Report to the Legislature

Sunrise Review

Optometry Scope of Practice

December 2021

Prepared by
Health Systems Quality Assurance

Washington State Department of Health

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Executive Summary

Senator Cleveland, chair of the Senate Health and Long Term Care Committee, requested the department review a proposal under the sunrise law (chapter 18.120 RCW) to expand the scope of practice for Optometrists. The Optometric Physicians of Washington is the applicant group for this proposal.

Draft bill S-3085.2 makes changes to the statute defining the scope of practice for optometrists (RCW 18.53.010) including clarifying language regarding what is and is not included in the scope of practice for optometry; granting the Board of Optometry (board) greater authority over its domain; expanding the scope of medications and therapeutic procedures an optometrist may prescribe or perform; granting the board authority for rule-making regarding educational standards; and specifying in an exclusive list which procedures are not considered the practice of optometry.

The applicant group maintains the proposed scope expansion is safe and will increase access to eye care for Washingtonians. Groups opposed argue that optometrists do not receive enough education, training, and hands-on experience to safely perform the proposed procedures and that no access to care issues exist for patients seeking an ophthalmologist.

Recommendation:

The department supports the concept of this proposal and the idea that all provider types should be able to practice to their highest level of education. However, the bill as written is too broad and does not adequately describe what procedures would be allowed. We recommend the following changes to S-3085.2 to ensure patient safety:

- Restructure the bill to specifically enumerate the additional procedures rather than listing broad categories and allowing the Board of Optometry to further define those categories in rule.
- Include a requirement that clinical training on the advanced procedures include supervised hands on experience with patients, rather than just laboratory. The board of optometry should identify how to achieve this through rulemaking.
- Require the national examinations for advanced procedures including Lasers and Surgical Procedures Examination (LSPE) and ISE Injections Skill Examination .
- Remove Section 6(3) of draft bill S-3085.2 to eliminate conflicts with the state constitution which stipulates the legislature determines scope of practice.

We also recommend maintaining from the original proposal the list of excluded procedures to ensure clarity on what is and is not allowable within the scope of practice for optometry, and the provision allowing optometrists to administer inoculations for systemic health reasons if authorized by the state health officer.

Summary of Information

Legislative Request

On May 27, 2021, Senator Cleveland, chair of the Senate Health and Long-Term Care committee, requested the department review a proposal under the sunrise review law (chapter 18.120 RCW) to expand the scope of practice for optometrists in Washington State.

Draft bill S-3085.2 makes changes to the statute defining the scope of practice for optometrists (RCW 18.53.010) including:

- Clarifying language regarding what is and is not included in the scope of practice for optometry such as including limited ophthalmologic procedures such as some laser treatments and minor surgical procedures (see Appendix XXXX for full details);
- Granting the Board of Optometry (board) greater authority over the practice of optometry in a manner consistent with other healthcare professional boards;
- Expanding the scope of medications an optometrist may prescribe and the scope of therapeutic procedures an optometrist may perform, consistent with national standards;
- Granting the board authority for rule-making regarding educational standards for any procedure the board designates within the scope of practice for optometrists; and
- Specifying in an exclusive list which procedures are not considered the practice of optometry.

Background

The practice of optometry, as outlined in chapter 18.53 RCW, involves examination of the human eye and vision system. It was established in 1975 with the passage of Substitute House Bill (SHB) 308. In 2003, the legislature expanded the scope for this profession to allow the range of drugs an optometrist may use or prescribe beyond topical drugs to include some oral drugs for diagnostic or therapeutic purposes, as well as injectable epinephrine for treatment of anaphylactic shock.[i] This was the last major change to the optometrist scope of practice in Washington, though there have been several other smaller bills passed affecting chapter 18.53 RCW since 2003 that fine-tuned but did not expand their scope.

Currently, optometrists can test patients' visual acuity, prescribe eyeglasses or contact lenses, prescribe visual therapy, and adapt prosthetic eyes. With additional education requirements, a qualified optometrist may also use or prescribe some topical or oral drugs for therapeutic or diagnostic purposes. To earn the right to apply topical drugs for diagnostic purposes, an optometrist must complete 60 hours of didactic and clinical instruction in general and ocular pharmacology and receive certification from an accredited institution. To earn the right to prescribe topical drugs for therapeutic purposes, an optometrist must complete the requirements above as well as an additional 75 hours of instruction. To use or prescribe oral

drugs, an optometrist must meet the above requirements for use and prescription of topical drugs as well as complete an additional 16 hours of didactic and 8 hours of supervised clinical instruction, and receive certification from an accredited intuition.

Summary of Applicant Report

RCW 18.120.030 requires the applicant group to explain a number of factors about the proposed legislation, including the problem it is attempting to fix, how it ensures competence of practitioners, and how it is in the public interest. The department refers to this as the "applicant report." The applicant report is intended to supplement the proposed legislation to help the department determine if the proposed change in scope of practice meets the criteria in RCW 18.120.010(2).

Once the department receives the proposed legislation and applicant report, we post the materials online and solicit public comments. We review all the data and comments received, draft our report with our initial recommendation, then solicit additional public comments on our draft recommendations. At the end of the public comment period, we review comments received and adjust our report and recommendations as necessary before submitting the final report to the legislature.

The applicant report submitted by Optometric Physicians of Washington (OPW) defines the problem and need for the proposal as addressing issues with access to care, such as a shortage of qualified eye care providers, especially ophthalmologists. It states optometrists are uniquely positioned to answer the need for primary eye care for the increasing aging population. Because optometrists' specialty training in ophthalmic care far exceeds any other non-ophthalmologic profession, and training on procedures and treatments continues to advance, the applicant report asserts that they should practice to their highest level of education.

The applicant report estimates a shortage of ophthalmologists of 6,180 nationally by 2025, with a shortage of 1,310 in the west alone, indicating the largest shortage of any medical specialty within the study. It states a stagnant number of ophthalmology residency programs and graduates, retiring ophthalmologists, and the increase in the population of those 65 years and older as contributing factors. [ii, 1]

The report also asserts that access and affordability are also challenged when providers do not accept a patient's insurance or require a patient to travel out-of-town for specialty procedures. This can create additional insurance costs for the public as well as costs for travel, lodging, and missing work, impacting quality of life due to care delays. Washington optometrists currently refer to ophthalmologists for procedures they could be providing, such as:

[1] Also supported by reports from Accreditation Council for Graduate Medical Education, and articles from Review of Ophthalmology and Healio.

- YAG capsulotomies[2],
- Selective laser trabeculoplasty,
- Peripheral laser iridotomies,
- Lid lesion removal,
- Intra-lesional steroid injections, and
- Subconjunctival steroid injections.

The applicant report asserts that expansion of the optometrist scope of practice could add $600 million per year in transaction cost savings and $4 billion per year in savings in access-related improvements in health outcomes. Increased competition could also add to these savings. The applicant report cites examples of improvements in access to eye care in Washington and reduction in costs to the consumer and healthcare system through expanding the optometrist scope of practice, such as:

- Potential savings in facility fees when optometrists provide office-based procedures like eye lesion removal or intralesional steroid injection since they typically provide them in their offices, rather than ambulatory surgical centers (ASC) and hospitals;
- Preventing delays in care because they work in nearly every county in Washington and the procedures could be done in the same office visit;
- Potential savings in transportation and lodging costs for consumers by avoiding out-of-town referral; and
- Increased access to care in rural counties, which are disproportionately affected by limits in scope of practice.

The applicant report states that other factors that impact the availability of eye care services that optometrists with an expanded scope could alleviate are:

- Imbalances in geographic distribution of optometrists and ophthalmologists, especially subspecialty ophthalmic providers like retina, cornea, pediatric, and glaucoma;
- Estimated travel times for consumers;
- Lack of acceptance of insurance like Medicaid and Medicare; and
- Time from referral to appointment.

The applicant report presents a number of maps to demonstrate a disparity in distribution of ophthalmologists and optometrists, with many counties without an ophthalmologist. It cites one example of Okanogan County, which has a population of 41,000 that has no ophthalmologists who accept Medicare within a 50-mile radius, while having eight optometry clinics within that same radius that accept Medicare.[3]

[2] Yttrium Aluminium Garnet (YAG) Capsulotomy
[3] Cites Medicare Provider Search Tool included in Figure A of applicant report.

To further support the assertion of a shortage of ophthalmologists and that optometrists could alleviate some of the burden on ophthalmologists by performing some limited ophthalmologic procedures, the applicant report includes recent articles that conclude:

- States with optometrists with expanded scope experience shorter travel times for patients, with the closest optometrist who accepted Medicare more than 30 minutes closer round trip than the closest ophthalmologist and the second closest ophthalmologist another 30 minutes away.
- In rural areas, nearly 40% of patients had a single ophthalmologist who would have to provide care for more than 50,000 patients in that area.[4]
- Based on 2011 data, there were only 5.7 ophthalmologists per 100,000 county residents compared to 14.3 optometrists per 100,000 residents.[iii]

The applicant report also cites a 2018 U.S. Department of Health and Human Services briefing on barriers to access to care[iv] that concluded restrictive scope of practice laws are one of the factors that lead to increased cost of care and providers such as nurse practitioners, physician assistants, pharmacists, and optometrists can all already provide many of the services provided by MDs or DOs effectively.

A Doctor of Optometry program consists of four years post-baccalaureate specialized biomedical classroom, laboratory, and clinical education accredited by the Accreditation Council on Optometric Education (ACOE)[5]. To enter a program, prospective students must have taken prerequisite courses in the basic sciences to include anatomy and physiology, general and organic chemistry, biochemistry, physics, microbiology, calculus, statistics, and psychology[6]. They must pass the Optometry Admission Test (OAT), similar to the Medical College Admissions Test (MCAT).

Optometry programs include extensive coursework dedicated to the structure, anatomy, function, and physiology of the eye, orbit, and surrounding adnexa, including systemic disease, ocular disease, and pharmacology. Credits vary between programs, from 174 credits at Western University of Health Sciences to 226 credits at Southern California College of Optometry. Programs spend the first and second years concentrating on basic and biomedical sciences in classroom and lab-based training. Patient care experiences typically begin in the third year with an increasing level of responsibility. This is carried into the fourth year, which is spent in eight to 16-week clinical rotations at multiple clinics in a variety of settings.[7]

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[4] Data included in applicant report, with urban vs rural areas of the states examined (OK, KY, NM). (Keyword Reference: Gibson 1)

[5] ACOE is recognized as an accrediting body by the U.S. Department of Education (USDE) and the Council on Higher Education Accreditation (CHEA). Through periodic reviews by both USDE and CHEA, the ACOE demonstrates compliance with their respective criteria.

[6] RCW 18.53.060 specifies required topics to be included in the program.

[7] Applicant report evidence document, page 7.

The applicant report states the current minimum training offered at optometry schools covers the proposed new procedures for current students. While this is acceptable for current and future optometry students, minimum training should be established for currently practicing optometrists. The proposed solution is continuing education courses to teach the new procedures to include:

- Northeastern State University Oklahoma, College of Optometry's (NSU-OCO) advanced procedure course, which includes 32 hours of approved continuing education to include 21 hours of medical knowledge, 8 hours of practice, and 3 hours of Grand Rounds case review. (See pages 23-24 of applicant report for details about the courses.)
- Pacific University College of Optometry (PUCO) offers a postgraduate course that covers all the advanced procedures except laser procedures, and if a proposed bill passes allowing laser procedures in Oregon, the applicant report states PUCO intends to offer a supplemental course for these procedures.
- Several other programs under development, along with testing for current and future optometry students to prove competency.

The applicant report states the National Board of Examiners of Optometry offers additional examinations to assess skills in the advanced surgical procedures including the Advanced Competence in Medical Optometry, and the Laser and Surgical Procedures Examination. These examinations compare with the National Board of Osteopathic Medical Examiners (NBOME), which includes both written and practical test components.

The applicant report includes a comparison of nurse practitioners and physician assistants, who are authorized to perform many of these procedures.[8] It concluded their training does not include the diagnosis, treatment, and technical skills required for these advanced ocular procedures, even though their current scope of practice allows them to perform them.

Both professions receive training in basic eye care, screening techniques, and diagnosis and treatment of common ocular conditions. However, they don't receive significant training in the diagnosis, treatment, and management of glaucoma, cataracts, and retinal disease like optometrists and ophthalmologists.

Physician assistants may perform the procedures if their attending physician feels they are qualified to perform them and the procedures are within the physician's scope of practice. Nurse practitioners are authorized to perform routine vision screenings, but not comprehensive vision exams, glasses or contact lens prescriptions or perform major surgery.

[8] Department staff met with representatives of the Nursing Care Quality Assurance Commission to discuss nurse practitioners performing procedures included in this proposal. While it is within their scope of practice, the nursing commission reports that nurse practitioners do not often seek to perform such procedures and if they did the commission would require evidence of sufficient training to safely perform said procedures.

Pages 30-31 describe physician assistant training, which are 18-24 month programs with entrance requirements of 2-4 years of undergraduate studies or 1-2 years of undergraduate study with specific basic science prerequisites. The programs cover a wide variety of topics that cover all major diseases and some less common conditions, along with pharmacology and technical skills required for their profession. The second year consists of rotations through clinical settings with hands on patient care.

Pages 31- 32 describe nurse practitioner training, which has two levels of education, a Doctor of Nursing Practice (DNP) and a Master's of Nursing (MSN), with most Washington programs now graduating DNPs. Nurse practitioner training typically begins earlier in undergraduate programs while working on their nursing degree (either a bachelor's in nursing or an associate's in nursing), which includes basic sciences. Prerequisite training for an MSN or DNP is not consistent, but many programs require experience as a registered nurse prior to admission.

The applicant report also describes ophthalmologist residencies to demonstrate that optometry training is adequate. For ophthalmology residencies, the standards are set nationally by the Accreditation Council for Graduate Medical Education (ACGME). The applicant report states that the ACGME requirements for minimum numbers of procedures place their emphasis on higher-level surgical procedures requiring a minimum of 86 cataract surgeries, 30 retinal procedures, and 28 oculoplastic procedures. For in-office ocular surgeries, the ACGME only requires 5 YAG Capsulotomies, 5 Laser Trabeculoplasties, 4 Laser Iridotomies, and 3 Chalazia Excisions be performed prior to completing a residency program. Though many programs include more procedures than the minimum, it is not a requirement to be deemed competent for full practice.

In addition, some of these procedures were not taught when currently licensed ophthalmologists completed their residencies, so they had to learn them through post-graduate courses. When new procedures or treatments are developed, physicians gain competence in them by continuing education courses, working with colleagues who can teach them, or training by industry representatives. The applicant report states that it's clear that their learning continues after residency.

The applicant report states the board of optometry will implement a system to designate the currently licensed optometrists who have been granted additional authority through additional training. Newly graduating optometrists will have obtained this additional training through their optometry program and must able to pass a board examination that covers the procedures in question to allow them to begin practicing to this higher level.

To keep uniform standards of practice, the applicant report indicates the intention is to have all practicing optometrists obtain the authorization for this advanced practice. This would ensure every optometrist has equivalent training by the date specified by the board of optometry. This is similar to how Washington implemented the first expanded authority to use diagnostic eye drops and then therapeutic eye drops and ensured all licensed optometrists were eventually held to the same professional standards.

Education and training

Department staff independently reviewed curriculum for 25 optometry schools across the country, as well as two post-graduate programs in Oklahoma and Oregon. All 25 optometry schools provided classroom instruction on oral steroid prescriptions, therapeutic injections, eyelid lesion removal, and in-office laser procedures. The two post-graduate programs also offered these same types of courses, except Oregon's post-graduate program does not include in-office laser procedures.

Of the 25 optometry schools, we were able to confirm four provide hands on training with live patients for advanced procedures. There are two other schools who provide hands on training with live patients for all the proposed advanced procedures except those involving lasers. This is largely due to scope restriction in state law in the state in which the school exists. If the optometry school is in a state that does not have expanded scope, students in that state cannot legally perform these procedures on live patients as part of their training.

Training in Proposed Advanced Procedures

It appears all optometry programs in the United States include advanced procedures, such as injections, laser treatments, and certain surgeries in their curriculum. The underlying optometry training serves as the foundation for clinical knowledge and application of the proposed advanced procedures. For example, courses for anatomy and physiology provide the foundations necessary for surgical procedures. Courses on physical optics provide the foundational knowledge to understand the properties of lasers. Advanced coursework on lasers and surgical procedures builds on this extensive foundation of hundreds of hours of clinical preparation.[9, v]

Programs' specific training in advanced procedures varies from 22 to 46 hours in length and focus on:

- Laser physics, biophysics, hazards and safety;
- Laser application, tissue interactions, indications, contraindications, and potential complications;
- Gonioscopy
- Specific laser procedures to include Laser Trabeculoplasty, Laser Peripheral Iridotomy, and Posterior Capsulotomy;
- Common complications in the lids, lashes, and lacrimal;
- Minor surgical procedures;
- Chalazion management;
- Overview of surgical instruments, asepsis

[9] Applicant report and "Doctor of Optometry Professional Education: A Review of Training in Ophthalmic Surgery," American Optometric Association and Association of Schools and Colleges of Optometry (ASCO), January 2021, and information from a number of optometry programs.

- Surgical anatomy of the eyelids;
- Emergency surgical procedures; and
- Local anesthesia techniques and complications.[10]

The American Optometric Association and Association of Schools and Colleges of Optometry (ASCO) have developed need-based competencies, *Framework for Developing Optometric Curriculum Guidelines and Educational Standards for Ophthalmic Surgery*.[vi] This framework was developed to establish general guidelines for all optometry programs and draws substantially from a number of sources, including the Accreditation Council for Graduate Medical Education (ACGME) core and the Accreditation Council on Optometric Education (ACOE) standards for the professional optometric degree. According to the applicant report, every optometry program in the United States has submitted legal affidavits attesting that they train their graduates to perform these advanced procedures (though it's unclear whether they are using the "framework").

In all schools, graduation also requires passage of the National Board of Examiners in Optometry (NBEO) examination. Students take part I (Applied Basic Science) the spring of the third year, part II (Patient Assessment and Management) in December of the fourth year, and part III (Clinical Skills) any time during the fourth year of the program.

National certification

In addition, there are voluntary national examinations that cover advanced procedures:

- Lasers and Surgical Procedures Examination (LSPE). This is a stand-alone NBEO elective exam offered to 4th year optometric students, optometric residents, and optometric practitioners. This examination consists of a clinical skills portion and a multiple-choice portion, which is administered in a computer-based testing (CBT) format.
  The laser section includes Selective Laser Trabeculoplasty, Laser Peripheral Iridotomy, and YAG Capsulotomy. It also includes complications/contraindications, laser settings, pre- and post-op ophthalmic drugs, indications for treatment, treatment protocols, and follow-up protocols.

  The surgical section covers suturing, eyelid surgery, injections, Chalazion excision, and anesthesia. It includes surgical site infections, Neoplasia screening, biopsies and report interpretation, complications/contraindications, indications for treatment, follow-up protocols, universal precautions, topical and injectable anesthetics, intramuscular

[10] Review of multiple optometry program web sites, including Ohio State University College of Optometry, which sates their advanced procedures curriculum "meets the Kentucky Board of Optometric Examiners laser course requirement (201 KAR 5:110 Section 1) for licensure in Kentucky." These are the required curriculum components in the Kentucky regulations." These procedures are included in Kentucky's regulation. Curriculum | OSU College of Optometry, accessed July 27, 2021.

injections, subconjunctival injections, intralesional injections, and management of lid lesions.

- ISE Injections Skill Examination is a voluntary NBEO clinical skills examination for optometry requiring fundamental skills that reflect actual practice. The testing facility's exam rooms simulate real-life optometric examination rooms and allow NBEO to provide the safety, security, and standardization necessary to ensure fairness and validity in a high-stakes testing environment.

  The required procedures to be completed are: Preparation for Intravenous (IV) Injection for Fluorescein Angiography, Preparation for Intramuscular (IM) Injection of Epinephrine, Performing an Intravenous Injection for Fluorescein Angiography, and Performing an Intramuscular Injection of Epinephrine.

Educational Programs

Clinical education on laser procedures varies based on where the school is located. The hands-on training for advanced procedures for most optometry programs is gained in the laboratory because the procedures are not currently in the state's licensing scope of practice. However, the department could confirm that three programs include the advanced procedures in their clinical training throughout the program and in their clinical rotations in the fourth year.

We highlight the following programs:

Northeastern State University Oklahoma, College of Optometry - 172 credits that includes foundational training for the advanced procedures throughout the program.[vii] For example:

- 5273 Ocular Disease I: Cataracts, Corneal, and External Disease. Taken during the 2nd year of the program and includes cataract pre-operative and post-operative care, indications for treatment of posterior capsular haze with Nd: YAG laser, and instruction of office-based surgical procedures.
- 5291 Clinical Practice I - performance of clinical procedures and observation with case discussion. Also taken during the 2nd year, students perform examinations under the supervision of clinical faculty within clinical and hospital settings, and observe office-based surgical procedures, including anterior segment laser procedures.
- 7095 Clinical Practice V – clinical practice under supervision of clinical faculty in the screening, examination, diagnosis, treatment and management of vision conditions and other health problems. Taken during the 4th year of the program, student performs optometric examinations and office-based surgical procedures, biopsies and anterior segment laser procedures under clinical staff supervision.

The program also includes courses specific to lasers and office-based surgery:

- 7031 Ophthalmic Applications of Lasers. Taken during the 4th year and includes a review of laser biophysics, hazards, safety precautions, indications and contraindications for specific procedures, performance of the procedures, and follow-up care including management of complications.
- 7042 Office Based Surgery – the role of office-based surgical practice within the comprehensive scope of current optometric practice. Includes application of evidence-based medicine and basic science human anatomy to office-based surgical patient selection, planning, instrumentation, procedures, anesthesia, and pre- and post-operative care.

The Illinois College of Optometry

Their core curriculum includes classroom, hands-on laboratory and clinical training for management of a wide array of ocular diseases, including use of oral medications, injections, lasers, and minor surgical procedures.[viii][11]

Southern California College of Optometry - Includes 226 credit hours of instruction focused on ocular disease diagnosis, management, and pharmacology, clinical and ocular procedures including advanced techniques, and direct patient care. Students have extensive hands-on experience with advanced procedures including the use of lasers and minor surgical procedures on the lids.[12] Their training aligns with the "Doctor of Optometry Professional Education: A Review of Training in Ophthalmic Surgery Synopsis." Specific courses on lasers and injections include:

- CLS 722: Ophthalmic Lasers, Injections and Medical Diagnostics – student becomes knowledgeable in the protocol of advanced complex diagnostic and therapeutic clinical procedures involving ocular disease conditions, with special emphasis on the indications and procedural application of anterior and posterior segment lasers, neuro-imaging, diagnostic and therapeutic injections, laboratory evaluation of patients, and emergency care;
- CLS 723: Ophthalmic Surgery – presents ophthalmic surgical procedures and advanced imaging techniques commonly encountered with special emphasis on pre-operative patient selection, variations of surgical procedures, assessment of normal and complicated post-surgical outcomes, and ordering and interpretation of imaging techniques.

Additional Training for Current Practitioners

Northeastern State University Oklahoma, College of Optometry (NSU-OCO)

[11] Letter from the Vice President for Academic Affairs/Dean
[12] Letter from the Dean of the Southern California College of Optometry

Its advanced procedure course includes 32 hours of approved continuing education for optometrists to review and practice the procedures in a didactic review and realistic wet-lab environment. The estimated breakdown of the 32 hours of education is estimated as 21 hours of medical knowledge necessary to perform procedures, 8 hours of practice, and 3 hours of Grand Rounds case review. This course covers:

- Surgical procedures - includes a review of facial and ocular anatomy, surgical instruments, asepsis, ocular lesions, anesthesia, injections including intradermal, intramuscular, sub-conjunctival, and intravenous, wound management, basic suture technique, and techniques for performing in-office optometric surgical procedures. Also covers indications for, alternatives to, and risks/benefits, and management of possible complications of all techniques.

  Laser therapy for the anterior segment – includes technical skills required for performing anterior segment laser procedures to include laser physics, laser tissue interactions, gonioscopy, including indications, contraindications, alternative treatment options, risks, benefits, procedural techniques, and management of possible complications. Includes an in-depth discussion of the most-commonly performed clinical anterior segment laser procedures:

  - YAG laser capsulotomy,
  - Laser peripheral iridotomy (PI),
  - Green laser trabeculoplasty (GLT),
  - Selective laser trabeculoplasty (SLT), and
  - Green laser peripheral iridoplasty.

Pacific University College of Optometry (PUCO)

Offers a postgraduate course that covers all the advanced procedures requested with the exception of laser procedures.[13] The Advanced Ocular Therapeutics (AOT) course is a 23-hour certificate course on systemic and injectable medications used in eye care and states it meets the didactic requirements for optometrists in Oregon, Washington, and Alaska. Includes an online exam.[ix]

Pacific University College of Optometry's program includes training on advanced procedures, excluding lasers.[14, x]

Other States

[13] Applicant report, page 22.
[14] Applicant report, page 36

Department staff evaluated similar laws that have passed in eight other states: Alaska, Arkansas, Indiana, Kentucky, Louisiana, Mississippi, Oklahoma, and Wyoming. We also considered reviewing neighboring states Oregon and Idaho, however neither of these states has passed a scope expansion including all the advanced procedures proposed by the applicant report. Oregon did consider a similar law during their 2021 legislative session, but the bill did not make it out of committee before the close of the 2021 session.

Alaska

Alaska passed their most recent scope expansion for optometrists in 2017. Regulations covering the expanded therapeutic procedures are found in 12 AAC 48.040 – Expanded therapeutic procedure.[xi] Expanded therapeutic procedures are defined as "an ophthalmic surgery approved by the board in compliance with AS 08.72.278 and may include anterior segment laser procedures, anterior segment surgical procedures, YAG laser capsulotomy, laser peripheral iridotomy, and laser trabeculoplasty." The board may authorize a licensee to practice these expanded procedures if their current license is in good standing, the licensee provides satisfactory evidence to the board that the licensee successfully completed a course meeting the requirements in 12 AAC 48.040(d), and the licensee passes a formal practical examination. Licenses for expanded procedures must individually list each expanded therapeutic procedure the licensee is authorized to perform. 12 AAC 48.040(h) contains a list of 17 procedures optometrists may not perform under any circumstances, including such procedures as laser-assisted in situ keratomileusis (LASIK) and photorefractive keratectomy (PRK).

The Chair of the Alaska Board of Examiners in Optometry submitted a letter affirming that they have received no complaints regarding care rendered under the expanded scope of practice since the law passed in 2017.[15]

Arkansas

In 2019, Arkansas passed legislation expanding the scope of optometrists in the state. Since the passage of that legislation, the practice of optometry means "the examination, diagnosis, treatment, and management of conditions of the human eye, lid, adnexa, and visual system, including the removal of foreign bodies from the cornea, conjunctiva, lid, or adnexa, but shall exclude other surgery of the lid, adnexa, or visual system which requires anything other than a topical anesthetic.[xii]" All optometrists are prohibited from performing cataract surgery, radial keratotomy surgery, selling prescription drugs, or using ophthalmic lasers for surgical procedures with some exceptions. Those excepted procedures which optometrists may perform include:

- injections (excluding intravenous or intraocular injections),
- incision and curettage of chalazion,

[15] Applicant Report, Evidence Document Page 148

- removal and biopsy of skin lesions with low risk of malignancy (excluding lesions involving the lid margin or nasal to the puncta),
- laser capsulotomy, and
- laser trabeculoplasty.

In order to perform surgical procedures, optometrists must either have graduated from an accredited institution meeting the educational requirements or have taken additional coursework covering required topics within the last five years, and pass several written exams. Once certified, an optometrist performing any laser procedures must report the outcomes of all laser procedures performed to the State Board of Optometry at least annually.[xiii]

Department staff reached out to the Arkansas State Board of Optometry requesting data on advanced procedures and outcomes, we have not heard back at this time.

Indiana

In Indiana, licensees can get a certificate added to their license that allows them to administer for therapeutic use, dispense, and prescribe certain legend drugs. To earn this certificate, an optometrist must apply to the board, pay a fee, provide proof of education in ocular pharmacology from a school or college approved by the board, and pass the Treatment and Management of Ocular Disease examination administered by the NBEO.[xiv]

Although the applicant report asserts that Indiana allows for advanced procedures as authorized by the state, we can find no evidence that the state has authorized any advanced procedures. Department staff reached out to the Indiana Optometry Board but were told they could not advise us as to the scope of practice in Indiana.

Kentucky

Kentucky passed the "Better Access to Quality Eye Care Act" in 2011. The scope of practice includes, but is not limited to:

- Prescribing and adapting lenses, contact lenses, spectacles, eyeglasses, prisms, and ocular devices,
- all routes of administration of pharmaceutical agents, except controlled substances classified in Schedules I and II,
- Employing vision therapy or orthoptics,
- low vision rehabilitation, and
- laser surgery procedures, excluding retina, LASIK, and PRK.
- "The practice of optometry includes the correction and relief of ocular abnormalities by surgical procedures not excluded in paragraph (b) of this subsection."

Paragraph (b) includes a list of 17 procedures an optometrist may not perform under any circumstances.

A letter submitted by the President of the Kentucky Board of Optometric Examiners states that, since the passage of the "Better Access to Quality Eye Care Act" in 2011, the state has

credentialed more than 410 optometrists to perform advanced procedures. As of May 19th, 2021 Kentucky reports over 40,000 laser and surgical procedures performed by Optometrists with no complaints or adverse outcomes reported relating to the advanced procedures in this expanded scope of practice.[16]

Louisiana

Louisiana Act 398 passed in 2014 and expanded the scope of optometry in that state to allow optometrists with qualified training to perform advanced ophthalmic surgery procedures, including laser procedures. To perform advanced procedures in Louisiana, a licensee must provide proof of satisfactory completion of a course of instruction approved by the board and pass a written test approved by the board on the Louisiana Optometric Practice Act pertaining to ophthalmic surgery procedures.[xv] The code also requires any optometrist licensed to perform ophthalmic surgery procedures to report the outcomes of such procedures to the board.

The Secretary of the Louisiana State Board of Optometry Examiners submitted a letter stating that of the 489 licensed optometrists in the state, 292 have become certified to perform advanced ophthalmic surgical procedures. Data from 2015-2019 show that these certified providers have performed 11,545 procedures with no negative outcomes reported. The Secretary also states there have been no complaints to the board from patients or other doctors regarding optometrists performing these procedures, and the board is not aware of any malpractice suits filed in relation to these procedures.[17]

Mississippi

Optometrists in Mississippi can be certified to three different levels: diagnostic optometrist, therapeutic optometrist, and Primary Eye Care Procedures (PEP) optometrist. A diagnostic optometrist is allowed to use pharmaceutical agents in their practice and must be certified by the board to do so. An optometrist wishing to be certified as a diagnostic optometrist must submit proof to the board that they have completed courses in pharmacology with particular emphasis on the topical application of diagnostic pharmaceutical agents to the eye, and pass an exam administered by the board. Any optometrist certified to use diagnostic pharmaceutical agents may also be certified to use therapeutic pharmaceutical agents. In order to earn this certification, an optometrist must satisfactorily complete:

- A course consisting of a minimum 64 hours of didactic education with particular emphasis on the examination, diagnosis, and treatment of conditions of the eye and adnexa, and
- A minimum of 80 hours of supervised clinical training as it applies to optometry with particular emphasis on the examination, diagnosis, and treatment of conditions of the eye and adnexa, and

[16] Applicant Report, Evidence Document Pages 149-150
[17] Applicant Report, Evidence Document Pages 146-147

- Pass a written exam approved by the board.

A PEP optometrist may provide procedures that employ incision, injection, laser, radiation, cautery, cryotherapy, vaporization, ultrasound, chelation, ionization, intense light, UV, radio frequency, and other surgical methods, chemical reactions, or instruments not otherwise excluded.[xvi] Excluded procedures include:

- Intraocular surgery, not including YAG laser posterior capsulotomy
- Intraocular injection
- Intraocular transplantation
- Intraocular aspiration or the ordering of for diagnostic purposes
- Intraocular penetration or the ordering of for diagnostic purposes
- Use of medications that must be injected or implanted into the eye or orbit
- Biopsy of any part of the globe or the ordering of for diagnostic purposes
- Injection of dermal filler and substances such as hyaluronic acid and poly-L-lactic acid for cosmetic purposes
- Removal of foreign bodies that involve the eyelid margins, lacrimal drainage structure, or extending deeper than the orbicularis muscle
- Reconstructive surgery of the eyelid, and
- Cataract surgery.

In order to be certified as a PEP optometrist, an optometrist must provide proof of holding a Mississippi therapeutic optometry license in good standing, provide proof of satisfactory completion of a course of instruction approved by the board, pass a written test approved by the board including aspects pertaining to PEP procedures, pass a clinical assessment on YAG laser posterior capsulotomy approved by the board, and participate in 8 additional hours working under a preceptor who is a PEP licensed optometrist or an ophthalmologist. Once certified, PEP optometrists must report annually to the board on the outcomes of PEP procedures.

The Executive Director of the Mississippi State Board of Optometry provided data that the state has 434 active optometrists and 138 of those are credentialed to perform “Primary Eyecare Procedures” (PEP) which most closely aligns with the proposed scope expansion. Mississippi does require optometrists performing advanced procedures to report to the board on outcomes, however the law in Mississippi is relatively new and the first reporting year closes this year, December 31, 2021 so Mississippi has no complaint or outcomes data to share with us at this point.

Oklahoma

Oklahoma defines the practice of optometry as the science and art of examining the human eye and measurements of the powers of vision by the employment of any means.[xvii] “Any means” includes:

- the use or furnishing of any self-testing device,
- the use of any computerized or automatic refracting device, including applications designed to be used on a computer or video conferencing via an Internet device either in person or in remote locations,
- the use of pharmaceutical agents,
- the diagnosis of conditions of the human eye, and the correcting and relief of ocular abnormalities by means including but not limited to prescribing and adaptation of lenses, contact lenses, spectacles, eyeglasses, prisms and the employment of vision therapy or orthoptics for the aid thereof,
- low vision rehabilitation,
- prescribing controlled substances Schedule III-V, with allowances for hydrocodone or hydrocodone-containing drugs regardless of schedule for a period not exceeding five days,
- laser surgery procedures, excluding retina, laser in-situ keratomileusis (LASIK), and cosmetic lid surgery.

The law also allows the Board of Examiners in Optometry to further define the scope of practice for non-laser procedures by promulgating rules.[xviii]

For administering or prescribing dangerous drugs, an optometrist must satisfactorily complete courses in general and ocular pharmacology at an accredited institution approved by the board. Prior to June 30, 2006, this was an additional certification licensees applied for in order to administer or prescribe dangerous drugs. However, as of June 30, 2006, the board stopped renewing licensees for any optometrist who did not meet the criteria so all licensed optometrists in Oklahoma are certified to administer or prescribe scheduled drugs, as outline in their rules.[xix]

The Executive Director of the Oklahoma Board of Examiners in Optometry submitted a letter to the department stating that between 1988 and 1998 laser procedures were allowed by law and approximately 5,000 procedures were reported in that period with no negative outcomes. Those procedures were based on an interpretation of the law in 1988, and in 1998 the legislature updated the statute to clarify the statutory definition of optometry and specifically allow for laser procedures. Since 1998, when legislation allowing laser procedures was passed, an additional estimated 50,000 laser procedures have been performed with no complaints registered with the board. The board did acknowledge there were 2 insurance settlements made involving PRK treatment.

Wyoming

Wyoming law states that the practice of optometry is occurring when a person employs primary human eye care procedures, including:

- The examination, diagnosis and treatment of abnormal conditions and diseases of the eye, its adnexa and visual system;

- Measuring the powers and range of vision of the eye to determine the accommodative and refractive state and general function of the eye;
- The adaptation, sale, prescribing and dispensing of frames and ophthalmic lenses in all their forms;
- Ordering and performance of diagnostic laboratory or imaging tests;
- The prescribing and administration of pharmaceutical agents, as provided in rule;
- Preoperative and postoperative care for those procedures excluded from the practice of optometry; and
- Any laser procedure as set forth by the board's rules and not excluded by rule.[xx]

The law also includes a list of 21 excluded procedures including prohibitions on administering or performing surgeries using general anesthesia, laser procedures including corneal procedures, procedures of the vitreous chamber for treating retinal or macular disease, retinal procedures, and a lengthy list of nonlaser surgical procedures. Laws also limit the use of scheduled substances to only those in Schedules III-V, and allowing for prescribing of hydrocodone or hydrocodone containing pharmaceuticals regardless of schedule.

The Wyoming legislature passed their scope expansion law (House Enrolled Act 0036) during the 2021 session. The board is currently working on rulemaking to implement the changes, but those rules are not yet final. As such, we also do not yet have a full sense of the regulations in Wyoming covering advanced procedures nor can we provide any data on outcomes or reported complaints related to optometrists performing advanced procedures.

Stakeholder Engagement

As part of the sunrise review process, the department solicited comments from the public and stakeholders on the applicant's initial applicant report. It received 317 comments. This section provides a high-level summary of all comments received. (A more detailed summary is included in Appendix XXXX.)

Comments in Opposition

We received 43, of 317, comments in opposition to the proposal. The breakdown of who the comments came from is below, followed by a summary of the comments grouped by theme. The full comments from each commentor are attached in Appendix XXXX.

15 ophthalmologists	14 MDs – did not specify specialty
6 professional associations	2 boards/commissions
1 state agency	1 retired MD
1 optician	1 member of the public
1 rehabilitation therapist	1 registered nurse

In general, we saw 5 main themes in the comments opposing the proposal.

Themes

Education and Training

Many of the comments received in opposition assert that optometrists lack the proper education and training to perform surgical procedures. Some specified the education was lacking around use of anesthesia in particular. Others emphasized that optometrist training does not include the type of hands on experience necessary to safely perform these procedures.

A few commentors asserted that the only acceptable level of training would be equivalent with medical or osteopathic doctors to ensure safe surgery and prescribing. Physician training includes very specific standards governed by the Accreditation Council for Graduate Medical Education which include supervision ratios, cohort sizes, and number of procedures that must be performed on human patients prior to completion of their program. Commentors stated that there are no equivalent requirements or standards for optometry postgraduate training.

Many commentors also expressed concerns that optometrists are not required to complete any standardized training program following their formal education.

Many ophthalmologists submitted comments asserting that patients do not understand the difference between an optometrist and an ophthalmologist, and they argue patients would choose ophthalmologists if they understood.

Risk of Patient Harm

Commentors opposed stressed that surgical procedures around the eye are exceedingly invasive and carry significant risk of patient harm. They assert optometrists do not have the breadth of skills and knowledge to determine when surgery is appropriate or not. Some commentors expressed strong concern that the proposal allows optometrists to administer anesthesia as this would risk significant patient harm.[18] Others acknowledged that general anesthesia and any surgeries using general anesthesia are excluded from the proposal, but continue to have concerns about other forms of anesthesia that the proposal would allow, including deep sedation, infusions, and regional blocks. Some also expressed concern about the proposal allowing injections and expanded prescriptive authority citing the potential for patient harm.

Further, some commentors suggest that authorizing this scope expansion would lower the standard of surgical care in Washington. They assert that the margin of error for eye

[18]Department staff believe this was a misread of the proposed legislation, which specifically *excludes* the administration of anesthesia from the optometrist scope of practice as well as excludes any procedures which must be performed using general anesthesia. See S-3085.2 Sec. 2(1)(c)(iii-iv).

procedures is minimal and optometrists do not have the preparation and judgement formed through years of medical school and residency to safely perform eye surgery. Some also emphasized that lasers are surgical instruments and can cut as deeply as any knife and could result in severe negative outcomes. A few comments also expressed concern that seemingly benign eyelid lesions may actually be cancerous and improper surgical techniques could cause the cancer to spread if not properly diagnosed and treated. One also expressed concern with section two of the proposed bill stating that an optometrist would not know if a lesion were malignant until after it is removed.

Lack of Access to Care

Comments suggested there is no access to care issue regarding ophthalmologists. Some feel that even if we assume there is, the solution is to increase medical residencies and investing in other solutions rather than expanding the scope of optometrists. A few cited a study performed by the University of Washington that concludes 97.6% of Washingtonians are within a 1 hour drive of an ophthalmologist. Some stated there has been no public request or outcry for optometrists to have this expanded scope and they assert since the proposal is not patient driven it is only for the benefit of optometrists themselves.

Oversight

Some commentors expressed concern that the proposal allows the Bord of Optometry to determine their own scope and set educational and other requirements. They assert that optometrists are not trained to perform advanced procedures, therefor they are not able to determine what appropriate education and training requirements are.

Scope in Other States

A few commentors pointed out that the other states which allow the advanced procedures in this proposal are significantly worse places to receive health care and have poorer population health than Washington.

Other comments

The department requested the Health Care Authority (HCA) review the sunrise proposals before us and provide feedback on impacts or concerns relating to reimbursement for services. HCA stated they would experience limited systems effects, and that the Public Employee and School Employee Benefit Board programs would be minimally affected. They concluded that the impacts would be minimal and that there is the potential for this proposal to positively impact access to care, however they do have concerns about the quality of care when the training requirements for the additional practices are not specifically outlined in the bill.

We also received comments from the Pharmacy Quality Assurance Commission. In general, they have concerns and do not support the bill as written. The provided the following suggested edits to improve the bill:

- Section 2. (1)(iv) includes dispensing of samples as new service for optometrists which was previously banned under the former rules. This would require further amendments to RCW 69.45.010 to recognize optometrist(s) as a practitioner notwithstanding their current scope of practice. This amendment would legally authorize drug manufacturers to distribute drug samples to optometrists.
- Section 2. (10)(a) states: Any optometrist authorized by the board shall be permitted to purchase diagnostic pharmaceutical agents for use in the practice of optometry. Any optometrist authorized by the board shall be permitted to prescribe therapeutic pharmaceutical agents in the practice of optometry. *Optometrists authorized by the board to purchase pharmaceutical agents shall obtain them from licensed drug suppliers or pharmacists on written orders placed in the same or similar manner as any physician or other practitioner so authorized.* Purchases shall be limited to those pharmaceutical agents specified in this section, based upon the authority conferred upon the optometrist by the board consistent with the educational qualifications of the optometrist as established in this section.

The proposed italicized language should align with the current term of art in the pharmacy practice for both "drug suppliers" and "written orders." Drug suppliers should be replaced with "wholesalers" and written order should be replaced with "prescription and/or chart order."

Comments in Support

We received 274, of 317, comments in support of the proposal. The breakdown of who the comments came from is below, followed by a summary of the comments grouped by theme. The full comments from each commentor are attached in Appendix D.

195 optometrists	40 patients/members of the public
10 ophthalmologists	6 colleges/universities
5 MDs – did not specify specialty	5 optometry students
4 professional associations	2 optometry residents
1 board/commission	1 hospital administrator
1 ophthalmic technician	1 occupational therapist
1 psychologist	1 retired optometrist

In general, we saw five main themes in the comments supporting the proposal.

Themes

<u>Scope in Other States</u>

Washington state's scope of practice is more restrictive than many other states. Many practicing optometrists submitted comments indicating they practice in multiple states and

have performed many, if not all, of the advanced procedures requested by this proposal in other states they practice in. They expressed how frustrating it is for themselves and their patients when they have to refer the patient to another provider even though they have the education and credentials to perform the procedures in other states. They argue that expanding the optometrist scope would improve patient access to care and patient satisfaction as the patient would be able to continue treatment with a doctor they already have an established relationship with and would not have to endure the frustration of additional visits, copays, travel, time off, etc.

Many commentors also pointed out that these procedures have been performed safely in other states for many years. This aligns with letters we received from the heads of the various state boards of optometry where advanced procedures are permitted stating that no adverse outcomes had been reported.

We received letters of support from most other states with expanded scope similar to the proposal we are reviewing reporting no instances of negative outcomes or complaints regarding advanced procedures. Of particular note is Oklahoma, where optometrists have been practicing with this expanded scope since 1988. They reported record of more than 55,000 advanced procedures performed, with no complaints reported and only 2 insurance settlements known over 30+ years of performing these procedures. Oklahoma shared that they have stopped requiring optometrists to report on advanced procedures because they are now considered common, routine procedures that do not require additional tracking and monitoring.

Some commentors also pointed out that the Veteran's Administration has a more relaxed scope than the state of Washington and that expanding optometrists scope would allow practitioners in our state to provide better care to veterans. One also asserted that the Indian Health Service also has a more expanded scope and this proposal would align Washington's scope with that of the Indian Health Service.

Education

Many of the comments we received expressed support for the education received by optometrists and felt the applicant proved sufficient education and training are provided in optometry school to support this proposed scope expansion. Many commented that optometric physicians are highly trained doctors who have completed undergraduate degrees, and at least 4 years of specialized biomedical training, with most going on to complete a residency and/or followship prior to beginning practice. They argue that Washington's scope of practice laws have not kept pace with the educational and technological advancements of clinical eye care in the last few decades.

Many optometrists also pointed out that, although it is optional, most (commentors cited between 70 and 80%) optometry graduates do participate in a residency or fellowship programs following optometry school.

We also received comments emphasizing that it is standard for professional boards to determine and establish in rule the education standards for procedures deemed within the profession's scope of practice.

Several MDs and Ophthalmologists submitted letters supporting their optometry colleagues performing these procedures as they are trained and tested to perform. They praised the quality and timeliness of the care patients received, and felt expanding the scope of optometrists would be a benefit to the citizens of Washington. A few expressed that other MDs and ophthalmologists support this proposal as well, but are afraid to do so publicly for fear of criticism from their ophthalmology peers.

We also received letters from 6 colleges of optometry with detailed information about their curriculum. We heard from:[19]

- Western University of Health Sciences
- Ferris State University – Michigan College of Optometry
- The Ohio State University College of Optometry
- Illinois College of Optometry
- Pacific University College of Optometry
- Southern California College of Optometry Marshall B. Ketchum University

Additional Costs to the Patient

We also received many comments, including from patients, who feel current law is burdensome to patients and forces additional costs on the patient when they must be referred to another provider. The additional costs come from additional co-pays, cost of travel/lodging, time off from work, etc. Providers and patients alike reported patients refusing necessary care rather than accept a referral to an ophthalmologist or optometrist in a neighboring state.

Some patients shared personal stories about needing more advanced care, but being unable to find an ophthalmologist nearby or accepted by their insurance so the patient ended up having to go to the emergency room and incurred much more significant costs as a result.

Some patients also pointed out that they were referred to an ophthalmologists office because they are considered "more qualified" by the state. However, when they went in for treatment with the ophthalmologist, the same tests as the optometrist performed were duplicated (adding unnecessary cost) and were performed by technicians rather than the more qualified ophthalmologist that they were referred to.

Access to and Delays in Care

[19] Department staff also performed significant independent research on education. We also reached out to schools and requested information and curriculum. A summary of what we found in our research can be found in the education section of this report.

The comments received, and the applicant report, assert that optometrists are sometimes the only eye care provider in a region, particularly in rural areas. Maintaining the current restrictive scope of practice harms patients. Expanding the scope of practice would allow for better, more cost-effective patient eye care especially in rural areas where other eye care professionals may not be reasonably available. It would benefit patients to utilize all provider groups to the highest level of training. Additionally, patients and providers both report delays in care due to the requirement to transition to a new provider when the optometrist is able, but not allowed, to perform advanced procedures. Several optometrists shared stories of patients who were upset their problem could not be treated immediately and expressed frustration that visiting the optometrist was a waste of their time. Other shared stories of patients who were refer to an ophthalmologist and the patients wished to stick with the provider they already knew and trusted, and did not want to have to establish a new relationship with a new provider.

Many commented that the inconvenience to the patient of having to go to another provider often results in the patient failing to follow through with the referral and no longer seeking the necessary care. Being forced to refer patients to other, often busier, clinics creates a bottleneck in care for patients. Many assert it is not in the patient's best interest to make them wait weeks or months to see an ophthalmologist when their optometrist are trained to perform the procedure.

Several patients shared personal stories of being unable to get an appointment with an ophthalmologist in a timely manner, or not being able to find a nearby ophthalmologist at all. Several also shared stories of struggles getting needed prescriptions following treatment as the optometrist could clean out an eye injury, for example, but could not prescribe the necessary antibiotics to complete the care.

Some commentors pointed out that ophthalmology is becoming an increasingly specialized area of medicine. They argue giving the ability to perform simple procedures to optometrists would improve the efficiency of eye care in the state overall as ophthalmologists could focus on those complex procedures only they are capable of performing.

Recruiting recent graduates

Many commentors, including current optometry students and residents, commented that the restrictive scope in Washington is driving the most qualified optometrists away from Washington, especially among new or recent graduates. We also heard from some current students and residents that they had chosen not to come to Washington because of the restrictive scope, but several are watching this proposal and may choose to come to Washington if the scope is expanded.

Several optometrists shared struggles with hiring as the recent graduates they attempt to recruit decline to work in a state with such a restrictive scope. Some optometry students shared similar stories of wanting to come to Washington but choosing to pursue other options once they became aware of the restrictive scope. Some retiring optometrists shared that they have

been unable to find an optometrist to take over their practice as many do not want to work in a state that "clips their wings."

Other comments

One commentor shared concerns about the use of the term "rehabilitation therapy" and requested that be changed to "visual rehabilitation therapy."

Some commentors pointed out that Advanced Registered Nurse Practitioners and Physician Assistants are both able to perform the advanced procedures in this proposal will much less training than an optometrist. Some asserted that, for example, a PA may only have a few dozen hours of training on a procedure such as YAG laser while an optometrist would have thousands of hours of training. They raised the question why would ophthalmologists support PAs performing such a procedure with such minimal training yet they decry optometrists wishing to perform the procedure with significantly more training.

Neutral

We received one neutral comment from a member of the public suggesting we should look at the national standard of care for this profession and align with that.

Department Assessment of Key Issues

Provider Shortages and Access to Care

Department staff reached out the Washington Medical Commission (WMC) and the Board of Osteopathic Medicine and Surgery (BOMS) to request data on the distribution of ophthalmology providers in Washington. Washington does not license medical providers by specialty, so we must rely on the annual demographic census which is required by law. We have received what data they have, unfortunately that data is incomplete due to non-response from approximately 25-30% of providers.

The data we received shows no ophthalmologists in 13 Washington counties including Adams, Columbia, Ferry, Franklin, Garfield, Grant, Klickitat, Lincoln, Mason, Pacific, Pend Oreille, San Juan, Skamania, and Wahkiakum counties. It is likely that some, but not all, of these counties do have an ophthalmologist but it wasn't reported in the demographic census.

We received many comments from optometrists and patients sharing anecdotes about being unable to find a local ophthalmologist or being unable to find one in a timely manner. There were also reported issues with finding an ophthalmologist that accepted a person's particular insurance. These reports are all anecdotal and may or may not represent an actual provider shortage in their area.

After reviewing all the comments and data received, we cannot adequately determine if a provider shortage does or does not exists affecting access to care.

Safety of Proposed Procedures

Research on scope of practice laws and related safety shows that some of the proposed procedures have a strong track record of safety. However, we are not able to confirm safety and proper education for other parts of the proposal. The recommendations section (page 32) in this report outlines all recommendations for this proposal. In this section, we outline those procedures we are recommending. The procedures listed below are demonstrably safe and optometrists receive sufficient education and training to perform these procedures.

Procedures for which we can confirm appropriate education, training, and testing:

- Common complication of the lids, lashes, and lacrimal
- Chalazion management, including injection and excision
- Injections – including intramuscular injections of epinephrine, and subconjunctival injections of antibiotics or steroids
- Management of lid lesions, including intralesional injection of steroids
- Selective laser trabeculoplasty
- Laser peripheral iridotomy
- YAG capsulotomy
- Pre- and post-operative care related to these procedures
- Use of topical and injectable anesthetics
- Suturing of the eye
- Eyelid surgery, excluding any cosmetic surgery or surgery requiring the use of general anesthesia.

In order to clarify the scope of practice in law, and ensure patient safety, we also recommend the following list of prohibited procedures, as proposed by the applicant:

- Retinal laser procedures, laser-assisted in situ keratomileus, photorefractive keratectomy, laser epithelial keratomileusis, or any forms of refractive surgery;
- Penetrating keratoplasty, corneal transplant, or lamellar keratoplasty;
- The administration of general anesthesia;
- Surgery performed with general anesthesia;
- Laser or nonlaser injection into the vitreous chamber of the eye to treat any macular or retinal disease;
- Surgery related to the removal of the eye from a living human being;
- Surgery requiring a full thickness incision or excision of the cornea or sclera other than paracentesis in an emergency situation requiring immediate reduction of the pressure inside of the eye;

- Surgery requiring incision of the iris and ciliary body, including iris diathermy or cryotherapy;
- Surgery requiring incision of the vitreous or retina;
- Surgical extraction of the crystalline lens;
- Surgical intraocular lens implants;
- Incisional or excisional surgery of the extraocular muscles;
- Surgery of the eyelid for malignancies or for incisional cosmetic or mechanical repair of blepharochalasis, ptosis, or tarsorrhaphy;
- Surgery of the bony orbit, including orbital implants;
- Incisional or excisional surgery of the lacrimal system other than lacrimal probing or related procedures;
- Surgery requiring full thickness conjunctivoplasty with graft or flap;
- Any surgical procedure that does not provide for the correction and relief of ocular abnormalities;
- Incision into the eyeball;
- Retrobulbar or intraorbital injection; or
- Pterygium surgery.

Curriculum from United States optometry schools demonstrated they all include classroom instruction in advanced procedures including injections, laser treatments, and certain surgeries. The clinical training on advanced procedures at most schools is laboratory-based because their states' scope does not allow optometrists to perform the procedures. However, we confirmed three colleges that offer hands on training under the supervision of clinical faculty for all the procedures listed above, including laser procedures: Northeastern State university Oklahoma College of Optometry, Illinois College of Optometry, and Southern California College of Optometry. We would also note that Pacific University College of Optometry in Oregon includes hands on training on advanced procedures but does not include any laser procedures in that hands on training as their scope does not yet allow that.

The Oregon State Legislature considered a bill during the 2021 session to expand their scope to include laser procedures, but the bill did not make it out of committee prior to the close of the 2021 session. Pacific University College of Optometry has shared they stand ready to include laser procedures as soon as the legislature allows it.

Department staff also confirmed there are national examinations administered by the National Board of Examiners in Optometry testing on each of the listed procedures. They are called the Laser and Surgical Procedures Examination (LSPE) and the Injection Skills Examination (ISE), and both include a multiple-choice exam and a clinical skills portion.

We also contacted every state with an advanced scope similar to the proposal and requested information on complaints and negative outcomes reported. We did not hear back from one state, but heard from all others that there have been no complaints nor reports of injury or negative outcomes related to optometrists performing advanced procedures. One state,

Mississippi, is in their first year of allowing these procedures and reporting on outcomes is not due until December 31, 2021 so we do not have data to report from Mississippi. Some states have been allowing these procedures for many years, with Oklahoma being the longest at 30+ years, and have no negative outcomes to report. We feel this indicates these procedures are safe to perform when performed by a trained and qualified optometrists. We did receive data from commenters in opposition to this proposal asserting that Oklahoma had roughly 60 complaints as captured by the National Practitioner Database (NPDB). Department staff went to the NPDB and pulled the relevant data, however the categorization of the data is not detailed enough to determine if those complaints were related to advanced procedures in any way.

We also reviewed the American College of Graduate Medical Education (ACGME) requirements for ophthalmologists and noted that the procedures requested by the applicant require significantly fewer procedures performed to meet ACGME requirements.[xxi] The table below shows the minimum numbers of each category of procedures that an ophthalmologist must perform in order to complete their residency. We noted that while some surgeries, like cataracts, require as many as 86 individual procedures to be performed, the procedures included in this proposal require as few as 3 or 5 procedures.[20] The procedures the department has recommended as safe are highlighted below for ease of finding them.

Category	**Minimum**
Cataract (S)	86
Laser Surgery – Panretinal laser photocoagulation (S)	10
Keratoplasty (S+A)	5
Pterygium/conjunctival and other cornea (S)	3
Keratorefractive surgery (S+A)	6
Strabismus (S)	10
Glaucoma – Filtering/shunting procedures (S)	5
Retinal vitreous (S+A)	10
Intravitreal injection (S)	10
Oculoplastic and orbit (S)	28
Oculoplastic and orbit – Eyelid laceration (S)	3
Oculoplastic and orbit – Chalazion excision (S)	3
Laser Surgery – YAG capsulotomy (S)	5
Laser Surgery – Laser trabeculoplasty (S)	5
Laser Surgery – Laser iridotomy (S)	4
Oculoplastic and orbit – Ptosis/blepharoplasty (S) 3 Globe trauma (S)	4

[20] The ACGME stresses that the procedure minimums do not signify competence, and that a program director may require residents to perform more than the minimum if they feel competency has not been met. From the same source above, page 3: "Minimum numbers represent what the Review Committee believes to be an acceptable minimal resident experience."

While the department does have concerns about the broad language used in the bill, for the specific procedures listed in this section, we feel there is sufficient education, training, and testing available to ensure competent and safe delivery of care.

Oversight

After reviewing all the comments submitted, we believe a clarification is required regarding regulatory oversight. No health care licensing or regulatory entity sets their own scope of practice in Washington. Per Article 20, Section 2 of the Washington state constitution,[xxii] all health care scopes of practice are determined by the Washington state legislature. Once the legislature has established the scope of practice for a profession, the regulatory entity is granted permission to further define or clarify the education, training, and performance requirements for practitioners within that legislatively set scope. Regardless of whether the regulatory entity is a board, commissions, advisory committee or otherwise, they may only establish rules for those issues the legislature has granted them authority. Section 6(3) of draft bill S-3085.2 must be removed from the bill to eliminate conflicts with the state constitution.

Review of Proposal Using Sunrise Criteria

The Sunrise Act, in RCW 18.120.010, states that a health care profession should be regulated only when:

- Unregulated practice can clearly harm or endanger the health, safety, or welfare of the public and the potential for the harm is easily recognizable and not remote or dependent upon tenuous argument;
- The public needs and can reasonably be expected to benefit from an assurance of initial and continuing professional ability; and
- The public cannot be effectively protected by other means in a more cost-beneficial manner.

For scope of practice proposals, the department interprets the three criteria slightly differently as the criteria outlined in RCW 18.120.010 are more applicable to regulating a new profession, rather than expanding the scope of an existing profession. Proposals to increase a profession's scope of practice must demonstrate they benefit the public by:

- Protecting the public from harm;
- Providing assurance of sufficient education, training, and professional ability to perform the scope of practice;
- Demonstrating the proposal is the most cost-beneficial option to protect the public.

First Criterion: Protecting the public from harm.

The department believes portions of this proposal are supported by sufficient evidence of optometrist training and education, and that there are sufficient means available to ensure public safety. Furthermore, having more available practitioners to perform these procedures may help protect patients from the harm caused by delays in care due to access issues or additional costs. There have been no reported cases of patient harm or complaints against an optometrists license in states where a similar advanced procedure law exists. In one state, Oklahoma, they have record of more than 55,000 advanced procedures being performed over 30 years with no negative outcomes reported.

Second Criterion: Providing assurance of sufficient education, training, and professional ability to perform the scope of practice.

It appears all optometry programs in the United States include advanced procedures, such as injections, laser treatments, and certain surgeries in their curriculum. The underlying optometry training serves as the foundation for clinical knowledge and application of the proposed advanced procedures. For example, courses for anatomy and physiology provide the foundations necessary for surgical procedures. Courses on physical optics provide the foundational knowledge to understand the properties of lasers. Advanced coursework on lasers

and surgical procedures builds on this extensive foundation of hundreds of hours of clinical preparation.[21][xxiii]

Clinical education on laser procedures varies based on where the school is located. The hands-on training for advanced procedures for most optometry programs is gained in the laboratory because the procedures are not currently in the state's licensing scope of practice. However, the department could confirm three programs include the advanced procedures in their clinical training throughout the program and in their clinical rotations in the fourth year.

The American Optometric Association and Association of Schools and Colleges of Optometry (ASCO) have developed need-based competencies, *Framework for Developing Optometric Curriculum Guidelines and Educational Standards for Ophthalmic Surgery*.[xxiv] This framework was developed to establish general guidelines for all optometry programs and draws substantially from a number of sources, including the Accreditation Council for Graduate Medical Education (ACGME) core and the Accreditation Council on Optometric Education (ACOE) standards for the professional optometric degree. According to the applicant report, every optometry program in the United States has submitted legal affidavits attesting that they train their graduates to perform these advanced procedures (though it's unclear whether they are using the "framework").

Licensure also requires passage of the National Board of Examiners in Optometry (NBEO) examination. Students take part I (Applied Basic Science) the spring of the third year, part II (Patient Assessment and Management) in December of the fourth year, and part III (Clinical Skills) any time during the fourth year of the program. In addition, there are voluntary national examinations that cover advanced procedures that could be required to test for proficiency.

Third Criterion: Demonstrating the proposal is the most cost-beneficial option to protect the public.

This criterion does not apply to this scope of expansion proposal. There is no financial cost to the public related to whether the scope of practice for optometrists is expanded or not. Legislation is the only means of adding procedures to the scope of practice, and rulemaking by the board of optometry is required to establish education, training, and safety requirements. There is no more cost beneficial way to expand a professions' scope and ensure patient safety.

[21] Additional information in applicant report from a number of optometry programs.

Recommendation

The department supports the concept of this proposal because it meets the sunrise criteria and supports the idea that all provider types should be able to practice to their highest level of education. However, we do not support the proposal as written because it is too broad and does not adequately describe what procedures would be allowed. The broad language used in the bill would allow for many more procedures than we are able to determine education and training for, or confirm the safety of those procedures. Furthermore, a significant component in the proposal is to have the Board of Optometry set the scope of practice, however this is unconstitutional per Article 20, Section 2 of the Washington State Constitution. We recommend the following changes to the proposed bill in order to ensure adequate education, training, and safety.

1. Restructure the bill to specifically enumerate the additional procedures rather than listing broad categories and allowing the Board of Optometry to further define those categories in rule. This is the best way to ensure patient safety and proper legislative oversight. We recommend the following procedures be enumerated as we can directly tie them to education received and there are national exams to ensure a practitioner can safely perform the procedures:

    - Common complication of the lids, lashes, and lacrimal
    - Chalazion management, including injection and excision
    - Injections – including intramuscular injections of epinephrine, and subconjunctival injections of antibiotics or steroids
    - Management of lid lesions, including intralesional injection of steroids
    - Selective laser trabeculoplasty
    - Laser peripheral iridotomy
    - YAG capsulotomy
    - Pre- and post-operative care related to these procedures
    - Use of topical and injectable anesthetics
    - Suturing of the eye
    - Eyelid surgery, excluding any cosmetic surgery or surgery requiring the use of general anesthesia.

Rationale: The department confirmed these procedures are included in the educational programs' didactic and clinical training and are included in optional national examinations to test proficiency.

2. Include a requirement that clinical training on the advanced procedures include practice on live patients, rather than just laboratory. The board of optometry could identify how to achieve this through rulemaking.

Rationale: Only three educational programs offer practice on live patients for advanced procedures and the department needs to ensure the bill addresses this gap.

3. Require the optional national examinations for advanced procedures, Lasers and Surgical Procedures Examination (LSPE) and ISE Injections Skill Examination .

   Rationale: These standardized exams will help ensure adequate understanding and application of the training received and should be added to the current examination requirements.

We also support the ordering of tests or labs, and any other related services necessary to support the execution of any of the listed procedures. We recommend maintaining the list of excluded procedures as provided in the draft proposal to ensure clarity on what is and is not allowable within the scope of practice for optometry. We also support maintaining the provision allowing optometrists to administer inoculations for systemic health reasons if authorized by the state health officer.

Additionally, Section 6(3) of draft bill S-3085.2 must be removed from the bill to eliminate conflicts with the state constitution.

Notes

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[v] "Doctor of Optometry Professional Education: A Review of Training in Ophthalmic Surgery," American Optometric Association and Association of Schools and Colleges of Optometry (ASCO), January 2021,
[vi] Association of Schools and Colleges of Optometry, "Framework for Developing Optometric Curriculum Guidelines and Educational Standards for Ophthalmic Surgery," 2020, optometriceducation.org/files/Curriculum-Framework-for-Ophthalmic-Surgical-Procedures.pdf
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[x] Pacific University Oregon, "Curriculum | Optometry," accessed July 27, 2021, www.pacificu.edu/optometry-od/curriculum
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[xv] Louisiana Administrative Code, Title 46, Part LI, www.doa.la.gov/media/ngudldca/46v51.pdf Accessed July 29, 201
[xvi] Mississippi State Board of Optometry Rules and Regulations Rule 1.1, www.msbo.ms.gov/wp-content/uploads/2021/07/MSBOO-Emergency-Rules-and-Regs-July-1-2021.pdf, Accessed July 29, 2021
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[xviii] 59 Okl.St.Ann. §581, www.oklegislature.gov/osStatuesTitle.aspx, downloaded July 30, 2021, beginning on page 496
[xix] Title 505:10-5-16, optometry.ok.gov/lawtitle505_4.htm, accessed July 30, 2021.
[xx] Wyoming administrative code 33-23-101, wyoleg.gov/statutes/compress/title33.pdf, beginning on page 245. Accessed July 30, 2021
[xxi] Case Log information: Ophthalmology. Review Committee for Ophthalmology, www.acgme.org/Portals/0/PFAssets/ProgramResources/OPH_CaseLogInfo.pdf?ver=2021-03-15-133325-270, accessed August 9, 2021

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