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Statement of Stephen McLeod, MD Chief Executive Officer American Academy of Ophthalmology House Committee on Veterans' Affairs Health Subcommittee Hearing September 19, 2023

"VA's Federal Supremacy Initiative: Putting Veterans First?"

Good morning, Chairwoman Miller-Meeks, Ranking Member Brownley and Subcommittee members. My name is Stephen McLeod, and I am the Chief Executive Officer of the American Academy of Ophthalmology. Thank you for the opportunity to present our views on the Department of Veterans Affairs' (VA) Federal Supremacy Initiative and its potential impact on our nation's veterans. The Academy is the largest association of eye physicians and surgeons in the United States that represents a nationwide community of nearly 20,000 medical doctors and surgeons. We protect sight and empower lives by setting the standards for ophthalmic education, supporting research, and advocating for our patients and the public. We innovate to advance our profession and to ensure the delivery of the highest-quality eye care to our patients.

In 2021, the VA initiated efforts to develop national standards of practice for more than 50 health professionals that practice within the Veterans Health Administration. The Academy applauds the VA's efforts to protect and boost veterans' access to health care services and we stand ready to work with the VA to ensure veterans have timely access to all of the health care services that they need. However, it is our firm belief that quality care and patient safety must remain paramount priorities in shaping these VA national standards of practice.

Throughout the United States and the Veterans Health Administration, much of eye-related care is delivered through a collaborative teambased approach, with each team member bringing forth an important skill set. Optometrists are vital members of the team, providing routine eye care services to patients in need. In multidisciplinary settings, Ophthalmologists, due to extensive training and clinical experience, are customarily the leaders of these clinical teams. This team-based approach enables ready access to basic needs including routine eye checks, glasses and contact lenses, swift detection of eye diseases and ensures timely, skilled and appropriate treatment for patients. Effective communication and rapid care transitions between optometrists and ophthalmologists working as a team enhance access, efficiency and patient outcomes.

Currently, the overwhelming majority of states do not allow optometrists to perform laser and other eye surgeries. This restriction aligns with longstanding VA policy, which also does not permit optometrists to perform laser surgery in veterans' health facilities – regardless of their state licensure. Furthermore, while a very few states permit optometrists to perform some surgical procedures, it is crucial to recognize that the prevailing norm in optometry practice across all 50 states does not encompass performing surgical procedures. The Academy is concerned that in developing the national standard of practice the VA may want to deviate from these practices and policies for VA optometrists by allowing these mid-level providers to perform eye surgery at the VA.

For decades, veterans have benefited and relied upon an established, consistent, and high-quality standard for eye surgery by ophthalmologists. Allowing optometrists to perform eye surgery in the VA would remove important patient safeguards. This decision could substantially elevate risks for veterans in need of surgical eye care without offering discernible benefits. Public surveys indicate that there is a lack of public support for eye surgery performed by optometrists, and it is reasonable to assume that veterans share these concerns and preferences.

Procedures that May be Included in the VA National Standard of Practice for Optometrists:

It's challenging to determine the specific surgical procedures the VA may include in the national standard of practice for optometrists. Some optometrists claim they can safely perform the following surgeries.

YAG Laser Capsulotomy: This procedure addresses post-cataract surgery vision issues by using a laser to rupture a membrane holding the lens implant in place that can become cloudy and reduce vision. Complications include inflammation, high ocular pressure, macular edema, lens implant dislocation, lens implant damage, and retinal detachment.

Argon and Selective Laser Trabeculoplasty: This procedure applies laser energy to the trabecular meshwork (a narrow zone around the base of the cornea that regulates eye pressure) in patients with elevated eye pressures or glaucoma. Often, these patients have failed other treatments. Energy spots are precisely applied. Overtreatment can damage the meshwork, exacerbating pressure issues. Misdirected energy can harm surrounding structures, causing no pressure reduction and potential damage. Complications include inflammation, scar tissue leading to angle closure glaucoma, corneal issues, and cataracts.

Laser Peripheral Iridotomy: This procedure uses a laser to create a hole in the iris to promote the flow of aqueous fluid (a thin, watery fluid located in the eye), preventing angle closure glaucoma (a form of glaucoma that occurs when the iris bulges). Precise placement and size are crucial to avoid issues like double vision, a "second" pupil, nerve-related pain, bleeding, damage to the cornea or lens, and pupil distortion. Proper energy selection prevents pupil disfigurement. Complications may also include high ocular pressure, and cataracts in addition to those associated with laser trabeculoplasty.

Scalpel surgery to remove eyelid lesions: This procedure involves local anesthesia, lesion excision or biopsy, wound closure and pathologist collaboration. For suspected malignancies, ophthalmologists must ensure clear margins while preserving function and appearance. This may entail cauterization, adjunct treatment, and addressing intraoperative abnormalities. Improper suturing can lead to eyelid dysfunction and chronic issues, potentially resulting in blindness. Complications include scarring, impaired vision, dry eyes, bleeding, infection, blood clots, pain, eyelid disfigurement, anesthesia risks, and vision loss.

These surgical procedures, whether performed with lasers or scalpel, are invasive, yet none are emergent. There is no compelling medical reason for a veteran not to have an ophthalmic surgeon perform these eye surgeries.

All Eye Surgeries Have Potential for Patient Harm:

Eye tissue is exceptionally fragile, and once harmed, full recovery is often impossible. Consequently, eye surgery ranks among the most difficult and delicate surgeries. No eye surgery is entirely safe, easy, or straightforward. While certain procedures carry higher risks, none are without risk, especially when performed by inexperienced providers. The table below summarizes complications associated with some laser and eyelid surgeries.

PROCEDURE	COMPLICATIONS
Chalazion management	Full-thickness incision, permanent lid deformity, perforated globe leading to blindness, missing the diagnosis of sebaceous cell carcinoma, seeding the orbit with cancerous cells
Selective/Argon Laser Trabeculoplasty (SLT/ALT)	Poor technique requiring more treatment, eye pressure elevation, anterior uveitis, synechiae (scarring) and angle closure glaucoma (ocular emergency)
YAG capsulotomy	Lens pitting/damage, lens implant dislocation, eye pressure elevation, retinal detachment, macular hole, macular swelling, uveitis; often requiring further surgery
Laser Peripheral Iridotomy (LPI)	Uncontrolled glaucoma, damage to cornea, cataract, bleeding inside the eye, double vision, iris scar/deformity, retinal damage with permanent vision loss
Pre- and Post-op care of the above	Acute management that occurs at the time of procedure is almost entirely outside the scope of optometrists
Use of topical and injectable anesthetics	Regional nerve blocks could lead to permanent nerve damage or death. Injectable anesthesia may result in inadvertent injection into the eye for a lid or conjunctival procedure leading to blindness or loss of an eye

Current Standards for Laser and Eye Surgery:

The overwhelming majority of states continue to maintain high standards for eye surgery. These states recognize that a comprehensive medical and surgical education is the best way to ensure patient safety. Only 12 states allow optometrists to perform some non-laser surgery procedures. Of those states, only eight states allow optometrists to perform some laser eye surgeries. One state allows optometrists to perform some laser surgeries but does not allow optometrists to furnish non-laser surgery procedures. These states also represent a small fraction of the U.S. population.

Within this limited subset of states, optometrists have variable scopes of practice. Some states permit optometrists to perform YAG laser capsulotomy but do not authorize them to perform selective laser trabeculoplasty (SLT), argon laser trabeculoplasty (ALT) or laser peripheral iridotomy (LPI).

STATE	LPI	SLT/ALT	YAG CAPSULOTOMY
AK	YES	YES	YES
AR	NO	YES	YES
CO	YES	YES	YES
KY	YES	YES	YES
LA	YES	YES	YES
MS	NO	NO	YES
OK	YES	YES	YES
VA	YES	YES	YES
WY	YES	YES	YES

The state scopes of practice are even more variable for non-laser surgical procedures. Some state statutes or regulations that authorize optometrists to perform non-laser surgical procedures contain an exclusionary list of surgical procedures. These exclusionary lists are not all the same. Other state statutes have an inclusionary list of procedures that optometrists may perform. Virginia, a state that just last year authorized optometrists to perform laser surgery, does not authorize optometrists to perform non-laser surgical procedures at all. Conversely, some states that authorize optometrists to perform non-laser surgery procedures do not authorize optometrists to perform laser surgery and only authorize a limited list of surgical procedures.

STATE	Authorized List of Non-Laser Surgery Procedures	Authorizes Laser Surgery
AK	Exclusionary List	Yes
AR	Inclusionary List	Yes
СО	Exclusionary List	Yes
IA	Inclusionary List	No
KY	Exclusionary List	Yes
LA	Exclusionary List	Yes
MS	Inclusionary List	Yes
NM	Inclusionary List	No

OK	Exclusionary List	Yes
TN	Inclusionary List	No
VA	No Non-Laser Surgical Procedures Authorized	Yes
WA	Inclusionary & Exclusionary List	No
WY	Exclusionary List	Yes

Variable Education and Training Requirements:

There also is considerable and concerning variation among states in training expectations for optometrists performing laser surgeries. In states that authorize laser eye surgery, Kentucky requires merely one proctored clinical session on a human subject. Colorado, Mississippi, Virginia and Wyoming also require proctored, clinical training but the statute does not specify that the training must include a human subject. Other laser states require no clinical training. In some states, optometrists may perform surgery on a patient without ever practicing on a live human eye under supervision.

Of the 24 US optometry schools, only two schools are located in states permitting laser surgery. That translates to 95.2% of optometry students attending schools where laser surgery is not permitted. This means that the overwhelming majority of optometrists, including those employed in the VA, have no or minimal practical surgical training on human patients. VA optometrists, most of whom are located in non-surgery states and went to optometry school in non-surgery states, have never performed surgery on human patients. To allow them to now perform surgery is inherently unsafe.



State Location of Optometry Students

Clinical surgical training is not typically part of the curriculum in most optometry programs. In contrast to the estimated 3,000 hours of training time specifically devoted to eye surgery typically undertaken by each ophthalmology resident, the common didactic certification course required by state optometry boards to authorize its licensees to perform laser and non-laser surgery is often conducted in a hotel conference room over 32 hours. This is de facto evidence that substantive clinical training on human subjects is unlikely to be a significant component of this course. For three of the four states that authorize non-laser surgery procedures – Iowa, New Mexico, and Tennessee – there does not appear to be any specific clinical educational requirement.

STATE	DIDACTIC EDUCATION	CLINICAL TRAINING
AK	32 Hours	NO
AR	32 Hours Graduates Since 2019 Waived In	NO
CO	Training Course Approved by the Board OR Graduated from Optometry School Since 2019 where Laser Procedures were Taught + Passage of National Standardized Exam Approved by the Board	One Proctored Clinical Session Before Performing Lasers OR Graduated from Optometry School where Laser Procedures were Taught Since 2019 + Passage of National Standardized Exam Approved by the Board; Repeat Session if Laser not Performed in 2 years
IA	NO	NO
KY	32 Hours	One Proctored Laser on a Living Human Eye
LA	32 Hours	NO
MS	32 Hours Graduates Since 2016 Waived In	8 Hours Working Under a Preceptor Graduates Since 2016 Waived In
NM	NO	NO

Thus, it is possible that the first surgery an optometrist performs on a human – whether supervised or unsupervised - could be a veteran.

OK	New Graduates Waived in; Other licensees may have taken a didactic course earlier	NO
TN	NO	NO
VA	Training Course Approved by the Board	Clinical Training Program Approved by the Board
WA	Training Course Approved by the Board	Supervised hands-on experience with live patients, or be supplemented by a residency, internship, or other supervised program that offers hands on experience with live patients
WY	Board Approved Course OR Graduated from Optometry School where Laser Procedures were Taught + passage of the NBEO Laser and Surgical Procedure Exam	One Proctored Clinical Session Before Performing Lasers OR Graduated from Optometry School where Laser Procedures were Taught + passage of the NBEO Laser and Surgical Procedure Exam; Repeat Session if Laser not Performed in 2 years

Although optometrists lack sufficient training, ophthalmologists are extensively trained to provide surgery. It takes thousands of hours of time, training and supervision to become a competent surgeon. After graduation from medical school and completion of an ophthalmology residency, an ophthalmologist will have performed hundreds of surgeries of varying complexity. The surgeries are mastered over 8+ years, through hours of closely monitored, one-on-one mentored surgical cases taught by board-certified ophthalmologists, themselves experienced surgeons. An ophthalmology resident observes many cases of each type of surgery first, then assists in the surgeries, before becoming the primary surgeon for any one type of procedure, even as supervision continues throughout training. Skills are layered and reinforced throughout the training program.

Becoming a skilled surgeon involves not only technical proficiency but also the development of critical pre- and post-surgical judgment to determine when surgery is necessary and how to approach it safely, and how to recognize postoperative complications and how to treat them. This judgment is honed through broad, mentored experience over years of training. Accumulating a sufficient number of cases is essential for learning to identify and manage complications that may arise during or after surgery. Trainees do not complete their residency until faculty is confident in their surgical abilities and judgment.

The Accreditation Council for Graduate Medical Education (ACGME), which accredits residencies and fellowships, establishes surgical volume requirements with the prerequisite that these surgeons have completed medical school, an internship, and possess a broad foundation of medical and surgical knowledge and skills. This includes experience in microsurgery and a range of complex procedures. By the time residents are directing lasers towards delicate structures in the eye - which are far thinner than a piece of paper - they have already sutured arteries together in vascular surgery, placed central lines, drained subdural hematomas, delivered babies by cesarean section, delicately carved the gallbladder from the liver, removed tumors from the lung and breast, to name just a few examples. From prior experience, surgeons understand what it means to be operating in a tissue plane where there is no room for error.



Difference Between Optometrists and Ophthalmologists in Years of Education

The chart below shows in greater detail the significant differences in time, subject matter, and didactic and clinical substance that distinguishes the education of optometrists and ophthalmologists. The result of these different educational pathways is that ophthalmologists are trained to perform surgery, but optometrists are not.

	Ophthalmologist (MD)	Optometrist (OD)
Educational Requirements	 <u>12-13 years or more</u> 4 years of college 4 years of medical school 4 years of residency training 1-2 years of optional fellowship training 	<u>6 years</u> • 2-4 years of college • 4 years of optometry school
Clinical Experience	 17,000+ hours of clinical experience = 7 years of 40+ hours/week training more than optometrists 3,000+ patient encounters Hundreds of surgical cases 	 2,000 hours of clinical experience No hands-on surgical training in training in 21 of 24 schools Post-optometry school training to do lasers = weekend course at hotel (1-2 hours of real training)

An intensive and transformative three-year residency program in ophthalmology cannot be compared with a 32-hour optometry mini course over a weekend. A simple comparison of time highlights the substantial contrast in the duration and rigor of education and preparation between these two paths.

In addition, there are inherent limitations to teaching optometrists to perform even a limited set of surgical procedures with lasers and scalpels. As noted above, the overwhelming majority of optometry students (95.2%) attend optometry schools in states where optometrists are prohibited from performing surgery – meaning they themselves are prohibited from performing live surgery as part of their training. In addition, the number of optometry students is simply too large and patients with eye disease requiring surgical intervention are too few for optometry students to train on live patients.

Even at optometry schools located in states where some surgical procedures are allowed, as opposed to the strict standards that govern ophthalmology resident surgical training, there are multiple unknowns about optometric training. These unknowns include the qualifications of instructors, the number of live patients with disease needing surgery that are evaluated and treated by each optometry student for the different procedures in the state scope of practice, the frequency in which the procedures are performed, and the competency level of the students upon completing training.

Variable Quality Assurance Mechanisms:

Among states that authorize optometrists to perform surgical procedures, quality assurance measures vary widely. Some states that authorize optometrists to perform surgical procedures have no outcome reporting requirements. Others have limited outcome reporting requirements.

For those states that do collect data on outcomes, it is doubtful whether there has been sufficient data collected to draw statistically significant conclusions that could be used to set clear and consistent standards for quality assurance for surgical procedures performed by VA optometrists. Further, we have concerns whether state optometry boards themselves have the expertise to make accurate quality assurance assessments upon which the VA could rely to ensure patient safety amongst the veteran population.

State	Procedures Reported	Outcome Reporting
AK	None	No Reporting
AR	Lasers Only	Outcomes Reporting
со	Laser Procedures, Ocular Adnexa Treatments	Adverse Outcome Reporting
KY	None	No Reporting
LA	Ophthalmic Surgery	Outcomes Reporting

MS	Ophthalmic Surgery	Outcomes Reporting
OK	None	No
VA	Lasers Only	Adverse treatment outcomes associated with such procedures that required a referral to an ophthalmologist for treatment.
WY	None	No Reporting

The lack of a consistent system of quality assurance was underscored in a 2016 study published in the Journal of the American Medical Association - Ophthalmology.¹ The study found that there was a 189% increased hazard of requiring additional laser treatment in the SAME eye compared to the same laser done by ophthalmologists. The study concluded this could be due to multiple reasons, all of which are highly concerning. It could mean that as a group, optometrists are not adequately trained to perform SLTs resulting in ineffective treatment. It could mean that some optometrists are unable to reliably perform gonioscopy, which is a difficult test that evaluates whether a patient is an appropriate candidate for an SLT. It could mean that some optometrists do not recognize that the surgeon must wait 6-8 weeks before they can determine if the laser treatment was efficacious. This study illustrates a real concern for patient safety, raises substantial questions regarding quality of care, and demonstrates that it is NOT cost effective to have optometrists performing surgery.

Access to Care:

Along with quality, access is a priority. Veterans typically have ready access to ophthalmologists in VA facilities, and there is no documented concern over access for laser eye surgery. Moreover, the Community Care Program also provides veterans with timely access to medical services when the VA cannot provide the care needed. Combined, these programs support the VA's core strategy of providing high quality veteran-centered care.

In addition, a study published in JAMA Ophthalmology this year found that expansion of laser privileges to optometrists in Oklahoma, Kentucky, and Louisiana, it has not resulted in a statistically significant increase in access to laser procedures.² Furthermore, while there are regional variations, overall more than 90% of the US Medicare beneficiary population lives within a 30-minute drive of an ophthalmologist.³

Therefore, we do not believe that the increased risks to veterans that allowing VA optometrists to perform laser eye surgeries can be justified based access to care rationale.

Conclusion:

The Academy appreciates the opportunity to share our concerns about the VA's Federal Supremacy Initiative and how it could impact the quality of surgical eye care available to our nation's veterans. This initiative gives the opportunity to advance an efficient, reliable, and consistent system of coordinated team-based care.

Optometrists play a critical role on this eye care team. However, allowing optometrists with widely varying scopes of practice, highly variable but consistently inadequate education and training, would necessitate a patchwork of questionably effective quality assurance mechanisms that would not improve efficiency or quality within the veterans' health care system. Furthermore, it would not lead to improvements in access to care.

Rather, it would raise the potential for harm to veterans, contradicting a fundamental principle of the "High Reliability Organization" culture the VA is trying to establish. It would also unacceptably lower the standard of surgical eye care that veterans now rely on and clearly benefit from, putting our nation's veterans at considerable risk.

The Academy looks forward to working with you and the other members of the Health Subcommittee to ensure that our nation's veterans continue to receive the high-quality surgical eye they have become accustomed to receiving, and more importantly, have earned through their service to our nation.

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