice group of the immediately preceding two years.

b. Section 19(9)(3) prohibits the issuance of a prescription based solely upon an auto refraction, but is that prohibition applicable only when the optometrist is practicing telemedicine?

Prescribing solely off of autorefraction or manifest autorefraction, is not consistent with the standard of care, be it in-person or via optometric telemedicine.

Is it allowable for optometrists to issue prescriptions based upon auto refractions performed at an in-person exam?

We presume the phrase of "based upon" means "solely based upon." Therefore see above.

Are there any restrictions on this practice?

See above.

c. Section 18 allows an optometrist to provide treatment via synchronous telemedicine without performing a comprehensive exam within the prior 2 years, *only if the doctor is taking over the treatment of the patient from another doctor and has access to the patient records provided directly by the former doctor.* Is this interpretation correct?

This question is a misreading of Section 18. Section 18 is not part of Section 19 (the optometric telemedicine section), does not mention synchronous telemedicine, and makes no mention if the records have to be provided directly from an OD or OMD to another OD. Section 18 does not prohibit a patient from providing his or her records of a comprehensive examination to the OD directly. Nor is there any prohibition of OD A filling a valid and current prescription made by OD B.

Section 18 speaks to prescriptions, i.e., Section 18 prohibits the issuing, offering to issue, duplicating or extending of an ophthalmic lens for a person if the licensee has not performed a comprehensive examination of the patient, or does not have access to the complete results of the comprehensive examination that was performed on the person within in the immediately preceding 2 years. R101-24 includes an NAC for Section 18 that the intent of this section allows the originating licensee or licensee within the originating licensee's practice group in extenuating circumstances to issue, offer to issue, duplicate, or extend a prescription for the patient of the originating licensee or the originating licensee's practice group within the immediately preceding two years.

Ala Section 19(2) and (3) as described above, synchronous telemedicine is allowable only if the licensee first has from the immediately preceding 2 years comprehensive examination records or all information from the prior comprehensive examination.

What if the patient provides their own copies of their records to the new doctor (i.e. when a patient switches to a different practice)?

19(2) prohibits the new OD from practicing either kind of optometric telemedicine for examinations unless that new OD had completed a comprehensive examination of the patient within the immediately preceding 2 years.

19(3) allows for synchronous telemedicine for non-comprehensive examinations of new patients if the licensee has all the information from a comprehensive examination within the immediately preceding 2 years conducted by an OD or OMD. As already stated in response to question "a," R101-24 includes an NAC for 19(3) that "access" includes the act of reviewing such information prior to or contemporaneous with the examination, and that nothing in 19(3) is meant to prevent a licensee from providing care to a patient whom is already an existing patient within the licensee's practice group of the immediately preceding two years.

d. If a doctor takes over or joins the practice of another doctor, the new doctor may in that case duplicate or reissue prescriptions issued by the prior doctor. Is this interpretation correct?

See question "c" and the answer's first paragraph.

Again, what if the patient provides their own former records to the new doctor after moving from one practice to another?

If this is in reference to optometric telemedicine, no. Section 19(2) prohibits the licensee from performing such an exam unless the licensee performed a comprehensive examination of the patient within the immediately preceding two years.

If this is in reference to an in-person presentation and presuming such records are from a comprehensive examination within the immediately preceding 2 years, yes.

NRS 636.027 states the chapter does not apply to physicians and surgeons duly licensed to practice in this State.

Correct, that's an accurate summary of NRS 636.027(2).

Are there any restrictions on physicians in this state performing optometry at a practice owned by an optometrist (i.e. may a doctor licensed by the Board of Medical Examiners fill in at an optometrist's practice);

Yes, there are restrictions in the sense that MDs and DOs are not ODs, and therefore are not licensed to practice optometry in Nevada absent having an NV OD license. That said, an OMD can perform all of the duties of an optometrist, but must practice with a current *medical* license issued from the Nevada State Board of Medical Examiners at that location. But those acts would be classified as the practice of medicine under NRS 630 or NRS 633, and not

NRS 636. For example, fitting contact lenses is an act of optometry but NRS 636.387 recognizes that an OMD can do so.

As to whether an MD or DO can fill in at an optometrist's practice, NRS 636.373(5) prohibits an OD from employing a physician. (R066-19 has the same prohibition. We are unable to provide you an NAC citation other than to say it is subsection 2 of the NAC that starts with "If an optometrist forms an association or other business relationship with a physician pursuant to NRS 636.373...")

As used in NRS 636.373(5), "employ" is not defined one way or another if it is synonymous with "independent contractor" or "IRS 1099 status." But because NRS 636.373(1) specifically states "their respective services to patients," this means that a physician's care is not synonymous with an OD's care.

NAC 636.250(2)(b) states this employment preclusion in a different way, i.e., a licensee cannot serve as an employee or independent contractor of any person who is not licensed to practice optometry, but does not prohibit as an independent contractor (not employee) with a physician as defined in NRS 363.373. This includes a prohibition of an OD being a commercial corporation employee.

The question does not specify if the doctor is, e.g., an Ob-Gyn, or hematologist, or an OMD. But ODs are allowed to collaborate with OMDs per NRS 636.374 for surgical procedures. Note this statute does not state that ODs and OMDs are interchangeable. Indeed, NRS 636.374(4)(f) requires a written statement to the patient that the practice of optometry is regulated by this Board and the practice of opthhalmology is regulated by the BME or BOM.

is there any requirement to disclose they are not licensed as an optometrist?

NRS 636.374 allows for the collaboration between an OD and OMD regarding surgical procedures. This statute lists what kind of disclosures are needed to be provided to the patient regarding the OD's care and the OMD's care.

Employees of Optometrists

3. NRS 636.025 defines acts constituting optometric practice and prohibits the use of an autorefractor or other automated testing device by an unlicensed person, *unless performed under the direct responsibility of a licensed optometrist as authorized in NRS 636.346*. NRS 636.346 does not mention refractions specifically, but does require the "direct supervision" of the optometrist for various activities and states *the doctor must conduct the final examination of the patient*:

For specificity, the above question references a portion of NRS 636.025(1)(c).

NRS 636.346 governs the supervision of authorized activities by assistants. The question states that NRS 636.346 does not mention refractions specifically. But to be clear, NRS 636.346(2)(c) allows an assistant under the direct supervision of a licensed optometrist to perform "noninvasive testing of a patient in preparation for any subjective refraction . . ."

a. How does your board interpret the term "direct supervision". Does this mean the doctor must be physically present at the place of practice to oversee staff who are performing these activities?

There may be situations that while the assistant/technician is performing various authorized activities that the OD went to his or her car for something or went to get lunch. What matters is prior to discharge, the OD conducts the final examination of the patient pursuant to NRS 636.346(3); the rationale being the OD has the opportunity to identify any inaccuracies in the assistant's preliminary work-up and ultimately the final prescription, treatment and diagnoses is the responsibility of the OD. R101-24 includes a proposed revised NAC 636.210(4) that "Consistent with NRS 636.346, the optometrist has the ultimate responsibility over any conduct, treatment, act, or omission by the optometrist's employee, technician, or assistant, and all responsibility for all care provided to the licensee's patients."

b. Does your board interpret these provisions to mean a doctor's staff member may only perform autorefractions and fit patients with trial lenses when the doctor is on site and will be conducting a final examination of the patient during the same appointment?

Per NRS 636.346(2)(a)-(e), the OD's assistant can perform more than just autorefractions or fit trial lenses under the direct supervision of the OD. But yes, what matters is the OD conducts the final examination of the patient before discharge.

NRS 636.387(2) states that an initial fitting of a contact lens must be performed by an OMD or OD licensed in Nevada. NRS 636.387(3) defines initial fitting as measuring the health, integrity and refraction error of the eye to determine whether contact lenses are appropriate for the patient. In order to do so, standard of care is the OD views the patient's contact lenses on the patient's ocular surface through a slit lamp. NAC 636.680 clarifies the specifics for a contact lens prescription.

c. If the doctor does not need to be on site for these activities, what is the purpose of allowing unlicensed persons to conduct them if only the doctor may issue a prescription?

The OD needs to perform the final examination of the patient before discharge per NRS 636.346(3).

May the doctor issue a prescription based upon information collected by staff when the doctor was not present for the exam at any point?

Not solely based upon information collected by staff. We interpret the question's phrase of "not present for the exam" to mean a complete absence of synchronous optometric telemedicine. Therefore the answer is no as the Board interprets this.

d. If the doctor may issue a prescription based upon information collected by staff, are there any restrictions on this practice, such as requiring a comprehensive eye exam and manifest refraction by the doctor at an initial appointment? Are there any restrictions on auto refractions generally, other than those mentioned in Section 19 of AB 432?

The OD can issue a prescription based upon information collected by staff, but not solely based upon information collected by staff. The OD has to conduct the final eye examination of the patient to comply with NRS 636.346(3). Implicit in NRS 636.346(3) is that the OD must do so within the standard of care.

4. NRS 636.025 prohibits an unlicensed person from representing themselves as an optometrist or advertising the services of an optometrist. Does your board interpret this law to mean a doctor's employees must disclose to a patient whether the patient will be seeing the optometrist during an appointment? The patient may be under the impression they are seeing an optometrist for an eye exam when they are only seeing an employee of the doctor who performs an autorefraction.

NRS 636.295(6) authorizes disciplinary action for "Making false or misleading representations, by or on behalf of the licensee, with respect to optometric materials or services." If a patient makes an appointment and presents to the appointment that the optometric service would be performed by a licensee but no licensee ever does, then the statute is violated. If the patient is never seen by an OD, yet the assistant during a purported comprehensive exam performs all pre-testing and generates a prescription without any direct supervision by the OD, then the examination would be illegal.

5. Similarly, Section 28 of AB 432 states that an advertisement for an optometric examination, eye examination, vision examination, eye test, or vision test must include a specific disclaimer if certain services will not be provided. Does your board interpret this provision to mean the doctor and/or doctor's employees have a duty to disclose to patients at their appointments that they will not be receiving the listed services? Again, the patient may be under the impression they are receiving a comprehensive eye exam from the doctor when they are only receiving an autorefraction performed by an employee.

The Board is unable to answer this question as written. AB 432(28) regards administrative fines. Disclaimers and advertisements are not contained anywhere in AB 432. The Board presumes the question means to refer to NAC 636.190 which has similar language as the question. R101-24 includes a NAC to be edited with nos. 1-15 being revisions or new, but with no. 16 remaining from the prior version:

1. The documentation of the primary reason for which the examination is conducted;

2. A review of the medical history and ocular history of both the patient and his or her immediate family;

- 3. A review of any medications used by the patient;
- 4. A review of any allergies of the patient;
- 5. A review of documentation identifying the patient's primary care physician;

6. General medical observations, including, without limitation, neurological and psychological orientation;

- 7. Eye pressure;
- 8. Gross, confrontation or formal visual fields;
- 9. A basic sensorimotor examination;
- 10. A complete pupillary assessment, including, without limitation, an examination of the presence of an afferent pupillary defect;
- 11. Eye alignment;
- 12. Visual acuities;
- 13. Keratometry or autokeratometry;

14. Anterior segment examination using a slit beam and magnification, as through a biomicroscope slit lamp, to include ocular adnexa, eyelid, eyelashes, conjunctiva, pupil, cornea, anterior chamber and lens;.

- 15. A manifest or subjective refraction.
- 16. A dilated fundus examination.

So yes, if a patient presents for a comprehensive examination and the above are not disclaimed and not performed, such an examination violates the law.

Two-Door Policies (Optometry and Opticianry Practices in Shared Business Spaces)

6. The minutes for the Board of Optometry's 1/29/2019 meeting detail complaints related to optometrists co-mingling operations with optical establishments owned by a large corporation. The minutes indicate your board intended to conduct an educational campaign and make regulatory changes to address the issue. Section 34 of R066-19 does address these issues, but we would like some clarification on how to deal with violations:

a. Many Nevada optometrists lease space and/or equipment from large optical retail corporations that employ opticians in the same retail space. Do you interpret your provisions to mean you have enforcement authority against corporations that pursue illegal leasing terms with Nevada optometrists (e.g. if the lease specifies the optometrist will be sharing physical space, equipment, electronic systems, or staff)? Or would enforcement action only be taken against the optometrist?

Some relevant law for your Board's review: 1) NRS 636.372 governs ODs leasing from non-ODs; 2) NAC 636.240 clarifies what the lease cannot include; 3) NAC 636.250 clarifies the specific requirements for the separation between an optometry office and other business; and 4) R066-19 has an NAC with 4 subsections which clarifies what the OD must do when forming an association or business relationship with a physician.

The Board only has jurisdiction upon licensed ODs. Any violations of OD law would be sought upon the violating OD. It is incumbent upon the NV OD to know NV OD law, to not enter into leases which violate NV OD law, and if necessary obtain legal counsel or approach the Board with an advisory opinion to ensure the lease does not violate NV OD law before entering into it.

b. If there is a report of a corporation putting pressure on an optometrist and/or the opticians who are employed by the corporation to co-mingle operations, do you interpret this as a violation of optometry law?

The Board does not regulate the profession of dispensing opticians. In fact, the only time "optician" appears in NRS 636 is in NRS 636.025(1)(b) that nothing in that paragraph is to prevent a licensed dispensing optician from engaging in the practice of ophthalmic dispensing.

NRS 636.300(2) defines unprofessional conduct as an OD accepting employment, directly or indirectly, from a person not licensed to practice optometry in furtherance of practicing optometry.

As to any non-OD corporate pressures, NRS 636.373(4) prohibits any non-OD employee or agent of any commercial or mercantile establishment from directly or indirectly controlling, dictating, or influencing the professional judgment of the practice of optometry by a licensed optometrist. It is incumbent upon the licensee to know NV OD law and standards of care, and to not violate either one. Should a complaint be brought, an OD's would-be defense of "a commercial corporation's employee or agent pressured me to violate Nevada law so I then violated Nevada law" will likely not be deemed a meritorious defense by the Board.

The Board of Opticians has some jurisdiction over optical businesses, but it does not relate to leasing agreements. Would you consider our boards as having co-jurisdiction over these complaints? If so, what do you see as the correct process for handling them?

This answer depends on the facts alleged. NRS 636.310(2) allows our Executive Director to refer the complaint to another regulatory board if the complaint relates to any matter within the jurisdiction of another regulatory board. This Board cannot speak for your Board, but obtaining a similar statute in NRS 637 could be in the best interests of the public safety from this Board's perspective. This Board encourages an open dialogue between your Board and our Executive Director when your Board knows that ODs violating NV OD laws.

7. We would also like to conduct an educational campaign for our licensees on these issues and provide them with written guidelines and information on where to direct complaints. Does your board have any interest in preparing and distributing a joint policy agreed upon by both boards?

NAC 636.650 states that the Board will consider petitions for advisory opinions relating to the applicability of any statutory provision, regulation or decision of the Board. It is this Board's understanding that its membership is well aware of the Board's capacity and willingness to address membership concerns and issue advisory opinions as to such statutes. It is the Board's understanding that conscientious and forward-thinking ODs do so routinely. Indeed, such agenda items for the Board's meetings occur nearly every time on some level. Moreover, optometry laws, particularly changes to or contemplated changes to, are the subject of multiple newsletters distributed to the membership inclusive of hyperlinks for the ease of the membership's access and review.

The Board's position is consistent with a plain reading of its public complaint statute. Where to send complaints is simple- if any person believes an optometrist is engaging in unprofessional conduct and the complainant understands his or her identify at some point will not be anonymous, the Executive Director entertains all such complaints. This Board's DAG has advised that there is nothing to allow Boards preparing a joint policy. Therefore a formal joint policy might be problematic. That said, this Board welcomes and encourages a continuing dialogue between our two Boards regarding mutually impactful topics.

Respectfully,

/s/ Adam Schneider Adam Schneider, Esq. Executive Director

Materials for Item No. 13 re

• Draft Minutes for 4/25/2024 meeting

NEVADA STATE BOARD OF OPTOMETRY



MINUTES OF PUBLIC MEETING April 25, 2024

- Action Item 1. Roll Call, Call to Order, Welcome, Introductions. President Mariah Smith, O.D. opened the live meeting at 12:03 p.m. President Smith and Board members Jeffrey Austin, O.D., Julieta Alamo-Leon, O.D, and Drew Johnson were present via Zoom. Executive Director Adam Schneider attended via Zoom. Deputy Attorney General (DAG) Todd Weiss, Esq. attended via Zoom. Pursuant to AB219, public telephonic access number 669-444-9171, meeting ID 898 7147 5470, Passcode 276684 were read into the record.
- 2. **Public Comment**. President Smith invited public comment. All Board members confirmed they had read the meeting materials in advance. The following persons expressed opposition to proposed NAC 636.670(5): Kent Wellish, M.D., Stephanie Lee, O.D., Chen Young, O.D., Jacquey Julio, O.D., and Danny Thompson.
- 3. Action Item- NAC 636.670(5) discussion and vote for submission of 1/2024 NAC Workshop results to Legislative Counsel Bureau. At Dr. Smith's invitation, Dr. Austin discussed removal of proposed NAC 636.210(1)(b) about licensees representing themselves as specialists unless approved by the Board, and instead be converted to a Board policy.

Next discussed was proposed NAC 636.670(5) about spectacle lens prescription expirations. Dr. Smith commented about the lack of submitted proof any adverse effects one way or another, that less rules tend to be better than more rules, that there have been no reports of licensees abusing the prescription length, and to keep as-is the prescription length being at the doctor's discretion.

Dr. Austin noted the 670(5) does not take away doctor discretion, but the membership feels differently and that must be taken into account. 670(5) is not anti-consumer or a burden upon healthy patients, that there have been no complaints as to prescription length based upon inquiry into past Board members over the past 20 years during their tenures. It is a well-intentioned solution, but solves a problem that does not exist nor is there any public outcry as to glasses prescription expiration lengths. There are plenty of opportunities for any patient to get glasses produced at any optician business. There is professional consensus on this, which must be taken into account. The intent was not to take away doctor discretion. Additional research into the website worldpopulation review.com showed not 29 States, but only 4 States of which Nevada is not one of those

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four, that had mandatory 2-year prescription lengths. The proposal would be of minimal help to consumers, but has high likelihood of harm to public harm. The proposal should be dropped, and left to the doctor's discretion.

Dr. Alamo-Leon concurs with Drs. Smith and Austin. It is not a public health issue in this State or other States, and that 670 as-is is the best we can obtain in Nevada.

Public Member Johnson stated Nevada law does not speak to doctors' discretion, and the proposal does not impact doctors' discretion. His initial interest in the proposal was to ensure that patients present to optometry offices for proper care, and help avoid young and healthy people looking to less effective online service for their eye care. The intent is not about taking power away from the doctors, and that it still allows doctors within their professional judgment to encourage their patients to present more often. He encouraged the membership to attend the Board's meetings more often. He disagreed with the opposition arguments that the proposal was politically motivated, when he first raised this issue in June 2020, and to counter against protectionism when the Board's interest should be in the interests of public health and safety. The markets with 2-year lengths do not have worse eye care outcomes or increased blindness. The opposition does not address that many patients have contact lenses, which those patients will present for annual examinations anyway.

Dr. Smith noted Public Member Johnson as an ethically sound and good person, and the proposal was well-intentioned. Public Member Johnson noted he intentionally did not write an op-ed or actually make it a campaign issue of his.

Dr. Austin moved to remove 210(1)(b) as an administrative code and instead make it a Board policy, and to remove 670(5) before submission of the workshop results to the Legislative Counsel Bureau. Dr. Smith seconded. Dr. Alamo-Leon voted in favor. Public Member Johnson voted in opposition. Dr. Austin noted that Public Member Johnson has been raising this issue for many years, it is not related to his political aspirations, and was well-intentioned but not the right time.

4. Action Item- Certificates of Deposit. Director Schneider noted this item comes at the urging of Public Member Johnson to help reduce operating costs of the Board and pass those savings onto the membership by lessening their dues by using FDIC-insured vehicles like certificates of deposits to help monetize the Board's cash on hand. Director Schneider reminded the Board that: 1) R066-19 section 3 says the Board has to have 13 months of operating budget at all times, which as a gross approximation is \$200,000 and that the Board has been in compliance with that since his tenure; and 2) the Board is self-funded, so the Board has to live on the influx of funds after the end of February in even-numbered years all the way into Q4 of even numbered years, i.e., for the next 20 months. The proposals are all FDIC-insured so long as under \$250,000. As additional vetting, the Board of Opticians, Accountancy, Landscaping, Architecture, and Engineering all use this same bank and its instruments. The three-month term at present is the better return on investment.

Director Schneider recommended: 1) the Board vote yes, use funds from the accounts receivable account; 2) appoint a Board member tasked with oversight of himself and the

funds to show the membership that checks and balances are being implemented; and 3) the Board authorizes the banker's checklist provided in the meeting materials. Director Schneider answered Board Member Johnson's question that the motion can be selfexecuting and continual so as to avoid special meetings every 85 days on what to do about the funds when a CD's term is about to end.

Dr. Austin moved to legally and prudently to invest the funds into CDs, have Board Member Johnson and Director Schneider jointly manage the funds and report back to the Board on the statuses. Dr. Smith seconded. Motion passed unanimously. Director Schneider commented for the membership's knowledge that these instruments do not lose principle.

5. **Board of Dispensing Opticians cross-over issues.** Director Schneider reminded the Board this was brought up at the prior meeting that the Board of Dispensing Opticians' Executive Director is encountering similar issues and public complaints as this Board, and would be providing a list of questions for this Board's perspective. Director Schneider noted: 1) there are 7 overarching topics that the Optician Board wanted the Board's perspective; and 2) as opening salvos, AB 432 needs to be read as a whole, nothing in AB 432 abrogates already existing law, AB 432 presupposes licensees adhere to the standard of care, and that the questions are not specific enough to provide responses as truisms, but the Board as a gesture of good faith should answer these questions to the best of their ability.

Dr. Smith noted that a comprehensive eye examination has to be done in person, and synchronous telehealth would be for non-comprehensive exams where the doctor has seen the patient in the past two years and has access to the records of a comprehensive exam in the prior two years. An example would be obtaining an update on a contact lens fit to then order the contacts. Telehealth is not to replace the standard of care. Asynchronous telehealth is for consultations only, when requested by a different provider such as being requested to look at a retinal photo, and are not allowed to make a diagnosis or treatment plan.

As to AB 432(19)(9), a vision prescription using only an autorefraction or manifest refraction is not standard of care whether in-person or telehealth.

As to AB 432(18) regards restrictions on prescriptions. The Board confirmed valid prescriptions from one optometrist can be filled by another optometrist.

As to AB 432(19), there is no specification on where the prior comprehensive examination records comes from, so the records can be provided to the examining optometrist by the patient or the prior optometrist.

As to whether an MD can fill in at an optometrist clinic, the MD or DO practices medicine whereas the optometrist practices optometry. An ophthalmologist has the ability to perform all of the care an optometrist could, so long as duly licensed. In any physician-optometrist relationship, there cannot be an employment contract. The optometrist has his or her role and cannot exceed their statutory scope of practice, which is separate from the ophthalmologist's role in treating the patient.

"Direct responsibly" mentioned in section 346 does not mean that the optometrist has to oversee the entire process, but must perform the final examination before discharge.

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As the corporate pressures, there is a statute on point that non-optometrists cannot influence optometrist judgment. The person in trouble in this scenario is the optometrist for not following optometry law. This would not be a joint jurisdiction all the time, but would instead depend on the facts.

As to an educational campaign, the Board already has an NAC that the membership is well aware of to use to ask the Board about its interpretation of its laws applied to specific scenarios. DAG Weiss commented that there is nothing to allow multiple Boards preparing a joint policy. Dr. Smith welcomed education to both Boards, especially in light of the new laws. A proposed letter answering the Board of Dispensing Opticians' questions will be part of the Board's next meeting for Board approval.

- 6. Action Item- Complaint 24-11 hearing scheduling Colloquy as to Board hearing options for July 31, 2024 or August 28, 2024. DAG Weiss commented he is in touch with counsel who could become the licensee's counsel, and who had asked for something three to four months away due to a busy summer trial schedule. Dr. Smith moved for DAG Weiss to issue an Order to conduct the hearing on July 31, 2024. Board Member Johson seconded. Motion passed unanimously.
- 7. Action Item 16. Complaint 24-13. Director Schneider read a statement in the record:

NRS 636.310)(3) authorizes the Executive Director to notify the Board of an investigation for further consideration by the Board if deemed necessary by the Board after an investigation.

This public complaint submitted on or about April 15, 2024 is being presented in a double-blind manner, i.e., the Board is not being told during the course of this agenda item who the complainant is or who the subject licensee is.

The materials associated with this agenda item are redacted to eliminate any identification of party identities, gender, locality, whether the practice is commercial or private, or whether the licensee is new to Nevada or not.

I am requesting the Board not ask any questions of me about such information as this is immaterial to the Board's evaluation of the allegations, the licensee's response and the licensee's submitted documents in support of the response. As I have made the licensee aware telephonically on April 22nd and in writing on April 16, the purpose of this double-blind presentation is to afford the licensee due process and avoid any undue influence upon the Board by mere virtue of who the complainant may or may not be or who the licensee may or may not be, and in order to balance the statutory directives of protecting the public while balancing the licensee's due process rights.

The allegations regard an advertisement for free examinations at the licensee's then-future primary practice location. It is the licensee's then-future location because the licensee has since retracted the location as the primary location in light of the business's advertisement.

Both the optical business and the licensee separately state that the licensee did not know about advertisement and the optical business has stated that all responsibility lies with it and not the licensee.

The licensee acknowledges her knowledge that advertisements for free services are illegal within Nevada optometry laws. The licensee has since confirmed that not only has the original post been taken down, but the posts which the optical business controls have been taken down and no longer exists on social media according to her and her counsel.

I will now ask the Board to deliberate and discuss what it wants to do next in this matter. Options available to the Board include closure of the investigation, issuance of a letter of concern then closing the investigation, authorization of the Executive Director to issue additional subpoenas and/or request a supplemental response from the licensee, or request that the Attorney General's office pursue a formal complaint against the licensee and prosecute the matter as provided under NRS 636.325. If the Board votes for authorizing a formal complaint, which the Executive Director is not advocating for one way or another, it will be up to the Attorney General's Office to apply laws to facts and decide what specific charges should be included in the formal complaint.

Dr. Smith noted the licensee made a good faith effort in complying with the investigation. The issue is if the optical business is advertising for the optometrist to perform free examinations, this suggests that the optometrist would be paid by the optical business. The materials produced thus far do not answer those questions. Dr. Smith commented that under the circumstances there may be a contract between the licensee and the optical business. Colloquy and agreement for a letter of concern and to request the contract, particularly when the licensee may be associating with the optical business in the future. Such concerns include is the licensee an actual independent contractor, how the licensee had planned on being paid, and this investigation remains open. Dr. Smith moved for a letter of concern and to request a copy of the executed contract be provided presuming the licensee executed one, and no formal hearing at this point in time. Dr. Austin seconded. Motion passed unanimously. DAG Weiss noted disciplinary action for a contract that never occurred and was essentially only an idea would be difficult to be actionable.

- 8. Action Item- Consideration and approval of March 28, 2024 Board Meeting Minutes. Dr. Smith confirmed all Board members had looked over the proposed Minutes. Dr. Austin moved to accept as proposed. Dr. Alamo-Leon seconded. Motion passed unanimously.
- 9. **Public Comment.** Dr. Smith invited Public Comment. Dr. Kopolow expressed concern about independent contractors, potentially mislabeled as such, when actually are employer-employee and from an IRS perspective would not be deemed as true independent contractors. The most traditional arrangement would through subleasing, and is not a substitute for the independent contractor relationship. Dr. Smith requested of Director Schneider to place the independent contractor related laws be placed on the Board's running list for 2025 legislative session.
- 10. Action Item- Adjournment. Dr. Smith moved to adjourn the meeting. Public Member Johnson seconded. Motion passed unanimously. The meeting adjourned at 1:32 p.m.

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FY 2023-2024 Regular meeting schedule

Thursday 5/30/2024 12:00p.m. (pst) Reg. Bd. Meeting- phone or Zoom Thursday 6/27/2024 12:00p.m (pst) Reg. Bd. Meeting- phone or Zoom

FY 2024-2025 Regular meeting schedule

Wednesday 7/31/2024 12:00p.m. (pst) Reg. Bd. Meeting- phone or Zoom Wednesday 8/28/2024 12:00p.m. (pst) Reg. Bd. Meeting- phone or Zoom

These minutes were considered and approved by majority vote of the Nevada State Board of Optometry at its meeting on May 30, 2024.

/s/

Adam Schneider, Executive Director