

**VERMONT SECRETARY OF STATE  
OFFICE OF PROFESSIONAL REGULATION**

**STUDY OF OPTOMETRIC ADVANCED PROCEDURES**

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*During the 2019 Legislative Session, the Vermont Optometric Association (“VOA”) came before the House Government Operations Committee (the “Committee”) to testify in support of a proposal to expand the optometrist scope of practice to permit this profession to perform “advanced procedures” (“proposed advanced procedures”).<sup>1</sup> The Vermont Ophthalmologist Society (“VOS”) and the Vermont Medical Society (“VMS”) adamantly opposed this proposed change in the scope of practice of optometrists.<sup>2</sup> The Committee determined that a study was needed to “evaluate the safety and public health needs of enlarging the scope of practice of optometrists to include advanced procedures.” Act 30, Section 13 (2019).*

*In Act 30, the General Assembly directed the Office of Professional Regulation (the “Office” or “OPR”) to conduct this study. The General Assembly further instructed OPR to “evaluate, among other considerations, approaches to advanced procedures in jurisdictions outside Vermont, patient need for access to additional practitioners, effects on patient access to care, effects on patient safety, costs to the health care system, and the existing education and training for optometrists, including the degree to which it addresses training in advanced procedures” and to “inquire into the specific clinical training for both optometrists and ophthalmologists for specific procedures.” Id.*

*After consulting with stakeholders and conducting extensive and thorough research, OPR cannot conclude that optometrists are properly trained in and can safely perform the proposed advanced procedures. Further, OPR finds that there is little need for, and minimal cost savings associated with, expanding the optometric scope of practice to include advanced procedures. For these reasons, OPR recommends against expanding the optometric scope of practice to include the proposed advanced procedures.*

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<sup>1</sup> Vermont. House of Representatives. Committee on Government Operations. *Testimony on House Bill 104: An Act Relating to Professions and Occupations Regulated by the Office of Professional Regulation. February 21, 2019.* 2019-2020 Legislative Session. (testimony of Dean Barcelow, O.D., President of the Vermont Optometric Association).

<sup>2</sup> See e.g., Vermont. House of Representatives. Committee on Government Operations. *Testimony on House Bill 104: An Act Relating to Professions and Occupations Regulated by the Office of Professional Regulation. February 21, 2019.* 2019-2020 Legislative Session. (written statement of Vermont Ophthalmological Society). and Vermont. House of Representatives. Committee on Government Operations. *Testimony on House Bill 104: An Act Relating to Professions and Occupations Regulated by the Office of Professional Regulation. February 21, 2019.* 2019-2020 Legislative Session. (written testimony of Dr. Amy Gregory, M.D., President of the Vermont Ophthalmological Society).

## Legal Standards and Analytical Structure

To guide its analysis in this report, OPR has relied on the following language in Section 13 of Act 30:

### Sec. 13. OFFICE OF PROFESSIONAL REGULATION; STUDY OF OPTOMETRIC ADVANCED PROCEDURES

- (a) The Office of Professional Regulation shall conduct a study to evaluate the safety and public health needs of enlarging the scope of practice of optometrists to include advanced procedures. In conducting this study, the Office shall consult with relevant stakeholders, including the Vermont Board of Optometry, the Vermont Optometric Association, the Vermont Board of Medical Practice, the Vermont Department of Health, and the Vermont Ophthalmological Society.
- (b) The study shall evaluate, among other considerations, approaches to advanced procedures in jurisdictions outside Vermont, patient need for access to additional practitioners, effects on patient access to care, effects on patient safety, costs to the health care system, and the existing education and training for optometrists, including the degree to which it addresses training in advanced procedures. The Office shall inquire into the specific clinical training for both optometrists and ophthalmologists for specific procedures.
- (c) On or before January 15, 2020, the Office shall report its findings, including any recommendations for legislative action, to the House Committees on Government Operations and on Health Care and to the Senate Committees on Government Operations and on Health and Welfare. *Id.*

Though not specified in Act 30, OPR also considered the policy and criteria set forth 26 V.S.A. Chapter 57 (“Chapter 57”) in its analysis of whether to recommend expanding the optometric scope of practice. Typically applied by OPR in analyses of whether to initiate or continue the regulation of a profession, the Chapter 57 policy and criteria require regulation in circumstances when the following can be demonstrated:

- (1) it can be demonstrated that the unregulated practice of the profession or occupation can clearly harm or endanger the health, safety, or welfare of the public, and the potential for the harm is recognizable and not remote or speculative;
- (2) the public can reasonably be expected to benefit from an assurance of initial and continuing professional ability; and
- (3) the public cannot be effectively protected by other means.

-26 V.S.A. § 3105(a).

The law does not currently require OPR to consider the Chapter 57 policy and criteria when determining whether the scope of practice of a profession should be expanded. However, OPR finds that this policy and these criteria are equally applicable and valid in the circumstances of scope of practice expansion as in the determination of whether to recommend new regulated profession or an evaluation of continued regulation of a profession. Thus, in its analysis of whether the optometric scope of practice should be expanded to include the proposed advanced procedures, OPR considered whether regulation of the proposed procedures is necessary to protect the public, as well as whether the public's interest will be served by such regulation and whether there are alternative means of protecting the public. These considerations underly the analysis, below.

In this report, the impact on public safety of scope expansion will be addressed first, followed by an analysis of the need for scope expansion to facilitate access to care, and then, an examination of the costs of scope expansion. Each section – safety, need and access, and costs – includes the arguments in support of expansion, those against, and OPR's research findings. The first section of the report includes policy recommendations from OPR.

## Outreach and Methodology

### *Outreach*

Rather than hold a public hearing on the matter of expanding the scope, the Office met with each stakeholder named by the General Assembly in Act 30 – the Vermont Board of Optometry (the “Board”), the VOA, the Vermont Board of Medical Practice (the “BMP”), and the VOS<sup>3</sup> – individually to allow the stakeholder the opportunity to share its complete views on the proposed expansion of the optometrist scope of practice. Additionally, OPR invited stakeholders to share any additional information or questions that may develop or be thought of after the in-person meeting.

At the stakeholder meetings, OPR asked the stakeholder questions regarding education and training, patient safety, access to care, and costs. Additionally, VOA was asked to provide the list of advanced procedures that optometrists wanted to be permitted to perform under an expanded scope of practice.<sup>4</sup>

<sup>3</sup> The General Assembly also instructed OPR to consult with the Vermont Department of Health. Upon receipt of an inquiry from OPR, the Vermont Department of Health referred the Office to the Board of Medical Practice for input.

<sup>4</sup> VOA stated that it would prefer the list of advanced procedures remain open so that, as optometric education and training advanced, optometrists could adapt their practices. VOA's suggested provisions included permitting optometrists to perform those procedures “as taught” in optometry school or deferring to the Board of Optometry to evaluate and declare, by Rule, what procedures were within the optometric scope of practice. OPR requested a specific list of procedures for several reasons: (1) the “as taught” language was too open-ended given that it was not then clear – and is still not clear – which procedures are consistently taught in optometric school; (2) the specific list was needed to evaluate whether optometric schools provided consistent and/or sufficient education and training on the requested procedures; and (3) in Vermont, the scope of practice of a profession is established by law through the legislature rather than using the rulemaking process to determine scope.

OPR asked VOA to reach out to optometrists and their patients and to have these individuals call or email OPR directly to share stories about challenges accessing the proposed advanced procedures under the current optometric scope of practice. Five individuals emailed OPR to share their stories regarding accessing the proposed advanced procedures. Two additional patients shared their stories with OPR through their optometrist, Dr. Steven St. Marie. OPR believes this direct outreach to optometrists and patients was more effective than holding a general public meeting, as it permitted affected individuals to share their complete stories without interruption and it did not require consumers to travel or to share in a large group.

OPR also asked the directors of the 21 schools of optometry in the United States to provide detailed curricula, course descriptions, syllabi and other information about optometric training and education on the proposed advanced procedures. None of the directors or schools responded to OPR. As a result of OPR's request to the school directors, the President of the Association of Schools and Colleges of Optometry ("ASCO"),<sup>5</sup> Dr. Elizabeth Hoppe, OD, MPH, DrPH, contacted the Office to discuss optometric education and training. Dr. Hoppe could not provide information about the course offerings, curricula or syllabi from the schools of optometry. She did share the guidance documents that ASCO provides to its member schools regarding competencies optometry students should meet upon graduation from optometry school and recommendations for assessment of these competencies.

### *Research*

OPR conducted extensive research regarding the expansion of the optometric scope of practice and the impacts thereof. OPR considered the following sources and information in its review:

- Data regarding the number and location of optometrists and ophthalmologists in Vermont
- Optometric scope of practice laws in other states
- Policy reports on optometric scope expansion from other states
- National Practitioners Data Bank data
- Disciplinary data and information for Vermont-licensed optometrists
- Disciplinary actions and complaints against optometrists in other states
- Course catalogues and course descriptions from U.S. schools of optometry, where available
- Applicable editorial, policy and scientific literature
- Advocacy materials from professional associations

OPR believes these methods of outreach, research and information gathering were comprehensive and effective and that it has thoroughly explored varying perspectives and the available information on the issue of optometric scope expansion.

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<sup>5</sup> ASCO is a "non-profit education association representing the interests of optometric education." *Background, Mission and Vision*, ASCO, <https://optometriceducation.org/about-asco/background-and-mission> (last reviewed January 15, 2020).

## History and Background

### *The Ongoing Debate*

The VOA's scope expansion proposal is part of a 100-year, national effort by the American Optometric Association ("AOA") to expand the optometric scope of practice in each state. In the February 2012 edition of the AOA's Journal *Optometry*, Sherry L. Cooper, the then Associate Director of State Government Relations for the AOA, described the goal of the AOA as having every state's scope of optometric practice permitting a license holder "to examine, diagnose, treat, and manage diseases or conditions of the vision system, eye, and related structures with any appropriate means" including "every facet of the practice of modern optometry, from the use of lenses and prisms...to the use or prescription of appropriate drugs, including controlled narcotic substances; to the performance of non-surgical and surgical procedures."<sup>6</sup>

In response to these efforts by the AOA, ophthalmologists and physicians have organized on the state and national levels to oppose proposed scope expansions. The American Academy of Ophthalmology ("AAO") established the Surgical Scope Fund for the purpose of collaborating with state ophthalmological and medical societies to oppose these efforts to expand the optometric practice. These ophthalmologist groups argue that optometric scope expansion poses a threat to patient safety because optometrists lack the education and training necessary to perform the procedures proposed.<sup>7</sup>

Throughout these debates, similar arguments and points of contention have arisen: (i) whether optometrists can safely provide the optometric procedures proposed; (ii) whether there is a need for an expanded optometric scope of practice to address a lack of patient access to ophthalmological services; and (iii) whether costs savings would be realized from an expanded optometric scope of practice. It is, thus, appropriate that Act 30 charges OPR with evaluating safety, access and need, and cost associated with the expansion of the optometric scope of practice.

### *Other States' Experiences*

Other states have expanded the optometric scope of practice in various ways. Currently, five states – Oklahoma, Kentucky, Alaska, Louisiana and Arkansas<sup>8</sup> – permit optometrists to prescribe pharmaceuticals and to perform all of the proposed advanced procedures (i.e., laser treatments, injections, and removal of lesions and growths). Five states permit optometrists to remove lesions and growths, without lasers,

<sup>6</sup> Sherry L. Cooper, *1971-2011: Forty Year History of Scope Expansion Into Medical Eye Care* (Saint Louis, MO: American Optometric Association, 2011).

<sup>7</sup> *Advocacy*, AAO, <https://www.aao.org/advocacy/surgical-scope-fund/overview> (last reviewed January 15, 2020).

<sup>8</sup> Arkansas' legislature passed a law in 2019 expanding the optometric scope of practice to permit the advanced procedures proposed by the VOA. The law has yet to take effect.

and to prescribe pharmaceuticals.<sup>9</sup> The remaining forty states (including Vermont) do not currently permit optometrists to perform the proposed advanced procedures.<sup>10</sup>

Washington, New Mexico and Nebraska issued policy reports when considering whether to expand the optometric scope of practice to include the proposed advanced procedure. After these reviews, Washington and Nebraska declined to expand the scope of practice while New Mexico expanded the scope to permit injections and the non-laser removal of lesions. Laser procedures remain prohibited in New Mexico.

### *Vermont's History*

There have been prior expansions of the Vermont optometric scope of practice, including in 1983, 2004, and, most recently, in 2019. A similar debate between optometrists and ophthalmologists about scope expansion occurred in the 2003 legislative session, this time about optometrists using therapeutic pharmaceutical agents. On December 31, 2003, OPR issued a “Report on S. 54: Expanded Scope of Practice for Optometrists”, which concluded that, with the appropriate safe guards, the public would not be harmed by expanding the optometric scope of practice to permit optometrists to use therapeutic pharmaceutical agents.<sup>11</sup> Subsequently, the General Assembly passed Act 108, which permitted optometrists holding an additional “endorsement” on their optometry license (a) to use pharmaceutical agents for the “appropriate diagnosis, management, and treatment of the eye and adnexa,” and (b) to “perform epilation of the eyelashes including electrolysis, punctal dilation, and lacrimal irrigation, and

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<sup>9</sup> *Optometrist Scope of Practice*, NCSL, <http://www.ncsl.org/research/health/optometrist-scope-of-practice.aspx> (last reviewed January 15, 2020). Nine states defer to the state’s Board of Optometry to define the optometric scope of practice. None of these states permits optometrists to perform all of the proposed advanced procedures, though there are a few minor exceptions. California permits optometrists to perform “Intravenous injection for the purpose of performing ocular angiography at the direction of an ophthalmologist as part of an active treatment plan in a setting where a physician and surgeon is immediately available.” CA Bus. & Prof. § 3041(d)(15). Additionally, with a special license endorsement, California-licensed optometrists may provide immunizations. CA Bus. & Prof. § 3041(f). Iowa permits optometrists to perform minor surgical procedures that do not require any injectable or general anesthesia, lasers, moderate sedation, or penetration of the globe. Optometrists in West Virginia may perform minor surgical procedures and administer medications by injection (though no retrobulbar or peribulbar injections are permitted). West Virginia prohibits optometrists from performing surgery using lasers, and from performing cataract or retinal surgery. North Carolina permits optometrists to perform injections.

<sup>10</sup> *Id.*

<sup>11</sup> Vermont: Secretary of State, Office of Professional Regulation, *Report of S.54: Expanded Scope of Practice for Optometrists* (December 31, 2003) available at <https://www.sec.state.vt.us/media/411945/optometryscopereport.pdf>. OPR acknowledges that the 2003 report arrived at a different policy recommendation despite analysis of similar factors. However, the activities that the optometrists were seeking authorization to perform in 2003 were of a different nature and there was additional information about education and training standards. For instance, the ACOE Professional Optometric Degree Program Standards 2000 referenced by the Optometrists and relied on by the Office in 2003 are no longer available. Notably, in 2003, even the VOA proponents of scope expansion stated that “ophthalmologists receive extensive training for years in surgery and tertiary medical eye care *that optometrists do not receive.*” The VOA went on to state that optometrists “receive the necessary specialized ocular education and clinical training required to provide primary eye care.”

insert punctal plugs.” Act 108, Section 5 (2004). The Board of Optometry and OPR then promulgated rules establishing qualifications and requirements for obtaining this endorsement.<sup>12</sup>

Notably, the 2004 law expressly prohibited optometrists from performing surgery (defined as “any procedure in which human tissue is cut, penetrated, thermally or electrically cauterized except when performing electrolysis, or otherwise infiltrated by mechanical or laser means”), as well as the use of injections (except for when needed for emergency stabilization of a patient) and the removal of skin lesions. Act 108, Sec. 5 (2004) *amending* 26 V.S.A. § 1728.<sup>13</sup>

## Recommendations

The Office of Professional Regulation recommends against expanding the optometrist scope of practice to include the proposed advanced procedures. At this time, the Office cannot conclude that optometrists have the education and training to safely provide these procedures. Nor can it find that there is a need for expanded access to the proposed advanced procedures or a reduction in costs associated with scope expansion.

### *Safety*

The proposed advanced procedures, if performed by untrained individuals, pose risks to the health and well-being of the public. This is evidenced by the complexity of each procedure and the potential complications thereof. There has been little uncontroverted evidence provided supporting the conclusion that optometrists are capable of safely performing these advanced procedures or managing these risks. The VOA offers only that the procedures are “simple” and straightforward. However, the VOS has provided ample evidence that these procedures require a degree of skill to perform the procedure, to determine who is a good candidate for the procedure, and to manage unforeseen complications. The states that have expanded the scope of practice report that there have been no complaints, complications or malpractice cases against any optometrists. However, the data from the National Practitioner Data Bank (“NPDB”) contradicts these reports. VOA references low malpractice insurance rates as an indicator of safety, but the insurance industry itself disputes this characterization.

Most significant for OPR is the lack of evidence showing that optometric education prepares optometrists to perform these proposed advanced procedures. Despite multiple efforts through various sources, OPR was unable to gather specific or detailed information about the curricula and courses offered by the U.S.

<sup>12</sup> In 2019, the optometric scope of practice was revised again to permit all optometrists holding a Vermont license to use pharmaceutical agents in the treatment of glaucoma without an additional endorsement on the license. Act 30, Section 12 (2019).

<sup>13</sup> The express prohibition was removed from 26 V.S.A. §1728 in 2019 via Act 30 as part of the process of permitting all optometrists holding a Vermont license to use pharmaceutical agents in the treatment of glaucoma without an additional endorsement on the license. OPR’s interpretation of the law remains the same, however -- it is unprofessional conduct for Vermont-licensed optometrists to “practice”, “offer to practice”, “perform” or “provide” laser surgeries, removal of lesions or growths, or injections. *See e.g.*, 26 V.S.A. §1719.



schools of optometry in these advanced procedures. Other states attempting to gather such information have met with similar refusal to disclose detailed curricula.<sup>14</sup>

Even the more stringent and comprehensive optometric educational programs do not provide the level of training and experience obtained by ophthalmologists. What information is available about U.S. optometry schools shows that (a) curriculums vary widely (there is no standardized course of study regarding these advanced procedures); and (b) courses on lasers, injections and minor surgical procedures are very limited – they are short courses, with little to no lab time, and minimal practical experiences. Continuing education courses on advanced procedures present similar limitations. They are very short and have negligible practical experience requirements.

Providers who perform the proposed advanced procedures need to be trained in assessing the systemic condition of patients, to be educated on how to adjudge whether a patient is a candidate for a procedure, and to be qualified to address medical complications. OPR cannot conclude that optometrists have this necessary education and training. OPR is thus concerned that permitting optometrists to perform these advanced procedures poses a risk to the public's safety

#### *Need and Access*

The Office finds that there is insufficient evidence showing a need for expanded access to care that can be addressed by expanding the optometric scope of practice. OPR acknowledges that there are patients who have experienced longer wait times than preferable and that have had to drive further than desired. However, the evidence shows that, in most cases, there is little delay in treatment, there is no reported detriment from the delays that do exist, and there is additional capacity:

- In the reports to OPR, initial examinations with ophthalmologists have typically occurred within weeks after a referral from optometrist. Ophthalmologists reported in survey results that they are available to provide necessary advanced procedures immediately, should an urgent case arise.
- Commenters also stated that advanced procedures were delayed following the initial ophthalmology exam. The timing of the advanced procedures following the initial exam is part of an ophthalmologist's professional assessment. OPR is reticent to interfere with or opine on whether an ophthalmologist's assessment about the course and timing of treatment in these cases is appropriate.
- No evidence was presented showing that patients are experiencing detrimental disease consequences due to waiting for procedures.
- According to Medicare data and reports from providers, there are relatively few of these advanced procedures performed every year and ophthalmologists around the state have said they have the capacity to care for these patients.

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<sup>14</sup> Joseph Acierno, M.D., J.D., *Director's Report on the Proposal to Expand the Scope of Practice of Optometrists*, Nebraska: Department of Health and Human Services, Division of Public Health (March 10, 2014).



Additionally, there does not appear to be a need for making these advanced procedures available in locations closer to Vermont residents. Vermont data shows that there is an ophthalmologist located within 30 miles of most Vermont residents.<sup>15</sup> Even if there is a need for locating these services closer to patients, expanding the optometric scope of practice is unlikely to address this issue. Most Vermont ophthalmologists and optometrists are located in the same places.<sup>16</sup> In turn, permitting optometrists to perform the advanced procedures would simply make patients drive equally as far to see their optometrist rather than an ophthalmologist. Supporting this supposition is the experience in states where optometric scope expansion has occurred. In these states, few optometrists have chosen to perform these advanced procedures and those who do are located near ophthalmologists (typically near a population center).

Regarding patient choice, the confusion of the public regarding the differences between optometry and ophthalmology shows that the public does not have the information necessary to make an informed choice between providers when it comes to seeking these advanced procedures. In this case, a move to expand the scope of optometric practice could actually create additional confusion for patients. Based on the information available, OPR cannot find that there is a need for greater access to care or that an expanded scope of practice would address this need.

#### *Costs*

OPR concludes that there will be little, if any, cost savings associated with the expansion of the scope of practice. Patients may be saved the additional costs of seeing a new doctor, repeating an exam, and traveling twenty minutes to see another provider. However, it is not clear to OPR that these costs savings are beneficial to the patient. Evidence provided by the VOS and experiences in other states show that optometrists sometimes refer patients for or perform unnecessary advanced procedures. At least in one study showed that significantly more repeated procedures were required when the initial procedure was performed by an optometrist. Thus, the initial costs savings to the patient may be outweighed by the costs of an unnecessary or repeated procedure.

Further, the VOA acknowledges that the number of advanced procedures would increase in the short-term as optometrists begin using lasers. The cost of the equipment is also significant and may drive up utilization. Because of these increased costs that are not offset by other apparent savings, OPR cannot conclude that expanding the scope of optometric practice would result in any cost savings.

For the above reasons, OPR recommends against expanding the optometric scope of practice to include the proposed advanced procedures.

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<sup>15</sup> See Figures 2 and 3 in Appendix A.

<sup>16</sup> See Figure 1 in Appendix A.

## Proposed Advanced Procedures

The VOA has asked OPR to include the following proposed advanced procedures in the optometric scope of practice:

- Anterior Segment Laser Procedures:
  - Laser Capsulorhexis
  - YAG Capsulotomy
  - Laser Trabeculoplasty
  - Laser Iridotomy
- Injections of the Eyelids and Adnexa
  - Injections into the eyelid
  - Injections of the subconjunctival space
  - Intramuscular and subcutaneous injections
  - Intravenous injections
- Removal of benign eyelid and eye growths (e.g., pedunculated lesions, papilloma, keratosis, cutaneous cysts, etc.)<sup>17</sup>

Following is a brief description of the proposed advanced procedures. Also described are the purpose of the procedures and associated risks and complications.

### Anterior Segment Laser Procedures

#### A. Cataracts: Laser Capsulorhexis and YAG Capsulotomy

- *Laser Capsulorhexis* – A laser capsulorhexis is the process of using a laser to make an incision around the capsule of the eye to permit the removal of the lens during cataract surgery.
  - Whether performed by an optometrist or an ophthalmologist, this procedure must be done in an operating room because surgery to remove the cataract and replace the lens follows. The VOA proposes to offer this procedure as the beginning part of a cataract surgery and then turning the patient over to an ophthalmologist to complete the removal and replacement of the lens.
  - This procedure can be done manually, as well as with a laser. There is currently one FEMTO laser, the laser that performs this surgery, in Vermont. The VOS reports that ophthalmologists prefer the manual method of performing a capsulorhexis (i.e., using a blade to create the incision), as there can be problems with the lasers cutting all the way

<sup>17</sup> Dean Barcelow, O.D. Letter to the House Committee on Government Operations and Representative Copeland-Hanzas, *Re: Guidance on What Procedures Optometry is Expecting to Look at Once Rulemaking Statute is in Place* (February 12, 2019).

through the tissue and the resultant need to repeat the incision. Additionally, there are reported challenges controlling the size and contour of the incision with the laser.<sup>18</sup>

- Complications
  - Imprecise and/or incomplete incision
  - Repeated surgery
  - Poor visual acuity following surgery
  - Repeat tear of the rhexis (the incision)
  - Blindness
  - Loss of eye<sup>19</sup>
  
- *YAG Capsulotomy* – After cataract surgery, the capsule that holds the lens can become cloudy. A YAG capsulotomy relieves this cloudiness by using a YAG laser to create a clear hole at the back of the capsule, thereby allowing light through.
  - The development of capsule cloudiness is common in patients who have had cataract surgery and multiple capsulotomies may be needed over time.
  - Complications
    - If the hole tears further or creates weaknesses in the capsule, the lens can slip or dislocate completely. This requires surgery to retrieve and, likely, replace the lens.
    - Secondary effects from the laser energy include interfering with the function of the trabecular meshwork (see Glaucoma section), which can lead to an intraocular pressure spike.
    - Retinal detachment can also occur from this surgery if a preexisting retinal weakness is exacerbated or disturbed by the laser energy.
    - The shock waves of the laser can create white dots (“pits”) on the new lens which effect the clarity of vision.
    - Additional complications include intraocular bleeding, pupil distortion, intraocular pressure rises, corneal abrasions, conjunctivitis, reactivation of ocular herpes, corneal decompensation, cataracts, blindness.<sup>20</sup>

## B. Glaucoma: Laser Trabeculoplasty and Laser Iridotomy

Fluid in the front of the eyes typically drains through the trabecular meshwork located at the junction of the iris and the cornea. When more fluid is produced than can drain through the meshwork (from diseases such as glaucoma), the pressure inside the eye increases. A person can go blind if the pressure becomes extreme and is not relieved. To reduce pressure, ophthalmologists sometimes use a laser to create a

<sup>18</sup> *Capsulorhexis Strength with FLACS Surgery*, Investigative Ophthalmology & Visual Science, <https://iovs.arvojournals.org/article.aspx?articleid=2526362> (May 2016).

<sup>19</sup> Vermont Ophthalmological Society, *Additional Descriptions of “Advanced Procedures” Under Consideration* (October 2019).

<sup>20</sup> *Id.*

“hole” through which the fluid can flow. Two of these procedures include the laser trabeculoplasty and the laser iridotomy.<sup>21</sup>

- *Trabeculoplasty* – When the junction between the iris and the cornea is not completely closed (i.e., it is not completely “occluded”), a laser can be used to create a hole in the trabecular meshwork, a “hair thin” line of tissue, and allow fluid to again flow through this passage.
  - Complications
    - The laser must be precisely targeted on the narrow trabecular meshwork. Laser energy hitting the surrounding structures could damage those structures and result in no decrease in pressure.
    - Similarly, over treatment can result in damage to the surrounding structures and limit their function, resulting in an increase in pressure.
    - Other complications include corneal abrasions/infections/ulcers, conjunctivitis, reactivation of ocular herpes, corneal decompensation, cataracts.<sup>22</sup>
  
- *Laser Iridotomy* – When the junction between the iris and the cornea is nearing complete occlusion (i.e., the trabecular meshwork is no longer visible and the iris sits close to the cornea), a laser can be used to make a hole at the edge of the iris to restore the flow of fluid and relieve pressure.
  - Complications
    - If an iridotomy is placed in the wrong location, the patient will effectively have two pupils, resulting in vision distortion and double vision.
    - As the iris contains blood vessels and nerves, so placement of the laser is important to avoid bleeding and pain. Bleeding in the eye can result in an increase in pressure that can require surgery to relieve.
    - Cataract can result if the hole is not made far enough out on the iris.
    - Other complications include corneal abrasions/infections/ulcers, conjunctivitis, reactivation of ocular herpes, corneal decompensation, cataracts.<sup>23</sup>

### Injections of the Eye and Adnexa

The VOA did not provide the types or purposes of injections it is requesting in the expanded scope of practice. Nor did it specify the medications to be injected. Rather, the VOA proposed a list of anatomical structures optometrists would be allowed to inject. The VOA notes that it is not seeking to do intraocular injections.<sup>24</sup>

- *Injections into the eyelid* – VOA proposes to inject topical (local) anesthesia into the eyelid before removal of growths or lesions on the eyelid and to inject steroids for chalazion (i.e., sty) removal.

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<sup>21</sup> *Id.*

<sup>22</sup> *Id.*

<sup>23</sup> *Id.*

<sup>24</sup> Dean Barcelow, O.D. Letter to the House Committee on Government Operations and Representative Copeland-Hanzas, *Re: Guidance on What Procedures Optometry is Expecting to Look at Once Rulemaking Statute is in Place* (February 12, 2019).

- *Injections into the subconjunctival space* – VOA proposes to inject glaucoma medications into the subconjunctival space (i.e., the space between the conjunctiva – the thin clear membrane covering the eye and the inner eyelid – and the lens). VOS notes that injections into the subconjunctival space are very rarely done and, when performed, are done by surgeons.
- The VOA also notes that some states permit optometrists to inject vaccines in public health emergencies. VOS notes that intramuscular injections are also used for performing Botox procedures.
- *Intravenous injections* – The VOA proposes to use intravenous injections to perform fluorescein angiography through the eye. This is the process of injecting a dye into the bloodstream that then highlights the blood vessels in the back of the eye, allowing them to be photographed.<sup>25</sup>

Improper injections can result in infection, excessive bleeding and bruising, damage to the nerves surrounding the eyelid resulting in the inability to open or close the lid, damage to the surrounding systems, and the needle slipping into the eyeball.<sup>26</sup>

#### Removal of Benign Eyelid and Eye Growths

The VOA has proposed being permitted to remove benign eyelid and eye growths, including “pedunculated lesions, papilloma, keratosis, cutaneous cysts, etc.”<sup>27</sup> VOA states that they would remove a growth and send the tissue to a pathologist to determine whether the growth is benign or malignant, similar to the process ophthalmologists currently follow.

VOS notes that the eyelid is very thin, and lesions may involve muscles and nerves beneath the lid. Additionally, optometrists would be cutting near complex and delicate systems, such as the lacrimal (tear) drainage system. An additional risk is that it is not always clear whether a growth is benign or malignant, the determination of which may impact the extent and complexity of the procedure.

- **Complications**
  - Damage to the muscles or nerves beneath the eyelid can result in the permanent drooping of the lid or the inability to close the lid (which can require a skin graft to remedy).
  - Damage to the lacrimal system can result in permanent tearing or dry eyes.
  - Improper removal of a malignant growth (e.g., not making sure all the margins of the removal are “clean”) can result in the spread or regrowth of the cancer.

<sup>25</sup> *Fluorescein Angiography*, Healthline <https://www.healthline.com/health/fluorescein-angiography> (last visited January 15, 2020).

<sup>26</sup> Vermont Ophthalmological Society, *Additional Descriptions of “Advanced Procedures” Under Consideration* (October 2019).

<sup>27</sup> Dean Barcelow, O.D. Letter to the House Committee on Government Operations and Representative Copeland-Hanzas, *Re: Guidance on What Procedures Optometry is Expecting to Look at Once Rulemaking Statute is in Place* (February 12, 2019).

- Suturing may be required when the growth is larger underneath the skin than anticipated or if the skin tissue spreads farther than expected.<sup>28</sup>

## Summary of Arguments For and Against Optometric Scope Expansion and Analysis of Findings

### Patient Safety

After a thorough review of the research and consultation with the stakeholders, OPR finds that there is little evidence demonstrating that optometrists have the education and training necessary to provide the proposed advanced procedures safely. The following section details the arguments that optometric scope expansion is safe, and those arguments that scope expansion will endanger the public. The report then states OPR's findings.

#### *I. Argument that Expanded Scope will Protect Patient Safety*

##### A. Advanced Procedures and Safety

Dean Barcelow, O.D., President of the VOA, and Steven St. Marie, O.D., an optometrist and member of the VOA, met with OPR on August 5, 2019.<sup>29</sup> The VOA contends that the proposed advanced procedures are straight-forward, minor procedures that are a part of providing “primary eye care” to patients.<sup>30</sup> The “difficult part” of these procedures, according to the VOA, is pre- and post-surgical management, which optometrists are charged with handling under the current scope of practice. The VOA referred OPR to YouTube videos showing the proposed advanced procedures as evidence of the simplicity of the techniques involved in the surgical portion of the procedure.<sup>31</sup>

Regarding injections, Dr. Barcelow stated that intraocular injections (i.e., into the globe of the eye) should not be permitted, but that the other forms of injections (eyelid and adnexa, subconjunctival, intramuscular and subcutaneous, and intravenous) should be allowed. He also noted that optometrists should be permitted to remove growths and lesions and send them to a pathologist to analyze whether the growth is malignant or benign, just as an ophthalmologist would do.

<sup>28</sup> Vermont Ophthalmological Society, *Additional Descriptions of “Advanced Procedures” Under Consideration* (October 2019).

<sup>29</sup> Meeting Notes, *Vermont Optometric Association* (Vermont: Secretary of State, Office of Professional Regulation, August 5, 2019).

<sup>30</sup> *American Optometric Association. Doctors of Optometry are America’s Primary Eye Care Providers* [Fact Sheet]. Received July 24, 2019.

<sup>31</sup> See e.g., American Academy of Ophthalmology, *YAG Capsulotomy After Cataract Surgery* (YouTube) (February 16, 2017).

## B. Potential Complications

When asked about the risks for complications, Dr. St. Marie contended that accidents happen to even the best surgeons but that the rate of complications would be no greater with optometrists than with ophthalmologists. He cited the low premiums for malpractice insurance in Oklahoma, where optometrists are permitted to perform the proposed advanced procedures, as evidence of this low risk of complications. Dr. St. Marie further stated that the riskiest complication from performance of these eye procedure was post-procedure inflammation, which optometrists treat and address already. The other proposed advanced procedures, per Dr. St. Marie, pose minimal risks of complications.

## C. Safer to Treat Faster

Dr. St. Marie and Dr. Barcelow both argue that, by permitting optometrists to perform these advanced procedures, patients will receive treatment faster, which benefits safety. When a referral to an ophthalmologist is required, the patient must wait to attend the initial ophthalmological appointment, have another exam, and, then, perhaps schedule and wait for a surgical appointment. These delays and redundancies, it is argued, result in a delay in care during which diseases can worsen and medications, which are symptomatic treatments only, must be taken. Additionally, delayed care may lead to patient non-compliance with treatment recommendations.

## D. Education and Training

Dr. Barcelow stated that he believed the proposed advanced procedures are being taught in all U.S. optometry schools. VOA provided a table listing courses at each optometry school, as copied from the schools' websites, that referenced the proposed advanced procedures. Dr. Barcelow also reported that education and training on these advanced procedures can be obtained through continuing education courses. He reported taking a weekend-long course that covered these procedures in lectures and that included clinical practice on other students.

The VOA and other advocates for scope expansion further argue that optometrists, like other doctoral-level health professionals, should be trusted to only perform those procedures in which they are trained and capable. Thus, even if the optometric scope of practice is expanded, optometrists would not provide the advanced procedures if they are not qualified to do so.

The VOA also provided a factsheet developed by the AOA giving a general overview of optometric education in the U.S. and comparing it to medical education. The factsheet shows 47 total courses completed in most U.S. optometry schools, including one labeled "Injections and Minor Surgical Procedures" and one labeled "Ophthalmic Lasers".<sup>32</sup> No further description of course content is provided.

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<sup>32</sup> *Id.*



## II. Argument that Expanded Scope will Harm Patient Safety

### Board of Medical Practice

OPR consulted with the Executive Director of the Board of Medical Practice, David Herlihy, regarding the opinions of the BMP on expanding the optometric scope of practice. At its November 6, 2019 meeting, the BMP passed a motion stating its position that, regarding expanding the scope of practice, “There is no evidence of [sic] justification for accepting greater risk on behalf of Vermont patients. The evidence shows no problem with access to care for the procedures at issue.”<sup>33</sup> The BMP noted the vast differences between ophthalmological and optometric education and training, and the risks posed by surgical procedures on eyes.<sup>34</sup> The BMP also noted that there is less information available about the “adverse history of optometrists” than there is about physicians, who are often required to report adverse events.<sup>35</sup>

### Vermont Ophthalmological Society and Vermont Medical Society

OPR consulted with Dr. Amy Gregory, M.D., Chair of the Vermont Ophthalmological Society (“VOS”); Dr. Jessica McNally, M.D., an ophthalmologist at the University of Vermont Medical Center in Berlin; Jessa Barnard, Director of the Vermont Medical Society; and Stephanie Winters, the Executive Director of the Vermont Ophthalmological Society. The following are the arguments presented by VOS and VMS.

#### A. Risks of Advanced Procedures

Dr. Gregory and Dr. McNally contended that the proposed advanced procedures are complex procedures that require years of training to determine when patients require such a procedure, to ensure efficacy, and to avoid or to quickly address complications. The doctors explained that the YouTube videos cited by VOA as evidence of the ease of these advanced procedures, are actually made by ophthalmologists for patient education and reassurance. The videos are intentionally non-technical, simplifications of the procedures created to ease patients’ minds and to provide general information. To demonstrate the complexities of these procedures, the ophthalmologists showed videos of the entire procedure being performed. The videos showed the very thin (“human hair width”) and difficult-to-detect line of the trabecular meshwork during a laser trabeculoplasty, the challenges with creating a complete cut using a FEMTO laser during a capsulorhexis, and the potential for damage due to a slight misplacement of the laser during an iridotomy or capsulotomy.<sup>36</sup>

In addition to the complications outlined in the “Advanced Procedures” section, herein, and the complexity of each of the proposed advanced procedures, the doctors also noted the following specific challenges with several of the advanced procedures:

- Capsulorhexis –
  - The ophthalmologists state that capsulorhexis is an integral part of the cataract surgery and there is no need to create a separate, second surgery in which the optometrist performs the capsulorhexis prior to an ophthalmologist performing the cataract removal and lens replacement. The doctors stated that this would result in

<sup>33</sup> Vermont: Department of Health, Board of Medical Practice, *Minutes of the November 6, 2019 Board Meeting*, 4-5 and Appendix B (November 6, 2019).

<sup>34</sup> *Id.*

<sup>35</sup> *Id.*

<sup>36</sup> See e.g., Chris Teng, M.D., *Selective Laser Trabeculoplasty (SLT) Compilation* (YouTube) (January 29, 2013).

unnecessary multiple procedures, which adds complexity, time, and cost, and increases the chances for complications.

- The doctors also reported that this procedure is typically, and preferably, done with a blade rather than a laser.
  - They further noted that there is currently only one FEMTO laser in Vermont (the laser that performs this procedure). This, in turn, poses a threat to safety, as providers will not have the opportunity to gain the necessary experience to become competent at performing the laser capsulorhexis procedure.
- Injections –
    - Regarding injections, the doctors noted how rarely subconjunctival injections are performed. The doctors stated that it is not medically recommended or safe to perform subconjunctival injections in an office setting. They reported that a surgeon may give a subconjunctival injection prior to an intravitreal (or intraocular) injection (which the VOA stated they did not wish to include in an expanded scope), or before surgical removal of an eye ball tumor.
    - The ophthalmologists also noted that it was unusual to request to do intramuscular and intravenous procedures in an office setting and that the purpose of doing these injections (e.g., for which diseases or conditions) was unclear.
  - Removal of Growths and Lesions –
    - Regarding removal of growths and lesions, the ophthalmologists emphasized that knowing whether a growth or lesion is malignant or benign is often not clear when beginning a procedure. However, the doctors noted that, through frequent exposure to and experience with removing these growths and lesions, one can become better at predicting whether the condition is malignant or not. This experience and exposure, the doctors argue, comes from many years of medical education and training. Similarly, this education and training prepares providers in knowing how to suture and how to anticipate the way the skin will stretch and spread when cut. Providers without this experience may not anticipate that, for example, a small skin tag could result in a large wound needing significant suturing.
    - The ophthalmologists also note that the most recommended treatment for chalazions is to use warm compresses, not to surgically remove the chalazion or inject it with steroids.

## B. Evidence of Risk or Harm

The ophthalmologists provided anecdotal data about the safety risks of expanding the optometric scope of practice to include the proposed advanced procedures. Specifically, the doctors shared letters from ophthalmologists in Kentucky and Oklahoma (two states with expanded scopes of optometric practice)

who reported treating patients with complications resulting from botched and/or unnecessary optometrist-performed procedures.<sup>37</sup>

Despite these anecdotes, the ophthalmologists could not point to any outcomes data showing an increased risks of patient harm due to expanded optometric scopes of practice.<sup>38</sup> The doctors argued, however, that the default assumption, in the absence of outcomes data showing harm, should not be that the expanded scope is safe. Rather, when it comes to permitting individuals to perform surgery, the doctors argued that the patient is better protected if there is affirmative evidence showing safety.

### C. Malpractice Insurance Rates

The ophthalmologists contended that the malpractice premium rates are not good indications of the low risk of an expanded optometric scope of practice, as these rates are based on optometric practice in all states, not solely on those states where the proposed advanced procedures are permitted. The ophthalmologists provided a letter from the Ophthalmic Mutual Insurance Company (“OMIC”), which insures over 800 optometrists nationwide, stating that optometry malpractice insurance premiums remain low because most optometrists are not permitted to perform laser procedures, surgery or injections.<sup>39</sup> In turn, there are fewer “opportunities” for malpractice.<sup>40</sup> OMIC also notes in its letter that the optometric scope expansions are very recent in most states. Oklahoma was the first to expand the optometric scope of practice in 2004. The next state to expand the scope of practice was Kentucky in 2011, followed by Louisiana in 2014, Alaska in 2017 and Arkansas in 2019. Since malpractice cases take many years to adjudicate, OMIC states that the impact of any cases arising in these states with newly expanded scopes of practice would not yet be reflected in insurance premium rates.<sup>41</sup>

### D. Over-Utilization

The doctors argue that the repeated examination that they perform on all patients referred to them is essential for protecting patient safety. Dr. McNally estimated that, after a repeat examination, about one-third of patients referred to her by optometrists for advanced procedures do not need the advanced procedure for which they were referred. This is particularly true with capsulotomies, where patients may have some opacifications but there is no impact on vision and, thus, no procedure needed. She argued that the risk to these patients is not having a second exam but rather having an unnecessary surgical procedure which carries the inherent and heightened risks of all surgeries.

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<sup>37</sup> Cynthia A. Bradford, M.D., Letter to the Texas House of Representatives, *Re: Opposition to HB 1798 which would allow optometrists to perform eye surgery* (Oklahoma, February 25, 2019) and Woodford S. Van Meter, M.D., Letter to the Texas House of Representatives, *Re: Opposition to SB 2123 and HB 1798 which would allow optometrists to perform eye surgery* (Kentucky, March 4, 2019).

<sup>38</sup> The VOS provided a study from the Journal of the American Medical Association (“JAMA”) finding a significant increase in repeated YAG capsulotomy procedures when the initial procedure was performed by an optometrist. Joshua D. Stein, M.D. *et al*, “Comparison of Outcomes of Laser Trabeculoplasty Performed by Optometrists vs Ophthalmologists in Oklahoma”, *Journal of American Medical Association Ophthalmology* (July 28, 2016) available at [jamanetwork.com/journals/jamaophthalmology/fullarticle/2535226](http://jamanetwork.com/journals/jamaophthalmology/fullarticle/2535226).

<sup>39</sup> Timothy J. Padovese, *Statement on Optometric Malpractice Rates* (San Francisco, California: Ophthalmic Mutual Insurance Company, January 30, 2019).

<sup>40</sup> *Id.*

<sup>41</sup> *Id.*

## E. Education and Training

Dr. Gregory and Dr. McNally emphatically argued that a brief, one-to-two-day course in lasers or injections is wholly insufficient to prepare individuals to perform surgery. The doctors asserted that these brief courses on laser surgeries, injections and removal of growths cannot train optometrists in the complexities of systemic medicine, and teach optometrists how to safely perform procedures, address complications, and suture human tissue.

The doctors were unaware of any standardized, comprehensive curricula from U.S. schools of optometry that teach these essential components of laser surgeries, injections and removal of growths. However, as a contrast to optometric education, the doctors provided details of ophthalmology education and training, which follow.

- Ophthalmologists must complete eight years of education and training, including four years of medical school with a nationally standardized core curriculum, one year of internship and three years of residency. The first two years of medical school are spent learning the “basic science” of human biology and disease through class and laboratory work, including dissection and exploration of human cadavers. In the third and fourth years, medical students rotate through clinical assignments in which they gain hands-on experience with patients and a variety of diseases and conditions. While a medical student in their first 2 years in medical school may only have one-to-two lectures specific to the eye, the student will be gaining knowledge of the human body as a system which will inform their practice as an ophthalmologist. Further, during this time and during the third and fourth years, students get extensive training about human tissue (e.g., the texture and tendencies of different types of tissues when sutured), adhesions, needles, face structure and “line” following when suturing.
- Beginning in years three and four, those students who are interested in pursuing ophthalmology need to begin to develop ophthalmologic skills in order to get “matched” with a postgraduate internship and residency in ophthalmology. Good candidates for an ophthalmology internship and residency will have completed an ophthalmological clinical rotation at their home medical school and 2-3 clinical rotations at other medical schools and will have conducted relevant research. By the time a medical student is placed in an ophthalmological residency, they have a thorough and in-depth understanding of the human body in its entirety, as well as extensive knowledge about the eye, specifically.
- Ophthalmology students then enter their post-graduate internship and residency years. During the internship year, medical interns rotate through “fundamental clinical skills” education in “primary specialties” including “emergency medicine, family medicine, general surgery, internal medicine, obstetrics and gynecology, or pediatrics, or in primary critical care experiences (medical, surgical, or pediatric).”<sup>42</sup> This education continues the ophthalmology student’s education in suturing, surgery, systemic medicine, and conditions and disease. Medical interns also begin to observe and participate in ophthalmological clinics, procedures, and surgeries. Students will observe hundreds of procedures and patient interactions performed by physicians,

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<sup>42</sup> Accreditation Council for Graduate Medical Education, *ACGME Program Requirements for Graduate Medical Education in the Transitional Year*, 24 (eff. July 1, 2019).

as well as participating in some procedures and interactions. Throughout this internship, ophthalmology students are closely overseen by faculty and given only “conditional independence.”<sup>43</sup> There is a standardized process for evaluating a student’s progress toward becoming an “autonomous” practitioner based on the ACGME Program Requirements and associated “Milestones” evaluations.<sup>44</sup>

- After this “transitional year” of the internship, the ophthalmology student moves on to their residency. Typically, there are 3-4 residents in each program with 12-15 doctors participating in the mentorship and training of the residents. This allows for significant one-to-one mentoring, training and oversight. Every procedure, patient interaction and surgery the resident performs is overseen by a senior physician. If the resident seems unsure, makes a mistake or their hands shake, the senior physician takes over or remedies the error. Dr. McNally stated that these senior physicians will even tell a resident to choose a “non-surgical path” if improvement is not shown. These experiences take place entirely in a hospital, emergency department and associated clinics, where the acuity and pathology of disease and the needs of patients are often higher. Residents are on-call and must be available to “suture an eyeball or close a globe at 2AM” and to treat patients in varying states, including vomiting, shaking, and being uncooperative. By the end of their residency, all residents are required to have performed a “minimum number of procedures” for compliance with ACGME standards (e.g., a minimum of 5 YAG capsulotomy cases, 5 Laser Trabeculoplasty cases, 4 iridotomy cases, and 3 chalazion excisions).<sup>45</sup> However, the ophthalmologists note that residents perform hundreds of each of these procedures prior to finishing their residencies, and that the number of procedures completed are no longer logged after the ACGME requirements are met.

All of this experience results in a provider who has an extensive knowledge and understanding of the human body as a whole, who is aware of an expanse of diseases and conditions and how they present, who can think quickly and perform smoothly under stressful and varied conditions, and who has skill and comfort as a surgeon both when things go smoothly and when there are complications. Importantly, according to Dr. Gregory and Dr. McNally, this training also teaches ophthalmologists the judgment necessary to determine when a procedure is needed and to identify which patients are candidates for a procedure (i.e., when the benefits of a procedure outweigh the risks of the complications, based on a full understanding of the patient’s health).

#### F. Maintaining Competency

Finally, Dr. Gregory and Dr. McNally assert that there are not enough of the proposed advanced procedures performed in Vermont each year to ensure that optometrists seeing only these patients maintain competency. Dr. McNally provided procedure numbers from her own two-surgeon practice in Berlin, Vermont which takes referrals from 13 optometrists.<sup>46</sup> From January 2019 through October 2019,

<sup>43</sup> *Id.* at Preamble.

<sup>44</sup> Accreditation Council for Graduate Medical Education, *ACGME Program Requirements for Graduate Medical Education in Ophthalmology*, 17 (approved February 4, 2019; eff. July 1, 2020).

<sup>45</sup> Accreditation Council for Graduate Medical Education: Review Committee for Ophthalmology, *Required Minimum Number of Procedures for Graduating Residents in Ophthalmology* (2013).

<sup>46</sup> Practice Data, *Summary of Laser Usage in a 2 Surgeon Office in Berlin, VT with 13 Referring Community Optometrists* (January 2019 – October 2019).

each surgeon performed an average per month of 4 YAG capsulotomy procedures, 6-8 laser peripheral iridotomies, and 12 laser trabeculoplasties.<sup>47</sup> If these cases were then disbursed over 13 different optometrists, many of these providers would go months without performing a procedure. The doctors assert that this is not enough experience to maintain competence.

The doctors also note that there is no oversight of an optometrist's competence or measure of whether competence is maintained. In contrast, ophthalmologists must render a certain number of procedures to maintain privileges at hospitals and must maintain national board certifications through continuing education and re-taking the examination.<sup>48</sup>

### III. OPR's Findings Regarding Patient Safety and an Expanded Scope of Optometric Practice

#### A. Advanced Procedures

##### Primary Eye Care

Contrary to the VOA's contention, it is not clear to OPR that the proposed advanced procedures are "simple" and part of "primary eye care." Past assertions by the VOA indicate that the VOA did not always consider these procedures to be "primary eye care", either. During the 2003 Vermont optometric scope expansion report process, the VOA asserted that "surgical and tertiary medical eye care" went beyond "primary eye care." In his response to the President of the Vermont Ophthalmological Society's questions regarding the proposed 2003 scope expansion, Timothy Johnson, O.D., the then-legislative chairman of the Vermont Optometric Association, stated that "[o]phthalmologists receive extensive training for years in surgery and tertiary medical eye care *that optometrists do not receive...However, in areas where our [ophthalmologists' and optometrists'] scopes of practice do overlap (i.e. primary eye care), our basic health science background is comparable to medicine...*"<sup>49</sup>

The lack of a consistent, standardized curriculum for teaching these advanced procedures,<sup>50</sup> and the costly unique equipment required to perform them further indicates that these procedures are not part of primary eye care. Additional support for this conclusion is that laser, injection and minor surgical procedures are not included as "primary eye care" on the AOA's fact sheet detailing optometry education

<sup>47</sup> *Id.*

<sup>48</sup> The National Board of Examiners in Optometry – the organization that offers the exam that optometrists must currently pass to become licensed in Vermont – has recently (2019) begun to offer a Laser and Surgical Procedures Exam ("LSPE"). *Laser and Surgical Procedures Exam*, National Board of Examiners in Optometry, <https://www.optometry.org/lspe.cfm> (last visited January 15, 2020). This exam purports to evaluate competency in laser trabeculoplasty, iridotomy and capsulotomy in one section, and suturing, eyelid surgery, injections and anesthesia in a separate section. However, the exam is currently only offered at one location (Charlotte, North Carolina) and Dr. Barcelow was uncertain whether the exam is very "stringent". He suggested that the coursework out of Oklahoma and Kentucky optometry schools is more comprehensive for evaluation purposes.

<sup>49</sup> Vermont: Secretary of State, Office of Professional Regulation, *Report of S.54: Expanded Scope of Practice for Optometrists*, 17 (December 31, 2003) available at <https://www.sec.state.vt.us/media/411945/optometryscopereport.pdf> (emphasis added).

<sup>50</sup> While OPR was unable to obtain details of each U.S. optometry school's curriculum, it is clear to OPR that there are these advanced procedures are not taught consistently by all optometry schools in the country. For example, there is broad agreement, including from Dr. Barcelow, that certain schools, particularly Northeastern State University in Oklahoma, have a more rigorous and in-depth laser, surgical and injections program than other schools.

in the U.S., entitled “Doctors of Optometry Are America’s Primary Eye Care Providers”.<sup>51</sup> These considerations lead OPR to believe that the proposed advanced procedures are not “primary eye care.”

Nor can OPR conclude that these proposed advanced procedures are “simple.” The VOA encouraged the Office to review YouTube videos of the laser procedures as evidence of the simplistic nature of the procedures. The videos do show simplistic surgeries that are quick and seem noninvasive. However, these videos are clearly intended to be general overviews of the procedures directed at informing the layman patient. The videos show the effect of the laser on the eye (e.g., black spots appearing on an eye during a YAG capsulotomy) but do not explain or show the anatomical structures targeted by the laser or how the provider is placing or adjusting the laser. The VOS provided more in-depth videos of the procedures, which described the anatomical structures the laser was aimed at (e.g., “hair thin” lines), and the placement of the laser in “consecutive but not overlapping spots” to create the needed hole in the trabecular meshwork. These videos seem to show a much more complex procedure. OPR is not equipped with the expertise to know which presentation of the procedures is more accurate regarding complexity. Given the conflicting evidence, however, the Office is unable to conclude that these procedures are “simple”.

### Complications

As with the topic of simplicity, the VOA and the VOS urge opposite positions when it comes to the complications of these procedures. The VOS emphasizes the gravity of the complications while the VOA emphasizes the rarity thereof. The Office is not able to evaluate the severity of a complication or its frequency. That said, OPR finds that there is no evidence that, should a complication occur, optometrists are prepared to treat and/or correct the complication, thus minimizing severity and lasting impacts. An ophthalmologist, through his or her extensive training, is exposed to complications and learns various techniques and procedures to correct or address complications. There is no evidence that optometrists have similar experience or training. As noted below, if optometry schools teach these proposed advanced procedures at all, the courses are a small part of the curriculum and there is little to no experience with human patients.

Further, given that optometrists propose to perform these procedures in an office-based setting, there are no other providers who could offer support or guidance should a complication occur. If a complication should occur, an optometrist may need to transfer the patient to either another provider or a hospital setting, requiring more time for the procedure and added risk for the patient. Thus, though OPR cannot determine whether the complications associated with the proposed advanced procedures are severe or frequent, the Office finds that there is no evidence that an optometrist is trained or capable of addressing complications from these procedures.

## B. Other States’ Experiences

### States with Expanded Scopes of Practice

OPR considered the experiences with patient safety of other states that have expanded scopes of optometric practice – Oklahoma, Kentucky, Alaska, and Louisiana. OPR was particularly interested in

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<sup>51</sup> On this fact sheet, only “pre-operative and postoperative care before and after eye surgery” are listed as areas that optometrists are “highly specialized” in. *American Optometric Association. Doctors of Optometry are America’s Primary Eye Care Providers* [Fact Sheet]. Received July 24, 2019.



reports of complications, complaints from the public, and disciplinary records. The Office emailed the Board of Optometry in each state. Unfortunately, only the Oklahoma and Alaska Boards of Examiners in Optometry replied to OPR's inquiry.

The Executive Director of the Oklahoma Board reported that there have been no adverse outcomes reported to the Board of Examiners by any optometry patient between 1992 and 2019.<sup>52</sup> He did report that there were two malpractice cases settled out of court and a malpractice case, self-reported by the optometrist involved, alleging that the optometrist failed to refer a patient to an ophthalmologist in a timely manner. The Alaska Board of Examiners in Optometry reports that there have been no actions taken against an optometrist in the state since 2011.<sup>53</sup>

These reports are seemingly contradicted, however, by reports to the National Practitioner Data Bank ("NPDB"), a federal database of medical malpractice payments and certain adverse actions taken against health care providers, including optometrists.<sup>54</sup> According to the NPDB, between the years of 1992 and 2019, there were 59 malpractice payments and adverse events reported to the NPDB for Oklahoma optometrists.<sup>55</sup> This is much higher than the three cases reported by the Executive Director of the Oklahoma Board. Less striking, but nonetheless significant, while the Alaska Board only reports one discipline case against an optometrist since 2011, the NPDB reports five malpractice payments or adverse events from the State.<sup>56</sup> While the NPDB data does not offer conclusive evidence regarding whether the expanded scope of optometric practice has led to an increase in malpractice cases or adverse events, it does indicate that the professional boards in these states do not have a full understanding of the complications, adverse actions and malpractice cases occurring in the state.

An additional challenge is that the professional board members in Oklahoma, Kentucky and Louisiana are, themselves, optometrists, who have an interest in seeing the optometric scope of practice expanded nationally. This coupled with the seemingly inaccurate reports of adverse events, discipline and malpractice cases leads OPR to be reticent to rely on the reports of few to no adverse actions taken against optometrists as indicative of the safety of scope expansion.

There are also anecdotal reports from ophthalmologists in Oklahoma and Kentucky of adverse events resulting from the expanded scope of optometric practice. In March 2019, an ophthalmologist from the University of Kentucky submitted a letter to the Texas House of Representatives.<sup>57</sup> The Kentucky

<sup>52</sup> Laverty, Russel O.D., *RE: Vermont Secretary of State's Office of Professional Regulation seeking Optometrist Discipline Data*. Message to Dylan Bruce. Received November 6, 2019. (Email). In 1998, Oklahoma law permitted optometrists to perform procedures with anterior segment lasers. In 2004, the scope was again expanded to permit optometrists to perform non-laser surgery.

<sup>53</sup> Zimmerman, Marilyn A., *Records Request: Alaska Optometrist Discipline Data*. Message to Dylan Bruce. Received November 21, 2019. (Email).

<sup>54</sup> National Practitioner Data Bank, U.S. Department of Health and Human Services (2020). *Query on State-by-State Data Regarding Discipline and Malpractice Suits Against Optometrists* [Data file]. Retrieved from <https://www.npdb.hrsa.gov/guidebook/EOverview.jsp>. There are limits to the NPDB data. While OPR can determine how many malpractice payments have been made or adverse actions taken against optometrists in a specific state in a certain year, there is no information provided about the underlying malpractice case or adverse action. In turn, OPR is not able to determine whether the events reported in the NPDB are related to the proposed advanced procedures.

<sup>55</sup> *Id.*

<sup>56</sup> *Id.*

<sup>57</sup> Texas was considering a similar optometric scope expansion measure at the time.

ophthalmologist reported “a rise in surgical complications from the enactment of the Kentucky optometric scope legislation” (legislation which expanded the scope of practice to include the proposed advanced procedures), which went unreported to the state due to a lack of oversight and supervision.<sup>58</sup> In February 2019, an ophthalmologist at the University of Oklahoma College of Medicine also wrote a letter to the Texas House of Representative describing the “patient confusion and complications” she had seen due to the scope expansion in Oklahoma.<sup>59</sup> She reported cases in which optometrists failed to take medical histories and, as a result, performed an unnecessary and ineffective procedure in one case, and caused hemorrhaging in another case (due to failure to note that a patient was taking anticoagulants).<sup>60</sup> The Oklahoma ophthalmologist also reported numerous patients were referred to her for unnecessary procedures.<sup>61</sup>

#### States That Chose Not to Expand the Optometric Scope of Practice

Several states considered expanding the scope of practice for optometrists but decided against it. In 2009, the Washington State Department of Health (the “Department”) conducted a sunrise review on the proposal to expand the optometric scope of practice to include office-based medical procedures and to permit the administration of injectable medications, along with other practices.<sup>62</sup> Citing its mission to protect the public, the Department recommended against expanding the optometric scope of practice.<sup>63</sup> The Department’s reasons for recommending against permitting optometrists to perform office-based medical procedures were the lack of evidence of training in these procedures in optometry schools, a policy position of not wanting out-of-state optometry schools dictating Washington State policy through their curricula, the potential of laser procedures putting the public at risk, and optometric training not being the functional equivalent of ophthalmological training.<sup>64</sup>

Nebraska reviewed expanding the optometry scope of practice to include injections of medications and allowing minor surgical procedures in 2009 and 2014.<sup>65</sup> In 2009, a Technical Committee, created under Nebraska state law, recommended against expansion of the scope of practice concluding (1) the current scope of practice (i.e., optometrists were not permitted to perform minor surgical procedures or to inject medications) did not create a harm or a threat to the health, safety or welfare of the public; (2) the

<sup>58</sup> Woodford S. Van Meter, M.D., Letter to the Texas House of Representatives, *Re: Opposition to SB 2123 and HB 1798 which would allow optometrists to perform eye surgery* (Kentucky, March 4, 2019).

<sup>59</sup> Cynthia A. Bradford, M.D., Letter to the Texas House of Representatives, *Re: Opposition to HB 1798 which would allow optometrists to perform eye surgery* (Oklahoma, February 25, 2019).

<sup>60</sup> *Id.*

<sup>61</sup> *Id.*

<sup>62</sup> Washington: State Department of Health, *Optometry Scope of Practice Sunrise Review* (December 2009) available at <https://www.doh.wa.gov/portals/1/Documents/Pubs/631002OD.pdf>.

<sup>63</sup> *Id.* at 3.

<sup>64</sup> *Id.* at 11.

<sup>65</sup> Based on a Nebraska governmental process similar to the sunrise review process in Vermont, a Technical Committee was convened in 2009 to review an application from optometrists to expand their scope of practice. The Technical Committee voted to recommend against approval of the proposed scope expansion. Nebraska: Optometry Technical Review Committee, *Report of Recommendations and Findings* (October 16, 2009). In 2014, the Director of the Division of Public Health in the Nebraska Department of Health and Human Services then generated his own report, based on the Technical Committee’s report, also recommending against approval expanding the optometric scope of practice. Nebraska: Department of Health and Human Services, *Director’s Report on the Proposal to Expand the Scope of Practice of Optometrists* (March 10, 2014).

proposed scope expansion could potentially create a new danger to the public health, safety or welfare of the public; (3) the proposed scope expansion would not benefit the public health, safety or welfare; and (4) the public could be effectively protected by other means.<sup>66</sup> In his 2014 report, the Director of the Division of Public Health in the Nebraska Department of Health and Human Services concurred with the Technical Committee's decision.<sup>67</sup> The Director emphasized the lack of information about optometric training and education in his decision to recommend against expanding the optometric scope of practice.<sup>68</sup>

In 2005, New Mexico considered expanding the scope of optometric practice. The State does now permit optometrists to perform the non-laser removal, destruction or drainage of superficial eyelid lesions and conjunctival cysts. 16.16.18.8(A) NMAC (March 22, 2008). However, the State does not permit optometrists to perform laser procedures or to inject medications, except as necessary to perform removal of eyelid lesions and cysts. *Id.*

Not only the states have considered whether to expand the scope of optometric practice. In 2015, the U.S. Department of Veterans Affairs issued a Veterans Health Administration Directive specifying that "only ophthalmologists will be privileged to perform therapeutic laser procedures of the eye and the eyelids at the Department of Veterans Affairs (VA) medical facilities."<sup>69</sup>

#### C. Increased Risk for Repeat Surgeries

Based on experiences in other states and studies thereof, OPR remains concerned that expanding the optometric scope of practice could result in unnecessary and repeated advanced procedures. A study, reported in the October 2016 JAMA Ophthalmology, found that the need for repeat laser trabeculoplasty procedures nearly doubled when the initial procedure was performed by an optometrist rather than an ophthalmologist.<sup>70</sup> When considering expanding the optometric scope of practice, the New Mexico Human Services Department expressed similar concern that repeated procedures would be needed as optometrists developed "advanced surgical skills."<sup>71</sup>

#### D. No Evidence of Patient Safety Risk if Scope is Not Expanded

OPR found no evidence that the current system requiring referrals to an ophthalmologist impacted patient safety. OPR received seven emails from Vermont optometry patients sharing the challenges with having

<sup>66</sup> Nebraska: Optometry Technical Review Committee, *Report of Recommendations and Findings* (October 16, 2009).

<sup>67</sup> Nebraska: Department of Health and Human Services, *Director's Report on the Proposal to Expand the Scope of Practice of Optometrists* (March 10, 2014).

<sup>68</sup> *Id.*

<sup>69</sup> VHA Directive 1132, *Performance of Therapeutic Laser Eye Procedures in Veteran Health Administration Facilities* (May 5, 2015).

<sup>70</sup> Stein, Joshua M.D. *et al*, "Comparison of Outcomes of Laser Trabeculoplasty Performed by Optometrists vs Ophthalmologists in Oklahoma", *Journal of American Medical Association Ophthalmology* (July 28, 2016) available at [jamanetwork.com/journals/jamaophthalmology/fullarticle/2535226](https://jamanetwork.com/journals/jamaophthalmology/fullarticle/2535226). The AOA objected to the study's findings, arguing that the need for repeat laser trabeculoplasty procedures are not due to the quality of the procedure but rather a choice to use an "acceptable method" of performing the procedure in split sessions.

[<https://www.aoa.org/news/clinical-eye-care/trabeculoplasty-commentary>]

<sup>71</sup> New Mexico: Legislative Finance Committee, *Fiscal Impact Report: Amend Optometry Act, 2* (March 7, 2005).

to go to an ophthalmologist rather than receiving care from their optometrist. These patients all expressed difficulties with wait times and travel, but none reported experiencing adverse outcomes due to the referral and wait.

#### E. Malpractice Insurance Rates

OPR does not find that low malpractice rates indicate that expanding the optometric scope of practice is safe for the public. As noted by VOS and OMIC, malpractice insurance premium rates are based on the practice of optometrists in all states, not just those with expanded scopes of practice. Thus, given that there are only a few states that permit expanded scopes of practice and most optometrists do not perform laser procedures, injections or other minor surgical procedures, malpractice insurance rates have remained low for optometrists.<sup>72</sup> Additionally, premium rates remain low because scope expansion in those states that have allowed it is relatively new and malpractice cases can take years to settle or move through the courts.<sup>73</sup> In turn, any malpractice cases from these states would not yet be factored into the premium calculation.<sup>74</sup>

#### F. Volume Needed for Competence

It is not clear that Vermont optometrists would be able to maintain competence in these proposed advanced procedures given the low volume of the procedures performed in Vermont. The VOS' data survey data shows that these procedures are not frequently required. Other rural states considering expanding the optometric scope of practice also noted the low volume of these procedures.<sup>75</sup> Even in those states with expanded scopes of practice, optometrists performed only a few of each of the procedures (e.g., 180 chalazion removals, 87 eyelid abscess removals and 55 lid lesion removals between 2008 and 2014 in Oklahoma, Kentucky and New Mexico).<sup>76</sup>

#### G. Education and Training

##### Optometry Schools

OPR is unable to conclude that optometry schools provide consistent and adequate education and training in the proposed advanced procedures. In response to OPR's request for additional information about the curricula of U.S. schools of optometry, ASCO, the national trade association for optometry schools, shared its Framework for Developing Optometric Curriculum Guidelines and Educational Standards for Advanced In-Office Primary Care Ophthalmic Procedures ("Framework").<sup>77</sup> The Framework contemplates that

<sup>72</sup> Timothy J. Padovese, *Statement on Optometric Malpractice Rates* (San Francisco, California: Ophthalmic Mutual Insurance Company, January 30, 2019).

<sup>73</sup> *Id.*

<sup>74</sup> *Id.*

<sup>75</sup> Nebraska: Optometry Technical Review Committee, *Report of Recommendations and Findings*, 5 (October 16, 2009).

<sup>76</sup> Sanders, David S. M.D., Alan Sugar, M.D., Chris Andrews, PhD, Joshua Stein, M.D., M.S., University of Michigan (2017), *A Comparison of Performance of Therapeutic Procedures by Ophthalmologists and Optometrists in States with Expanded Scope of Practice* [Fact sheet] available at <https://pdfs.semanticscholar.org/c106/a504a522ab2677570d315221a0c33b63c071.pdf>.

<sup>77</sup> Association of Schools and Colleges of Optometry: ASCO Board of Directors, *Framework for Developing Optometric Curriculum Guidelines and Educational Standards for Advanced In-Office Primary Care Ophthalmic Procedures* (approved November 6, 2018).

optometric students will be able to demonstrate “appropriate use, indication, and action of ophthalmic ultraviolet, visible, and infrared radiation LASER procedures”, including for the performance of “trabeculoplasty, post-cataract capsulotomy, peripheral iridotomy, and corneal modification for refractive changes.”<sup>78</sup> The Framework also states that optometric students shall, upon graduation, “demonstrate the psychomotor and cognitive skills necessary” to remove lesions and growths, and to perform injections.<sup>79</sup> No information is provided about how these skills are taught in optometry schools (e.g., practical experience, amount of time devoted to each procedure), however, nor is there information about how these competencies are assessed upon graduation.<sup>80</sup>

The schools themselves were not willing to share syllabi or curriculum descriptions beyond course catalogs and brief course overviews. From these scant descriptions, the Office found that, if the proposed advanced procedures were taught at all, they were taught as one of several topics in a short course. Northeastern State University Oklahoma College of Optometry, widely regarded as the most rigorous of the optometry schools in matters of advanced procedures, offers several courses on advanced procedures and experience with human tissues and four courses regarding surgical procedures.<sup>81</sup> However, no other schools offered this number of courses or depth of coursework. For example, in 2009, Pacific University’s curriculum offered 4,811 contact hours, 1260 of which were in a clinical setting.<sup>82</sup> Ten of those hours related to providing injections. At Midwestern University Arizona College of Optometry, there is a course offered called “Advanced Ophthalmic Procedures” which addresses, among other things, “an introduction to physical assessment therapeutic ophthalmic lasers; intraocular, subcutaneous, intramuscular, and intravenous injections; and other advanced procedures.”<sup>83</sup> This course, offered in the winter of the third year, is four credits out of 252 credits required for graduation and there is no lab component.<sup>84</sup> The Illinois College of Optometry offers more courses – three – that provide education on advanced procedures.<sup>85</sup> The injections and minor surgical procedures course requires a total of six hours of lab and 18 hours of lecture.<sup>86</sup> The ophthalmic lasers course requires about six hours of lab and six hours of lecture. There is also a clinical rotation offered in advanced eyecare where students observe ophthalmic care.<sup>87</sup> This rotation offers about 24 hours of total observation.<sup>88</sup>

<sup>78</sup> *Id.* at 8 citing Standard C.7.

<sup>79</sup> *Id.* at 9-10 citing Standards C.8.-C.14.

<sup>80</sup> There is a document on ASCO’s website instructing schools on how to create an outcome assessment. The information is general, however, and not specific to each skill or procedure.

<sup>81</sup> *NCUOCO Course Catalog*, Northeastern State University Oklahoma College of Optometry, <https://optometry.nsuok.edu/Portals/5/PDF%20Files/nsuoco-course-catalog.pdf> (last visited January 15, 2020).

<sup>82</sup> Washington: State Department of Health, *Optometry Scope of Practice Sunrise Review*, 75-76 (December 2009) available at <https://www.doh.wa.gov/portals/1/Documents/Pubs/631002OD.pdf>.

<sup>83</sup> *Course Descriptions Arizona College of Optometry, OPTOG 1729: Advanced Ophthalmic Procedures*, Midwestern University Arizona College of Optometry, <https://www.midwestern.edu/glendale-az-campus-catalog/arizona-college-of-optometry/course-descriptions.xml> (last visited January 15, 2020).

<sup>84</sup> *Id.*

<sup>85</sup> *Course Catalog: OCD 368 Injections and Minor Procedures, OCD 369 Ophthalmic Lasers, and PCE 371 Specialty Rotation (Advanced Eyecare)*, Illinois College of Optometry (last visited January 15, 2020). The estimates of total time spent in lab, lecture and clinical rotation, provided herein, are based on the hours per week requirements in the course description and the total length of the semester.

<sup>86</sup> *Id.*

<sup>87</sup> *Id.*

<sup>88</sup> *Id.*

OPR further found that the courses on advanced procedures were mainly didactic in nature. Practical experience with human patients and advanced procedures was minimal if at all. While optometry students do complete basic science courses at the beginning of their education, like medical students, most optometric students do not also have a lab experience performing dissections on human cadavers. (Northeastern State University in Oklahoma does use cadaver dissection in its first-year labs.)<sup>89</sup> If any practical experience is offered, animals and computer models are more likely the subjects.<sup>90</sup>

Even the most in-depth and comprehensive optometry school program at Northeastern State University, however, is not the functional equivalent of ophthalmology training.<sup>91</sup> Medical education is highly standardized and consistent across schools and much more extensive than optometric training in the proposed advanced procedures. This education and training contribute significantly to patient safety. During their training, ophthalmologists see all manners of disease in various forms of manifestation. They are trained with direct oversight from experienced physicians on how to perform procedures, and they perform these procedures hundreds of times before they do so on their own. Ophthalmologists not only learn about the eye and related diseases and conditions, but they learn about other diseases, the impacts of disease on the entire anatomical system, how to suture human tissue, clinical judgment and how to address complications as they arise. While OPR cannot conclude that 16,000 hours of training is necessary to safely perform the advanced procedures proposed by the VOA, it is clear to OPR that more than one or two, short, lecture-based courses are needed to prepare a provider to safely render these procedures.

### Continuing Education

OPR also finds that a two-day continuing education course on the proposed advanced procedures is likely insufficient to prepare an optometrist to perform these on his or her own in a private office. A sample course curriculum on injections provided in the 2009 Washington policy report states that it is a two-day course, with one to four hours spent learning about and practicing each procedure.<sup>92</sup> Each procedure is practiced on a lab partner. The AOA offers a 16-hour course at its annual meeting teaching “the skills necessary to perform surgery in a primary eye care setting, including suture techniques, injections, anesthesia, wound management and other procedures.”<sup>93</sup> Both courses offer 8 hours of lab time and 8 hours of lecture.<sup>94</sup> There is a separate 16-hour Laser Procedures Certification course, providing “training for performing anterior segment laser procedures, including YAG capsulotomy, laser peripheral iridotomy,

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<sup>89</sup> *NCUOCO Course Catalog: Course 4167 Human Anatomy and Physiology*, Northeastern State University Oklahoma College of Optometry, <https://optometry.nsuok.edu/Portals/5/PDF%20Files/nsuoco-course-catalog.pdf> (last visited January 15, 2020).

<sup>90</sup> Schroeder, Michael, “Optometrists, Ophthalmologists Fight Over Eye Care Rights”, *Angie’s List* (June 16, 2011) available at [www.angieslist.com/articles/optometrists-ophthalmologists-fight-over-eye-care-rights.htm](http://www.angieslist.com/articles/optometrists-ophthalmologists-fight-over-eye-care-rights.htm) and *Student Catalog: OPT 516 Gross Anatomy, Histology & Radiographic Techniques*, 54, University of Kentucky College of Optometry, <https://www.upike.edu/wp-content/uploads/2019/09/KYCO-Catalog-2019-2020.pdf> (last visited January 15, 2020).

<sup>91</sup> Washington: State Department of Health, *Optometry Scope of Practice Sunrise Review*, 11 (December 2009) available at <https://www.doh.wa.gov/portals/1/Documents/Pubs/631002OD.pdf>.

<sup>92</sup> *Id.* at 49-52.

<sup>93</sup> *Need CE? Look no further than Optometry’s Meeting®*, American Optometric Association, <https://www.aoa.org/news/inside-optometry/continuing-education-optometrys-meeting-2019> (last visited January 15, 2020).

<sup>94</sup> *Id.*



gonioscopy, laser trabeculoplasty and other procedures.”<sup>95</sup> It is difficult to see how such a short course could prepare providers to perform these procedures and to address all complications that arise, let alone provide additional training in counter-indications for surgery and the clinical judgment of when surgery is needed.

For the above reasons, OPR is unable to conclude that expanding the optometric scope of practice to include the proposed advanced procedures would be in the interest of protecting public safety.

### **Need and Access**

Proponents of expanding the optometric scope of practice argue that Vermont’s eye patients face barriers to accessing these services, including such barriers as distance and wait time. Supporters of an expanded scope also argue that Vermont patients need to have a choice of providers when determining whether to undergo one of the proposed advanced procedures. Those opposed to the scope expansion argue that the current system of care – one in which optometrists refer patients to ophthalmologists to undergo the proposed advanced procedures – is functioning well and there are few if any access issues. Opponents further argue that, due to confusion in the marketplace, patients would not have a real, informed choice of providers should optometrists be permitted to perform the proposed advanced procedures.

Based on the evidence and research collected, OPR could not conclude that there is an issue with accessing these proposed advanced procedures in Vermont. OPR is also concerned that permitting optometrists to perform these procedures would create additional confusion in the marketplace about optometric training and education, and about the distinction between optometrists and ophthalmologists. This would negatively impact a patient’s ability to make an informed choice about care.

#### *I. Support for Scope Expansion: Access Challenges and Need for Choice*

##### **A. Access**

The VOA states that a combination of long wait times, long drives and redundant care create an access problem for Vermont patients. These barriers result in delayed care and increased risks for noncompliance with care. OPR asked the VOA to contact patients and have them speak with the Office about challenges the patients faced accessing care related to the proposed advanced procedures. Seven patients responded, two of whom sent their responses through Dr. St. Marie and two more of whom responded to a list of questions Dr. St. Marie presented to them. The following are summations of these patients’ concerns regarding traveling to ophthalmologists for the advanced procedures:

- One patient was initially seeing an ophthalmologist 2.5 hours from her home but is currently seeing an ophthalmologist 25 minutes from her home and is pleased with her current situation.
- Another patient shared the challenge of getting to Burlington or Dartmouth from Stowe for her appointments, especially given her inability to drive in bad weather.
- One patient reported that for each of his appointments with the ophthalmologist, first for an exam and then for the laser procedure, he had to have his wife drive him and wait for him during the procedure.
- Another patient had to travel 15-20 minutes each way to receive care from the ophthalmologist.

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<sup>95</sup> *Id.*



Another concern voiced by the VOA and the seven patients who contacted OPR was the long wait times for care from an ophthalmologist.

- Several of the patients who contacted OPR expressed preference for receiving the laser procedure on the same day they were there for their exam appointments.
- One patient was referred to Dartmouth Hitchcock Medical Center for an advanced procedure and had to wait so long for an appointment at that facility that he had to pay an additional insurance deductible. The patient did not report this delay to his optometrist and did not seek a referral to another ophthalmologist in Vermont.
- One patient from St. Albans reported seeing the ophthalmologist within two weeks for a repeat exam but having to wait 72 days (from his initial referral) for the first laser treatment and 97 days for the second laser treatment.
- Another patient from Richford was seen by an ophthalmologist within a month of the day he was referred for treatment and received laser treatments in 12 days (for one eye) and 21 days for the other.
- A third patient from St. Albans, whose story was related through Dr. St. Marie, stated that she had to wait 50 days after her referral from Dr. St. Marie to see an ophthalmologist for her initial exam. Her laser surgeries were performed 82 days and 118 days after the initial referral.
- Dr. St. Marie also related the story of a patient who was referred to an ophthalmologist in April and missed his first exam in June. Then, because of scheduling conflicts on both sides, his first exam was not until August. His laser surgeries eventually occurred in November and December.

In sum, three of the seven patients who contacted OPR regarding delays in care after being referred to a Vermont ophthalmologist were by seen that ophthalmologist for an initial exam within 4 weeks. Two patients experienced longer delays: one patient experienced a delay of 50 days before her first appointment, and one patient experienced a delay at Dartmouth-Hitchcock Medical Center. One patient missed his initial appointment, and one patient did not report how long it took for her initial appointment to be scheduled.

The VOA also noted that allowing optometrists to perform advanced procedures would help address access issues in emergencies when a lack of access to care may mean that a patient will go blind in days.

Finally, the VOA stated that, even if there are ophthalmologists nearby, they may be specialists who do not treat patients needing routine care. Thus, geographic proximity of ophthalmologists does not necessarily indicate that patients have access to advanced procedures.

#### B. Patient Choice

The VOA argued that patients should have a choice in providers. In support of this contention, the VOA shared a study performed by Avalon Health Economics (“Avalon”), a consultancy firm engaged by the AOA. In this study, Avalon avers that “80% of American voters when it comes to their eye health, report[ed] they’d rather have easy access to a doctor of optometry than have to travel further or wait longer to schedule with a specialist.”<sup>96</sup> Similarly, many of the patients who sent OPR emails about their

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<sup>96</sup> Schneider, John E. PhD and Cara M. Scheibling, “Optometry’s Essential and Expanding Role in Health Care: Assured Quality and Greater Access for Healthier Communities”, *Avalon Health Economics* (June 20, 2019)

experiences expressed a preference for receiving care from their optometrist with whom they had a longstanding relationship.

## II. Opposition to Scope Expansion: No Access Issues and Creating Confusion

### A. Access

In support of its position that there is not a problem with access to ophthalmic care in Vermont, VOS provided a map showing that 79.3% of Vermonters live within a 30-minute drive of an ophthalmologist's office. (Some of those offices are located in New Hampshire, New York or Massachusetts.) VOS also presented a map based on 2016 Medicare data showing that YAG capsulotomy procedures were performed in nine locations across all regions of the state, including locations in the Northeast Kingdom, around Rutland, in Windham and Bennington Counties, and in central and Northwestern Vermont.

VOS also pointed out that, in other states with expanded scope of optometric practice, most optometrists offering advanced procedures are located in urban locations in order to have enough patients to justify the costs of the equipment and to maintain competency. The patients in rural areas remain unserved.<sup>97</sup>

Additionally, VOS presented its findings from a survey it conducted of 28 ophthalmologists across the State of Vermont regarding wait times for procedures. The findings are as follows:

- For YAG capsulotomies and laser iridotomies, 85% of respondents said they could see a patient in less than 2 weeks and 100% of respondents said they could see the patient in 4-8 weeks.
- For laser trabeculoplasty (ALT/SLT), 82% of respondents said that they could see a patient for an initial exam in less than 2 weeks and 100% of respondents could see a patient in 4-8 weeks.
- 19/26 (73%) of responding ophthalmologists perform eyelid surgeries. 78% said they could do so in less than 2 weeks from the initial referral and 100% said they could do so in less than 4 weeks.
- The respondents noted that, if the eyelid surgery had to be performed at the hospital, there would be longer wait times due to scheduling OR time.
- 96% of providers said they could accommodate procedures in one week with a request from a referring provider and immediately if urgent.
- The VOS also noted that acceptance of insurance is a key to patient access to care. 100% of providers who responded to the VMS/VOS survey accept Medicaid payment.<sup>98</sup>

### B. Patient Choice

Ophthalmologists emphasized that they, too, are local providers with relationships with patients. The VOS also argued that the public does not have enough information to make an informed choice about care when it comes to choosing between an optometrist and an ophthalmologist because of confusion

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available at [https://avalonecon.com/optometrys-essential-and-expanding-role-in-health-care/?fbclid=IwAR3YUAWbhBjCix\\_fEdDvkFon-O8W2Lh3yNnVLh\\_Y3i3OcjFpQQk5K4wyXA](https://avalonecon.com/optometrys-essential-and-expanding-role-in-health-care/?fbclid=IwAR3YUAWbhBjCix_fEdDvkFon-O8W2Lh3yNnVLh_Y3i3OcjFpQQk5K4wyXA).

<sup>97</sup> Stein, Joshua D. M.D. *et al*, "Access to Ophthalmologists in States Where Optometrists Have Expanded Scope of Practice", *Journal of American Medical Association Ophthalmology* (November 22, 2017) available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5833600/?report=printable>.

<sup>98</sup> Vermont Ophthalmological Society, *Vermont Ophthalmology Survey on Access to Laser and Eyelid Surgery* (conducted in October 2019).

over the differences between the professions. VOS provided an AMA study showing that 47% of those surveyed believed optometrists were physicians, and 10% were not sure.<sup>99</sup> The survey also showed that 89% of respondents wanted only an M.D. or O.D. to be allowed to perform surgical procedures.<sup>100</sup>

### III. OPR Findings

#### A. Access

##### Access in Vermont

There are 130 licensed optometrists and 80 licensed ophthalmologists in Vermont.<sup>101</sup> Figure 1, in Appendix A, shows the locations of each of these providers. As shown on the map, there are only a few optometrists located in areas where there are no ophthalmologists. Similarly, there are only a few ophthalmologists located in areas without optometrists.

As shown on Figures 2 and 3 included in Appendix A, all Vermonters, except those living in a small area of the Northeast Kingdom, live within 30 miles of an ophthalmologist. Notably, there are no optometrists within 30 miles of the area in the Northeast Kingdom that is more than 30 miles from an ophthalmologist.

OPR is not able to find that there is a dearth of ophthalmologists in Vermont or that they are located far away from patients needing their services. All of the patients who contacted OPR report traveling 30 miles or less to see the ophthalmologist. The geographic data similarly shows that the vast majority of Vermonters lives within 30 miles of an optometrist. Further, when the geographic data is considered, it appears that most optometrists and ophthalmologists are located in the same towns or within a few miles of each other. Thus, permitting optometrists to perform these proposed advanced procedures would not reduce driving time for most patients.

Nor is OPR able to conclude that patients are experiencing inappropriately long wait times for eye care in Vermont. Only two patients provided evidence that they experienced a delay of longer than 4 weeks before their initial appointments with an ophthalmologist. Regarding the delays between the initial appointment and the laser treatments, there are considerations outside of capacity, and specific to patient care, that may be the source of these delays. Rather than opine that the time between initial examination and the advanced procedure was too long, OPR defers to the ophthalmologists, who examined the patients and concluded that the procedures did not need to be performed immediately, to determine the course of patient treatment.

OPR further notes that none of the patients who contacted OPR experienced any disease consequences due to the wait between the initial exam and the procedures. Nor did the optometrists in these cases think the need for the procedures was so urgent that they called and sought faster treatment for their patients. Considering the short wait times for an initial exam, deference to the ophthalmologists' professional judgment, and the lack of disease impact, OPR cannot conclude that Vermont patients are experiencing inappropriate long wait times for these proposed advanced procedures.

<sup>99</sup> American Medical Association, *Truth in Advertising Survey Results* (2018).

<sup>100</sup> *Id.*

<sup>101</sup> *Provider Lookup*. Vermont Medicaid Portal. <http://vtmedicaid.com/#/providerLookup>. Accessed in July 2019.

For these reasons, OPR does not find that there is an issue with access to these advanced procedures in Vermont that expanding the optometric scope of practice would fix.

#### Access in States with Expanded Scopes of Practice

A review of the research demonstrates that expanding the optometric scope of practice will not necessarily address access issues for rural patients. A 2018 JAMA Ophthalmology article found that, in Oklahoma, a state with an expanded scope of practice, only 12.2% of the advanced procedures performed by optometrists were performed in areas more than an hour away from the nearest ophthalmologist.<sup>102</sup> In Kentucky, only 0.8% of advanced procedures performed by an optometrist occurred in locations more than an hour away from an ophthalmologist.<sup>103</sup> In New Mexico, which does not permit optometrists to perform laser procedures but allows non-surgical removal of lesions and cysts, 34.8% of advanced procedures performed by an optometrist were conducted in a location more than an hour away from an ophthalmologist.<sup>104</sup> In these states, optometrists who perform these advanced procedures were located in more urban areas and patients in rural areas did not see improved access.

#### B. Patient Choice

OPR notes that the patients who contacted OPR, either directly or through their optometrists, had good relationships with their optometrists and wished to receive advanced procedures care from them. The Office is also aware, however, that there is evidence that the public does not have the information to make an informed choice between receiving care from an optometrist or an ophthalmologist. In a survey conducted by Angie's List, 93% of respondents claimed to know the difference between ophthalmologists and optometrists.<sup>105</sup> However, 25% of these respondents then went on to incorrectly identify optometrists as medical doctors.<sup>106</sup> The AMA study provided by VOS shows similar confusion.<sup>107</sup>

OPR is concerned that permitting optometrists to perform procedures traditionally performed by medical doctors would further obscure the distinctions between optometrists and ophthalmologists, and their respective education and training, thus creating more confusion among the public. In turn, OPR finds that maintaining the current optometric scope of practice would better serve the goal of helping the public make an informed choice about their care providers.

#### **Cost**

##### *I. Support for Scope Expansion: A Reduction in Redundancy and Other Costs*

The VOA admits that there may be a short-term increase in the number of laser procedures performed if the optometric scope of practice is expanded. The VOA argues, however, that long-term costs will decrease if the optometric scope of practice is expanded because a repeat exam performed by an

<sup>102</sup> Stein, Joshua D. M.D. *et al*, "Access to Ophthalmologists in States Where Optometrists Have Expanded Scope of Practice", *Journal of American Medical Association Ophthalmology* (November 22, 2017) available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5833600/?report=printable>.

<sup>103</sup> *Id.*

<sup>104</sup> *Id.*

<sup>105</sup> Schroeder, Michael, "Optometrists, Ophthalmologists Fight Over Eye Care Rights", *Angie's List* (June 16, 2011) available at [www.angieslist.com/articles/optometrists-ophthalmologists-fight-over-eye-care-rights.htm](http://www.angieslist.com/articles/optometrists-ophthalmologists-fight-over-eye-care-rights.htm).

<sup>106</sup> *Id.*

<sup>107</sup> American Medical Association, *Truth in Advertising Survey Results* (2018).

ophthalmologist will not be needed, and patients won't need to take additional time off from work or make long drives multiple times. VOA also argues that shorter wait times will reduce costs by improving patient compliance with care, thus avoiding increased morbidity associated with not caring for the disease, and by allowing patients to stop taking medications, which are used to treat the symptoms of the disease, faster. The Avalon study further estimated that "scope of practice expansion adds \$600 million per year in transaction costs savings and another \$4 billion per year in savings attributable to access-related improvements in health outcomes."<sup>108</sup>

The VOA also argues that the facility fee charged by hospitals will be saved when the procedure is performed in an office setting and that the increased number of providers in the market place will increase competition and drive down costs for laser procedures.

OPR also takes note of a patient commented that the prescription medications he takes to treat the symptoms of his eye disease cost \$400 every month. As a result, the 4 months it took for him to receive laser surgery cost him over \$1000 for medications, in addition to missing work and having to travel. He stated that, had he been able to receive the laser treatment from his optometrist on the same day he was diagnosed, he would have been saved those costs for medications.

Regarding the cost of equipment, the VOA says that the cost of equipment is minimal and can be handled by most optometry practices.

#### *II. Opposition to Scope Expansion: No Cost Savings*

The VOS contends that repeat examinations by ophthalmologists are necessary to prevent ophthalmologists from performing unnecessary or inappropriate procedures, which can save costs. Dr. McNally reports that about one-third of the patients referred to her by optometrists for a procedure do not need that procedure but can be managed through medication or other treatments. VOS argues this shows that, should the scope of practice be expanded, costs could actually increase due to over-utilization of these advanced procedures by optometrists who have not developed the clinical judgment to know when such a procedure is needed.

The VOS also states that the equipment to perform these advanced procedures, specifically the lasers, is expensive. Consequently, VOS contends, optometrists will need to see more patients to pay for the equipment or increase costs for other patients.

#### *III. OPR Findings*

OPR finds that permitting optometrists to perform the proposed advanced procedures will eliminate the need for a repeated exam by an ophthalmologist and may result in patients taking less time off work and traveling less. However, it is less clear that a scope expansion will lead to the realization of money or health care system savings. The VOS contends, and the VOA admits, that utilization would increase if the scope of optometric practice were expanded. As Medicare and Medicaid provide the same

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<sup>108</sup> Schneider, John E. PhD and Cara M. Scheibling, "Optometry's Essential and Expanding Role in Health Care: Assured Quality and Greater Access for Healthier Communities", *Avalon Health Economics* (June 20, 2019) available at [https://avalonecon.com/optometrys-essential-and-expanding-role-in-health-care/?fbclid=IwAR3YUawbhBjCix\\_fEdDvkFon-O8W2Lh3yNnVLh\\_Y3i3OcjFpQQk5K4wyXA](https://avalonecon.com/optometrys-essential-and-expanding-role-in-health-care/?fbclid=IwAR3YUawbhBjCix_fEdDvkFon-O8W2Lh3yNnVLh_Y3i3OcjFpQQk5K4wyXA).

reimbursement regardless of whether a procedure is performed by an optometrist or ophthalmologist, OPR can thus conclude that costs would increase based on utilization, at least in the short-term.

Additionally, OPR cannot conclude that there will be long-term, net cost savings if the optometric scope of practice is expanded. For instance, there is some evidence that permitting optometrists to perform these advanced procedures may result in an increased number of repeated procedures. A 2016 JAMA Ophthalmology study found a significant increase in the rate of repeated trabeculectomy procedures required when optometrists performed the initial procedure.<sup>109</sup> When New Mexico considered scope expansion, the New Mexico Human Services Department estimated that the number of procedures would increase “because the learning curve for developing advanced surgical skills would necessitate that numerous ‘re-dos’ be performed by ophthalmologists to fix problems caused by less experienced practitioners.”<sup>110</sup> The New Mexico Health Services Department estimated that the cost for the “re-dos” would be over \$200,000 in the State Medicaid budget.<sup>111</sup>

Nor is OPR inclined to rely on the unsupported cost savings cited by the Avalon study provided by the VOA. This study provides no explanation about the “cost-benefit analysis” that calculated the \$4.6 billion in savings, nor does it provide any additional information about what “transaction costs” or “access-related improvements in health outcomes” resulted in such significant cost savings.<sup>112</sup>

Further, the hospital facility fees that VOA considers as a long-term savings are already being “saved” by ophthalmologists, who provide these advanced procedures in their offices rather than in a hospital. In the survey of 28 ophthalmologists, conducted by VOS, only 2 stated that they regularly used hospital facilities to perform advanced procedures.<sup>113</sup> In turn, no savings of the “facility fee” would be realized from also permitting optometrists to perform these procedures in their offices.

Regarding equipment, OPR estimates the cost to purchase the equipment for SLT and YAG lasers would cost \$30,000 to \$50,000. A recent search yielded a refurbished SLT laser selling on eBay for \$17,900, and a combination refurbished YAG/SLT laser selling for \$49,995. OPR received a price quote of \$13,950 for a refurbished YAG laser from Insight Eye Equipment, an ophthalmic equipment vendor headquartered in St. Louis, Missouri. There are likely other costs associated with providing such a procedure that OPR is

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<sup>109</sup> Joshua D. Stein, M.D. *et al*, “Comparison of Outcomes of Laser Trabeculectomy Performed by Optometrists vs Ophthalmologists in Oklahoma”, *Journal of American Medical Association Ophthalmology* (July 28, 2016) available at [jamanetwork.com/journals/jamaophthalmology/fullarticle/2535226](http://jamanetwork.com/journals/jamaophthalmology/fullarticle/2535226). The AOA alleges this study is inaccurate because repeated trabeculectomy sessions is “an acceptable model” of care. *Criticized Laser Study Resurfaces in Scope Battles*, American Optometric Association, <https://www.aoa.org/news/clinical-eye-care/trabeculectomy-commentary> (last visited January 15, 2020).

<sup>110</sup> New Mexico: Legislative Finance Committee, *Fiscal Impact Report: Amend Optometry Act, 2* (March 7, 2005).

<sup>111</sup> *Id.*

<sup>112</sup> Schneider, John E. PhD and Cara M. Scheibling, “Optometry’s Essential and Expanding Role in Health Care: Assured Quality and Greater Access for Healthier Communities”, *Avalon Health Economics* (June 20, 2019) available at [https://avalonecon.com/optometrys-essential-and-expanding-role-in-health-care/?fbclid=IwAR3YUAWbhBjCix\\_fEdDvkFon-O8W2Lh3yNnVLh\\_Y3i3OcjFpQQk5K4wyXA](https://avalonecon.com/optometrys-essential-and-expanding-role-in-health-care/?fbclid=IwAR3YUAWbhBjCix_fEdDvkFon-O8W2Lh3yNnVLh_Y3i3OcjFpQQk5K4wyXA).

<sup>113</sup> Vermont Ophthalmological Society, *Vermont Ophthalmology Survey on Access to Laser and Eyelid Surgery* (conducted in October 2019).

unaware of and, thus, unable to estimate. A 2009 article stated that purchasing all the equipment needed to perform advanced procedures could cost up to \$500,000.<sup>114</sup>

Based on equipment costs, the JAMA and New Mexico research, and the predicted increased utilization accompanied by equivalent per-procedure reimbursement, OPR cannot find that expanding the optometric scope of practice to include these proposed advanced procedures would result in any costs savings.

### Conclusion

At this time, OPR recommends against the expansion of the optometric scope of practice to include the proposed advanced procedures. This conclusion is affected significantly by our inability to confirm that clearly-established and appropriately-tailored didactic and in vivo education and training in specified procedures is universal to accredited educational programs. Consistent with Title 26, Ch. 57, we analyze licensing restrictions, including those derived from scope limitations, with the presumption that the public and licensees alike are best served when professionals are lawfully empowered to offer services commensurate with the full scope of their training. Future evolution in optometric graduate education could warrant reevaluation of these conclusions.

*Respectfully submitted to the House and Senate Committees on Government Operations, the House Committee on Health Care, and the Senate Committee on Health and Welfare.*

STATE OF VERMONT  
SECRETARY OF STATE  
OFFICE OF PROFESSIONAL REGULATION

BY:



Lauren K. Layman  
Staff Attorney

January 15, 2020  
Date

APPROVED:



S. Lauren Hibbert  
Director OPR

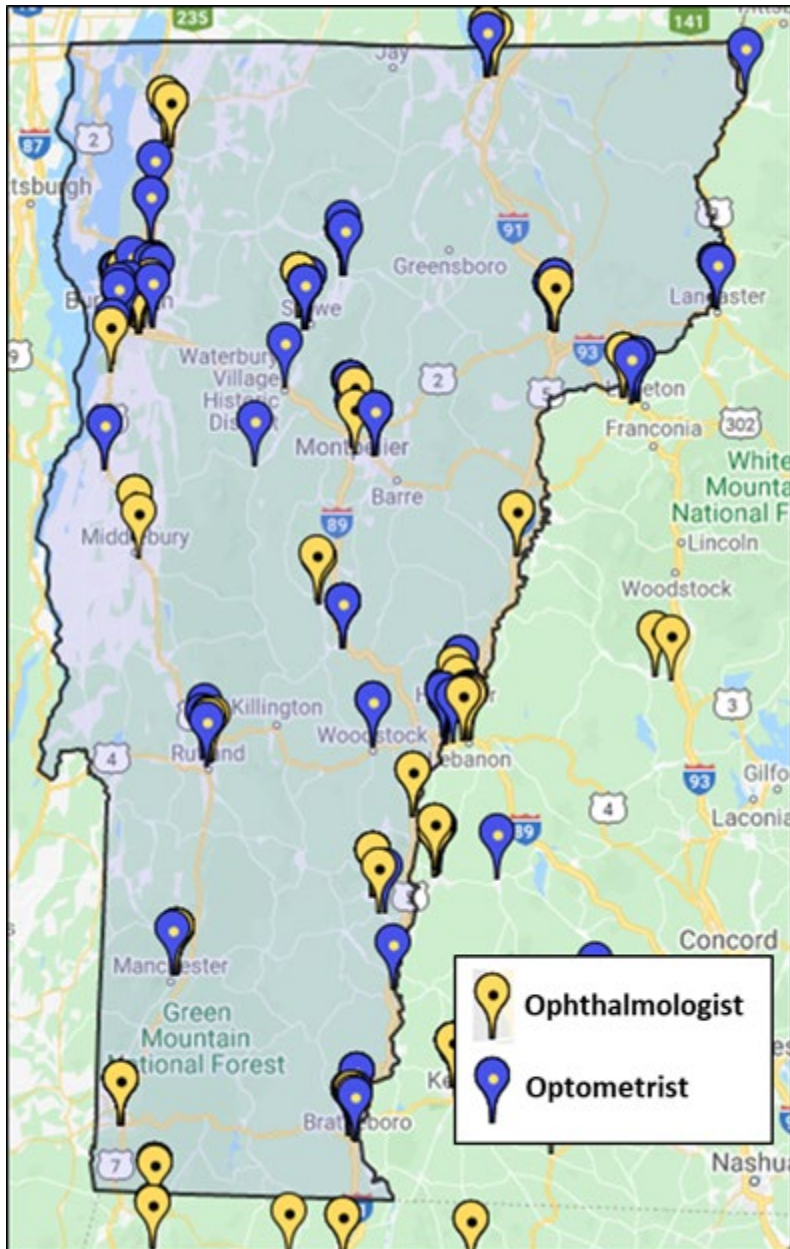
January 15, 2020  
Date

<sup>114</sup> Schroeder, Michael, "Optometrists, Ophthalmologists Fight Over Eye Care Rights", *Angie's List* (June 16, 2011) available at [www.angieslist.com/articles/optometrists-ophthalmologists-fight-over-eye-care-rights.htm](http://www.angieslist.com/articles/optometrists-ophthalmologists-fight-over-eye-care-rights.htm)



## **APPENDIX A**

Figure 1: Map of All Optometrist and Ophthalmologist Providers in Vermont<sup>115</sup>



<sup>115</sup> Figures 1, 2 and 3 are based on Vermont-enrolled Medicaid providers as of July 2019. *Provider Lookup*. Vermont Medicaid Portal. <http://vtmedicaid.com/#/providerLookup>. Accessed in July 2019.

Figure 2: Map of 30-Mile Radii from Vermont Ophthalmologists North of Montpelier

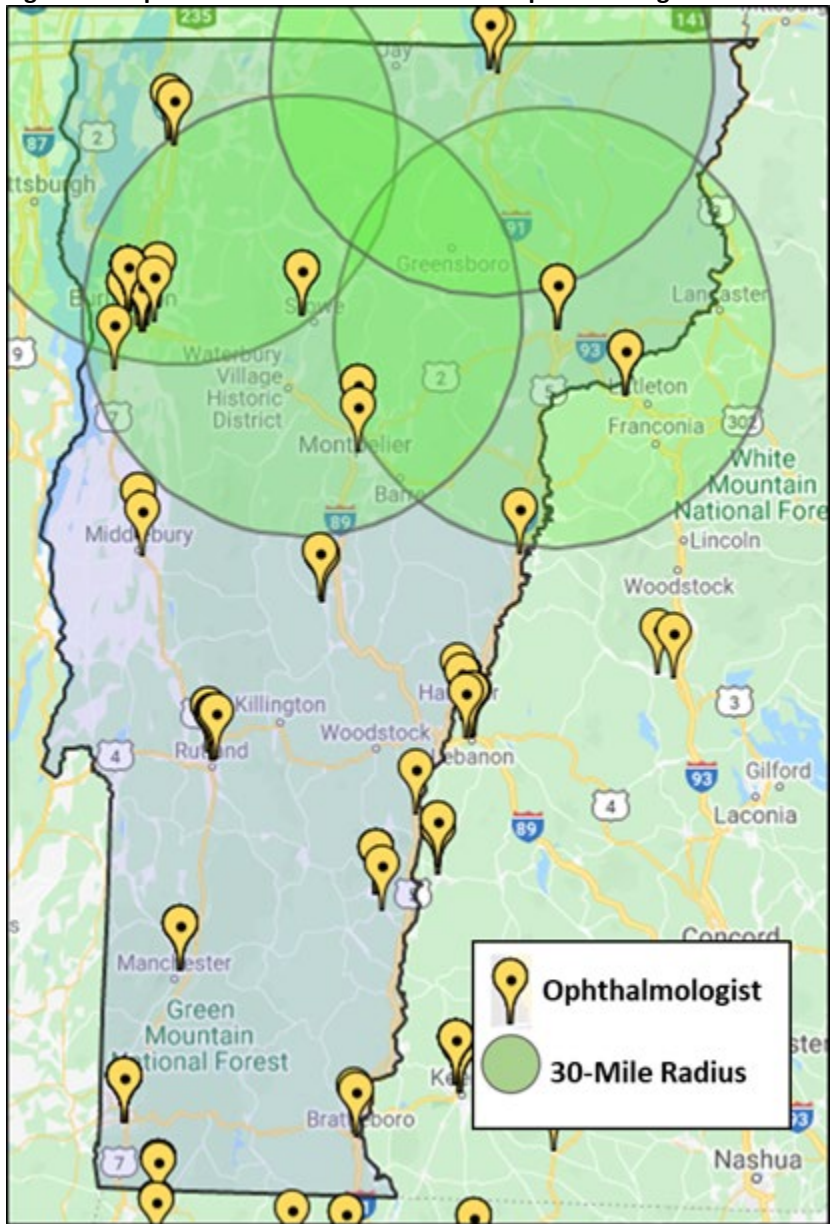


Figure 3: Map of 30-Mile Radii from Vermont Ophthalmologists South of Montpelier

