

Legislative Inquiry Report

Optometrist Laser Surgery Privileges

January 2023

Prepared in response to an inquiry submitted by Representative James Dunnigan (36th House District)

Context

Rep. Dunnigan asked the Office of Professional Licensure Review (OPLR) to conduct an independent review of a proposed amendment to the Optometry Practice Act (58-16a), which would expand optometrists' scope of practice to include three laser surgery procedures: 1) YAG laser capsulotomy (YAG), 2) selective laser trabeculoplasty (SLT), and 3) laser peripheral iridotomy (LPI). YAG is used to treat a complication of cataract surgery, and SLT and LPI are used to treat and prevent glaucoma. (See appendix).

Utah optometrists' scope of practice does not currently include authority to perform any surgery or laser surgery procedures. Only physicians are authorized to perform these procedures as part of the practice of medicine.¹ The scope of practice of the specialty of ophthalmology is not defined in Utah's medical practice acts.

OPLR has verified that nine² U.S. states currently allow some form of optometrist laser privileges: Alaska, Arkansas, Colorado, Kentucky, Louisiana, Mississippi, Oklahoma, Virginia, and Wyoming. These states are referred to as "post-expansion states" in this report. The majority of post-expansion states allow optometrists to practice YAG, SLT, and LPI procedures, with Arkansas and Mississippi restricted to a subset, and Oklahoma allowing any laser surgery procedures with the exclusion of LASIK, retina surgery, and cosmetic lid surgeries.

The majority of post-expansion states require optometrists to receive additional certification or training to perform laser surgery.³ Of the 8 states that allow optometrists to perform laser procedures, half require a 32-hour training, including didactic and clinical/in-vivo learning, followed by at least one exam.⁴ In Oklahoma, all optometrists are required to be certified for laser surgery, while Wyoming only requires optometrists to maintain documentation of training.⁵ Internationally, the UK has a long history of allowing optometrists to perform laser surgery procedures. In the UK, optometrists with additional training are allowed to perform laser surgery procedures in hospitals, where ophthalmologists are available on site for consultation.⁶ While the required training varies by hospital, it typically consists of both lecture and direct supervised practice under a specialized ophthalmologist, who must sign off on a number of procedures.^{7,8,9} Similarly, in 2022 New Zealand began allowing optometrists to perform YAG and LPI in hospitals.¹⁰

⁴ The other four states only require proof of education from an accredited institution.

¹ While the term "physician" may often include or refer to doctors of optometry in various contexts and in some federal statutes, the term is used in this report to refer to medical doctors or doctors of osteopathy, who are licensed in Utah under the title "Physician and Surgeon."

² The following analysis excludes Indiana and Wisconsin. Although OPLR has received anecdotal reports that optometrists are allowed to perform laser surgery procedures in those states, OPLR has not been able to verify those reports directly, having reached out to regulators in both states with no response as of the writing of this report.

³ See Part 2 of the appendix to this report, section titled "Optometric Training and Practice - US & UK"

⁵ Cronbaugh, E. (2023). [Email]

⁶ Gunn et al., 2022; Gibbons et al., 2018; Harper et al., 2015

⁷ Chadwick et al., 2019

⁸ See Part 2 of the appendix to this report, section titled "Optometric Training and Practice - US & UK"

⁹ Harper et al., 2015

¹⁰ Optometrists and Dispensing Opticians Board, 2022

Findings: Safety

To better understand the safety implications of the proposed scope expansion, OPLR 1) gathered safety data directly from regulators in post-expansion states, 2) reviewed existing academic literature, and 3) analyzed state and federal disciplinary action data. (See appendix).

Administrative data from regulators in post-expansion states indicates that optometrists are performing high volumes of laser surgery procedures with very low rates of negative patient outcomes. Altogether, post-expansion states reported at least 195,000 optometrist-performed laser surgery procedures, with one negative patient outcome, one disciplinary action, and one confirmed malpractice case recorded.^{11,12} While this evidence for the safety of YAG and SLT expansion is promising, it does come with limitations. The administrative data from post-expansion states do not allow for comparison with the safety rates of laser surgery procedures performed or report adverse outcomes. Reporting thresholds and requirements also vary between states,¹³ making it difficult to make comparisons between post-expansion states. Similarly, it is unclear what proportion of all negative outcomes are captured by these metrics (which are either self-reported by practitioners or complaint-based from consumers), leading to a potential undercount of negative outcomes.

The most recent academic research on optometrist-performed YAG in the US found that optometrists' services were effective and safe.^{14,15} However, it is important to note that this was a small trial and that the rates of reported adverse outcomes were not consistent with a larger YAG study's reported adverse event rate.¹⁶ This may be the result of various methodological differences, such as the Lighthizer trial's small sample size or differences between patient populations studied. The UK's National Health Service (NHS) has also produced research on the safety of laser procedures delivered by optometrists and other non-physician providers.¹⁷ Regarding SLT, a recent UK study found initial evidence that outcomes are comparable between optometrists and ophthalmologists.¹⁸ However, while the best available studies on optometrist-performed YAG and SLT have not shown frequent or serious risks to patients, the literature is still limited, many studies are statistically lower-powered, and few studies directly compare optometrists and ophthalmologists. It should also be noted that UK and US optometric practice settings differ, reducing the generalizability of UK findings to optometric practice in the

¹² Four malpractice cases were reported in Oklahoma in connection with optometrist-performed laser procedures, but only one of these was confirmed to be relevant to this review (a YAG procedure).
 ¹³ Arkansas regulators confirmed that optometrists must report "any [patient] outcome that is not desirable," Louisiana only requires "visually significant complications" that result be reported.
 ¹⁴ Lighthizer et al., 2023

¹¹ Administrative data provided directly to OPLR by regulators in post-expansion states.

¹⁵ The primary author of this study, Dr. Nathan Lighthizer, is an optometrist based in Oklahoma. While the study is peer-reviewed, Dr. Lighthizer has a direct economic interest in supporting scope expansion, as he delivers laser procedure training courses to U.S. optometrists. The findings of this study would also be strengthened by additional, independent replication, as the follow-up period was short and involved a small cohort of practitioners and patients.

¹⁶ <u>Dot et al., 2023</u>

¹⁷ Lee et al., 2023; Chadwick et al., 2019; Jones et al., 2021

¹⁸ Lee et al., 2023

US. Whereas many optometrists in the US practice independently, UK optometrists providing clinical services (i.e., laser procedures) practicing within the NHS work in a hospital based ophthalmological clinic, under varying degrees of supervision.¹⁹

In contrast to YAG and SLT, evidence for the safety of optometrist-delivered LPI is weak. OPLR was unable to locate any studies or data on the safety outcomes of optometrist-performed LPI or comparisons to LPI performed by ophthalmologists.

Findings: Access

The ophthalmologist workforce is projected to decrease over the next decade,²⁰ while the state's population over 65 (those most likely to need YAG and SLT) continues to grow,²¹ indicating a potential access issue in the future. However, separate from any consideration of access (current or future), health professionals who can demonstrate competency should not be prevented by the State from offering these services. Licensure's role in health care is to ensure that only those practitioners who can safely deliver care are legally authorized to do so. Licensure should not restrict or constrain training pathways or providers from competing in the market for health care services, assuming they can demonstrate adequate patient safety. Please see the appendix for OPLR's findings on access to laser eye surgery in Utah.

Recommendations

OPLR's analysis supports a measured approach to scope expansion for optometrist-performed YAG and SLT procedures. Whether through a pilot program or legislation, any such scope expansion should be conditional upon the creation of rigorous regulatory guardrails, objective safety standards, and systems for data collection. Further, the permanence of that expansion should be conditional on optometrists' safety outcomes consistently meeting predetermined thresholds over a defined period of time. Under these conditions, OPLR believes that optometric scope expansion is a reasonable course of action to recognize advances in optometric training and to address coming changes in eye care workforce and demand. OPLR does not recommend scope expansion for optometrist-performed LPI procedures, due to the lack of clinical safety evidence and potential negative impacts on access to care. (See appendix).

The boundaries of physicians' safe medical practice are continually expanded through a step-by-step progression from research and controlled experimentation to clinically validated and standardized practice, without the need to obtain legislative approval to implement each new practice. The legal inability of other health care provider groups (such as optometrists) to achieve similar evidence-based and competency-based advancement without repeated legislative intervention results in great inefficiencies within the regulatory and health care delivery systems. Safriet (2002) explains how these inefficiencies can be remedied:

¹⁹ See Part 2 of the appendix to this report, section titled "Optometric Training and Practice - US & UK"

²⁰ Berkowitz et al., 2023

²¹ Kem C. Gardner Policy Institute, 2019

"Every regulatory scheme should include clear standards and mechanisms for the demonstration of expanded professional competence. This approach... would acknowledge the reality of ever-increasing knowledge and skills among all [health care providers] and spare legislators the headache of having to proceed as if each such occasion were the first and last."²²

Two such mechanisms for conditional scope expansion could be appropriate in this case:

- 1. A pilot program conducted through Utah's regulatory sandbox (administered by the Utah Office of Regulatory Relief) and paired with a rigorous, independent clinical trial comparing outcomes for optometrists and ophthalmologists, or
- 2. Legislation granting scope expansion with robust certification requirements, systematic data collection, and a short initial sunset period.²³

Given the continuing declines in the ophthalmic workforce and Utah's growing population over 65, OPLR does not recommend maintaining the status quo.

²² Safriet, 2002

²³ See Part 1 of the appendix for detail on recommended regulatory and implementation frameworks.

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1. Recommendations

Option 1: Pilot Program & Clinical Trial

In coordination with Utah's regulatory sandbox program, conduct a clinical study to collect improved patient safety data and draw direct comparisons between ophthalmologist- and optometrist-performed YAG and SLT laser surgery procedures. Base future expansion decisions upon the results of this trial and pilot program.

A pilot program utilizing Utah's regulatory sandbox program and a corresponding clinical study would provide the highest-quality evidence on the safety and appropriateness of optometric scope expansion. OPLR recognizes that just as the medical field's knowledge, skills, and competencies have developed over time, other healthcare professions are also capable of achieving similar advances, assisted by ever-improving research, technology, and training resources. To ensure that Utah can take full advantage of all healthcare providers' skills and improve the effectiveness of healthcare delivery in the state, it is appropriate for the state to provide mechanisms through which appropriate expansion of non-physician health care providers' (HCPs) scopes can be accomplished, based on demonstrated competencies and patient outcomes that meet acceptable safety thresholds.

The results of the study would inform lawmakers' decisions as to the appropriateness of passing scope expansion legislation. The proposed study would directly compare not only the outcomes of YAG and SLT procedures performed by Utah ophthalmologists and optometrists, but also the degree to which optometrists can achieve comparable levels of diagnostic accuracy and appropriate treatment planning.

If realized, this initiative would put Utah researchers, HCPs, and regulators on the leading edge of patient safety and scope of practice research and could fill some of the research gaps that OPLR encountered over the course of this review. By utilizing the regulatory sandbox program, optometrists selected to participate in the clinical trial could be authorized to perform YAG and SLT laser procedures and have a legal avenue through which to demonstrate competency without the need to pass statewide scope expansion legislation. A rigorously designed clinical study would then provide objective, validated outcomes and safety data on which lawmakers in Utah and other jurisdictions could base future decisions about permanent optometric scope expansion.

It is important to note, however, that this would be a cost- and time-intensive process. Significant funding would be required to support a clinical trial, and the program timeline would be dependent on obtaining approval from the state's regulatory sandbox program. This would also require significant levels of coordination and cooperation between all parties involved. **Safety Considerations.** This option would introduce minimal risk because only a limited cohort of optometrists would be participating and providing patient care, and because more rigorous data collection and clinical safeguards could be implemented as part of the proposed study. As discussed earlier in this report, the existing academic literature and administrative data show no clear evidence that optometrist-performed YAG and SLT procedures pose a pressing risk to patient safety. Ideally, at least some of the participating ophthalmologists and optometrists would be practicing at the same study sites and evaluating the same patients, thereby introducing additional safety protections.

Access Considerations. During the pilot program period, the state would experience minimal increases in provider availability, as only a small cohort of optometrists would join the pool of ophthalmologists delivering laser surgery procedures during this period. Following the trial period, if optometrists' performance met acceptable safety standards and full scope expansion legislation were passed, the potential for increased provider availability and improved access to care would then increase, as opportunities to become laser-certified would be extended to all interested and qualified Utah optometrists.

Table 1. Recommended Framework - Option 1					
	Overview				
Description	 Grant laser privileges to a small cohort of optometrists through the regulatory sandbox program Pair this pilot program with a rigorous, independent clinical trial to directly compare optometrists' and ophthalmologists' outcomes 				
Rationale	 This would provide the highest standard of evidence for the safety of optometrist-delivered laser procedures New Zealand used a small but similar program to evaluate the safety of hospital-based optometrists 				
Potential Benefits	• Pursuing this option would produce objective, clinically validated safety data, with a lower safety risk given the small cohort size				
Potential Drawbacks	• This option is costly and time-intensive and would require a high degree of coordination between regulators, researchers, and health care providers				
	Implementation				
Research Topics	 For both YAG and SLT, measure: Rates of diagnostic and treatment planning agreement Rates of post-procedure complications and adverse events Treatment efficacy Additional measures (optional) Cost-effectiveness Access to care (wait times, travel time, etc.) 				

Administration and Funding	 Independent, balanced group of researchers not dominated by any one industry group or training provider; primary researchers should include both ophthalmologists and optometrists Funding independent of industry groups and training providers
Participants	 Utah ophthalmologists Utah optometrists (including both experienced optometrists who have completed laser surgery training after graduation, as well as optometry externs or recent graduates who have received training in school) Utah patients being evaluated for and receiving YAG and SLT
Other Notes	 At least some of the participating ophthalmologists and optometrists should be co-located, to facilitate measurement of diagnostic agreement after evaluating the same patients

Option 2: YAG & SLT Expansion with Guardrails

Expand optometrists' scope of practice to include YAG and SLT procedures, conditional on additional training and certification requirements. Pair this expansion with robust requirements for collaborative practice agreements, data collection, and outcomes reporting.

This option would involve expanding the option to become YAG and SLT certified to all Utah optometrists who complete additional training and certification. Optometrists gaining laser certification would be required to report all complications and adverse events occurring in connection with YAG and SLT procedures to state regulators, such as the Division of Professional Licensing (DOPL), including DOPL's advisory boards for optometrists, physicians & surgeons, and osteopathic physicians & surgeons.²⁴ This initial expansion would be bounded by a short sunset period (ideally no longer than 4-5 years) and close medical oversight, at the end of which the outcomes data would be analyzed and compared to a predetermined acceptable safety threshold set at the time of initial enactment. OPLR recommends that such medical oversight include requiring that 1) optometrists who wish to perform laser surgery procedures must enter into some form of collaborative or coordinating relationship with an ophthalmologist, and that 2) optometrists should either be required to notify an ophthalmologist or to receive an ophthalmologist's sign-off on the treatment plan before performing YAG or SLT.²⁵

The continuation of the expanded laser privileges policy would be conditional upon laser-certified optometrists (as a group) meeting acceptable safety thresholds during this initial reporting period. If safety outcomes do not meet such thresholds, the sunset period should not be extended past the initial 4-to-5 year period, and this scope expansion should be discontinued. If optometrists are found to be practicing safely as indicated by outcomes data, the extension of the sunset period or a permanent expansion of scope, as well as the reduction of some medical oversight requirements, should be considered. Preferably, this reporting would be paired with the collection of similar data on procedures performed by ophthalmologists in order to draw reliable comparisons. OPLR (or any other independent, competent analyst) could perform analysis of the data collected during this period.

Failure to comply with reporting requirements or falsifying reports would carry serious disciplinary & licensing consequences. For example, DOPL would have the authority to suspend or revoke an optometrist's laser certification, or to take broader action against an individual's license. This expansion would also be paired with mandatory patient disclosures, including patient education on the nature and risks of laser surgery procedures, when post-procedure care from an ophthalmologist would be necessary, and how to report adverse events and provider negligence or incompetence to state regulators. This approach could also include a

²⁴ This additional workload may require a fiscal note to increase DOPL or other regulators' capacity to collect and analyze data.

²⁵ This level of oversight would make Utah optometrists' practice of laser surgery procedures more comparable to that of UK optometrists', whose clinical efficacy and safety outcomes have been studied in more detail than that of independently operating US optometrists'.

requirement for laser-certified optometrists to maintain some type of coordination or cooperative relationship with board-certified ophthalmologists.

Safety Considerations. This option would introduce more potential risk than the pilot program and clinical study, because the opportunity to become laser-certified would be open to all interested Utah optometrists. However, as administrative data from post-expansion states has not shown that optometric scope expansion results in high rates of adverse outcomes, and because the existing literature suggests that optometrists can achieve good outcomes performing these procedures, OPLR believes that the rigorous entry, practice, and reporting requirements we propose here will mitigate much of the risk this option may introduce.

Access Considerations. While research on access to care in post-expansion states has not found that scope expansion significantly reduces patients' geographical distance or driving time to laser surgery providers (as optometrists and ophthalmologists both tend to concentrate in urban areas),²⁶ physical distance is not the only factor that can impact access to care. The availability of a greater number of providers still has the potential to shorten wait times and improve accessibility for Utahns seeking YAG and SLT treatment. Allowing scope expansion for both YAG and SLT holds the greatest potential for an increase in provider availability and thereby access to care, by extending laser surgery privileges to any qualified Utah optometrist who earns the required certification.

Assuming that the proportion of Utah optometrists who become laser-certified would be similar to that in other post-expansion states, Utah could expect to have approximately 500 laser-certified optometrists by 2030 (about 42% of licensed optometrists).²⁷ However, under OPLR's proposed conditions, which include more rigorous training, observation and reporting requirements than in other states, and some kind of required collaboration or cooperation with an ophthalmologist, this number might be slightly lower. Additionally, a shortened sunset period may encourage some practitioners to wait to become certified until a final decision about scope expansion is made at the end of the sunset period. Finally, the proportion of certified optometrists in the state cannot be assumed to produce a proportionally equivalent increase in Utahns' realized access to care—despite the significant rates of certification in several post-expansion states, it appears that the majority of optometrists.²⁸

Table 2. Recommended Framework - Option 2				
Overview				
Description	 Grant scope expansion for YAG & SLT only Require optometrists to earn an additional certification, paired with rigorous training and outcomes reporting requirements 			

²⁶ Shaffer et al., 2023

²⁷ Administrative data provided directly to OPLR by regulators in post-expansion states.

²⁸ Sanders et al., 2017

	This option could include a requirement for optometrists to maintain coordination or cooperative relationships with ophthalmologists
Rationale	 Data from post-expansion states does not indicate significant safety concerns Early academic research findings and long-running UK programs support optometrists' ability to practice safely
Benefits	 Pursuing this option has the greatest potential to expand provider availability and improve access to care
Drawbacks	• At the same time, it also poses the greatest uncertainty and risk in terms of potential impacts on patient safety & outcomes
	Structure & Governance
Shortened Sunset Period	 4-year sunset period (2024-2028), covering two license renewal cycles Renewal of expansion conditional on outcomes data meeting predetermined acceptable safety thresholds Safety thresholds set based on complication and adverse event rates as established in academic literature <i>OR</i> based on data collected on ophthalmologist-performed procedures during the same period
Patient Outcomes Data collection	 Number and type of procedures performed All complications & adverse events (e.g., intraocular pressure, edema, retinal detachment, other impairment or loss of vision) Medicare claims & other cost metrics as available
Other Considerations	 Regular reporting periods with clear reporting channels and easy-to-use forms or interface Clearly defined reporting thresholds If possible, collect similar data on procedures performed by ophthalmologists during the same period to facilitate direct, objective comparison and analysis
	Entry Requirements
Didactic training	 Training from an accredited college or school of optometry Completion of a minimum number of supervised, live procedures Passing scores on both written and practical examinations
Supervised procedures	 Applicants for certification must perform a minimum number of supervised, live procedures (both YAG and SLT) Minimum procedure quotas should be equivalent or greater to ACGME minimums required for ophthalmology residents
Examinations	 Written and clinical examinations Jurisprudence examination (including knowledge of reporting requirements, patient disclosure requirements, consequences of failure to report negative outcomes or falsification of reports)

Disciplinary History	• Applicants with previous substantiated complaints of practicing outside scope or negligence/incompetence would be required to complete additional board interview and supervision requirements				
	Practice Requirements				
Compliance with data reporting requirements	 Licensing/disciplinary consequences for failure to comply with reporting requirements or falsification of outcomes data (e.g., suspension, probation, revocation of license) 				
Regular recertification and continuing education	 Required recertification at time of license renewal period Continuing education specific to YAG and SLT procedures (could count toward total CEUs for optometry license renewal) Live observation by an ophthalmologist or other certified optometrist 				
Patient disclosures & education	 The nature, purpose, and risks of laser surgery procedures When to seek care from an ophthalmologist When and how to report provider incompetence/negligence to DOPL 				
Medical oversight	 Coordination or cooperative relationship with an ophthalmologist Requirement to notify ophthalmologist of intent to perform laser surgery procedure, or requirement for an ophthalmologist to sign off on a treatment plan before laser surgery procedures are performed 				

Further Discussion and Alternatives

Even if no action is taken to expand optometric scope of practice, decision-makers should take action to ensure that Utah's eye care workforce is prepared to meet projected demand for laser surgery procedures and other advanced eye care services.

OPLR does not recommend maintaining the state's current trajectory as it relates to eye care availability, because Utah is likely to experience measurable decreases in both rural and urban access to eye care within the coming decade.²⁹ This trend, combined with demographic projections that the proportion and total population of Utahns over the age of 65 will continue to grow,³⁰ will place increasing stress on Utah's advanced eye care workforce and may make it increasingly difficult for Utahns to access specialized care, particularly in rural areas.

While optometric scope expansion may help address this projected decrease in access by freeing up ophthalmologists' capacity to deliver more complex treatments, there are other ways in which the state can begin to mitigate future access challenges without passing optometric scope expansion legislation. The decline of the ophthalmology workforce is a bigger issue than Utah can tackle on its own, but there are alternative courses of action that may help maintain higher rates of ophthalmologist workforce adequacy, particularly in Utah's rural communities:

²⁹ Berkowitz et al., 2023

³⁰ Kem C. Gardner Policy Institute, 2019

- Introduce incentives (such as loan forgiveness programs) for ophthalmologists who choose to practice primarily in rural areas.³¹
- Incorporate rural rotations into medical training requirements, "...as participation in a rural clinical location has been found to be the strongest predictor of a later decision to practice in a rural area."³²
- Allocate funding for additional ophthalmology residency positions at the Moran Eye Center in Salt Lake City, which is the only ophthalmology residency site in the state.

Table 3. Implications of No Scope Expansion					
Description	No change in current optometric scope of practice				
Rationale	 Current academic research has not yet produced the highest standard of evidence for the safety of optometric scope expansion Outcomes data is not yet available from several recent post-expansion states 				
Benefits	• This "wait and see" approach allows for research and safety data to improve				
Drawbacks	• Utah's aging and growing population, alongside a shrinking ophthalmic workforce may lead to decreased access in the future.				

³¹ Feng et al., 2020

2. Context

Table 4. Laser Surgery Procedures Proposed forOptometrist Scope Expansion					
YAG capsulotomy	"Neodymium-doped yttrium aluminum garnet (Nd:YAG) laser capsulotomy is a relatively noninvasive procedure that is used in the treatment of posterior capsular opacification. Posterior capsular opacification is a common long-term complication of cataract surgery that causes decreased vision, glare, and other symptoms similar to that of the original cataract. Laser capsulotomy uses a quick-pulsed Nd:YAG laser to apply a series of focal ablations in the posterior capsule and create a small circular opening in the visual axis." ³³				
Selective laser trabeculoplasty (SLT)	"Selective Laser Trabeculoplasty, or SLT, is used when eye drop medications are not lowering the eye pressure enough or are causing significant side effects. It can also be used as initial treatment in glaucomaLaser energy is applied to the drainage tissue in the eye. This starts a chemical and biological change in the tissue that results in better drainage of fluid through the drain and out of the eye. This eventually results in lowering of IOP." ³⁴				
Laser peripheral iridotomy (LPI)	"Laser peripheral iridotomy (also described as 'laser iridotomy' or simply termed 'iridotomy') is a medical procedure which uses a laser device to create a hole in the iris, thereby allowing aqueous humor to traverse directly from the posterior to the anterior chamber and, consequently, relieve a pupillary block. It is commonly used to treat a wide range of clinical conditions, encompassing primary angle-closure glaucoma, primary angle closure (narrow angles and no signs of glaucomatous optic neuropathy), patients who are primary angle-closure suspects (patients with reversible obstruction) and even eyes with secondary causes of iridocorneal angle-closure." ³⁵				

 ³³ <u>Raja, 2021</u>
 ³⁴ <u>Francis, 2022</u>
 ³⁵ <u>Miguel et al., 2022</u>

Table 5. Optometrist and Physician Scopes of Practice

Optometric Scope of Practice

Utah Optometry Practice Act 58-16a-102. Definitions.

(11) "Optometry" and "practice of optometry" mean any one or any combination of the following practices:

(a) examination of the human eye and its adnexa to detect and diagnose defects or abnormal conditions;

(b) determination or modification of the accommodative or refractive state of the human eye or its range or power of vision by administration and prescription of pharmaceutical agents or the use of diagnostic instruments;

(c) prescription, ordering, administration, or adaptation of ophthalmic lenses, contact lenses, ophthalmic devices, pharmaceutical agents, laboratory tests, or ocular exercises to diagnose and treat diseases, defects, or other abnormal conditions of the human eye and its adnexa;

(d) display of any advertisement, circular, sign, or device offering to:

(i) examine the eyes;

(ii) fit glasses or contact lenses; or

(iii) adjust frames;

(e) removal of a foreign body from the eye or its adnexa, that is not deeper than the anterior 1/2 of the cornea; and

(f) consultation regarding the eye and its adnexa with other appropriate health care providers, including referral to other appropriate health care providers.

Medical Scopes of Practice

Utah Medical Practice Act 58-67-102 Definitions.

(19) (a) "Practice of medicine" means:

(i) to diagnose, treat, correct, administer anesthesia, or prescribe for any human disease, ailment, injury, infirmity, deformity, pain or other condition, physical or mental, real or imaginary, including to perform cosmetic medical procedures, or to attempt to do so, by any means or instrumentality, and by an individual in Utah or outside the state upon or for any human within the state;

(ii) when a person not licensed as a physician directs a licensee under this chapter to withhold or alter the health care services that the licensee has ordered;

(iii) to maintain an office or place of business for the purpose of doing any of the acts described in Subsection (19)(a)(i) or (ii) whether or not for compensation; or

(iv) to use, in the conduct of any occupation or profession pertaining to the diagnosis

or treatment of human diseases or conditions in any printed material, stationery, letterhead, envelopes, signs, or advertisements, the designation "doctor," "doctor of medicine," "physician," "surgeon," "physician and surgeon," "Dr.," "M.D.," or any combination of these designations in any manner which might cause a reasonable person to believe the individual using the designation is a licensed physician and surgeon, and if the party using the designation is not a licensed physician and surgeon, the designation must additionally contain the description of the branch of the healing arts for which the person has a license, provided that an individual who has received an earned degree of doctor of medicine degree but is not a licensed physician and surgeon in Utah may use the designation "M.D." if it is followed by "Not Licensed" or "Not Licensed in Utah" in the same size and style of lettering.

Utah Osteopathic Medical Practice Act 58-68-102. Definitions.

(19)(a) "Practice of osteopathic medicine" means:

(i) to diagnose, treat, correct, administer anesthesia, or prescribe for any human disease, ailment, injury, infirmity, deformity, pain, or other condition, physical or mental, real or imaginary, or to attempt to do so, by any means or instrumentality, which in whole or in part is based upon emphasis of the importance of the musculoskeletal system and manipulative therapy in the maintenance and restoration of health, by an individual in Utah or outside of the state upon or for any human within the state;

(ii) when a person not licensed as a physician directs a licensee under this chapter to withhold or alter the health care services that the licensee has ordered;

(iii) to maintain an office or place of business for the purpose of doing any of the acts described in Subsection (19)(a)(i) or (ii) whether or not for compensation; or

(iv) to use, in the conduct of any occupation or profession pertaining to the diagnosis or treatment of human diseases or conditions, in any printed material, stationery, letterhead, envelopes, signs, or advertisements, the designation "doctor," "doctor of osteopathic medicine," "osteopathic physician," "osteopathic surgeon," "osteopathic physician and surgeon," "Dr.," "D.O.," or any combination of these designations in any manner which might cause a reasonable person to believe the individual using the designation is a licensed osteopathic physician, and if the party using the designation is not a licensed osteopathic physician, the designation must additionally contain the description of the branch of the healing arts for which the person has a license, provided that an individual who has received an earned degree of doctor of osteopathic medicine but is not a licensed osteopathic physician and surgeon in Utah may use the designation "D.O." if it is followed by "Not Licensed" or "Not Licensed in Utah" in the same size and style of lettering.



Figure 1. U.S. states currently allowing optometrist laser privileges

Table 6. Summary of Scope Expansion Legislation by Year and Procedures Allowed						
State	Year Enacted	YAG	SLT	LPI		
Oklahoma	2004	~	~	v		
Kentucky	2011	~	~	~		
Louisiana	2014	~	~	~		
Alaska	2017	~	~	v		
Arkansas	2019	~	V			
Wyoming	2021	~	V	~		
Colorado	2022	~	~	~		
Mississippi	2022	~				
Virginia	2022	~	~	~		

Optometric Training and Practice - US & UK

OPLR reviewed statutes and rules in the nine post-expansion states to better understand the typical training requirements for optometrists with laser privileges. A review of UK regulatory frameworks for optometric licensure and training requirements was also completed. Because much of the academic research on optometrist-delivered laser surgery procedures has been carried out in the UK, understanding the similarities and differences in these areas provides important context for discussions as to the comparability of US and UK optometric practice, as well as the extent to which the results of UK research can be generalized to the US.

United States

Eight of the nine post-expansion states have updated their state codes and rules to reflect the expansion of optometric scope into laser procedures.³⁶ Half of these states require additional training and exams. Training requirements are fairly consistent across these states, with most requiring 32 hours of additional coursework that include fairly standardized requirements for course content areas and in-vivo observation requirements.³⁷ However, exam and certification requirements differ substantially between these states; Arkansas requires certification from the Board of Optometry and passing scores on three exams, Mississippi requires applicants to pass both a written exam and a clinical skills evaluation, while Louisiana only requires applicants to pass one written exam. The other 4 states only require educational documentation, of varying degree, with Wyoming additionally requiring certification from the Board of Optometry.

To become a licensed optometrist in the United States, applicants must have a Doctor of Optometry degree from an accredited university.³⁸ Accredited universities offering Doctor of Optometry degrees differ in their emphasis on laser procedure training, likely affected by scope of practice limitations in their respective states. All programs feature multiple classes on ocular diseases and the treatment of those diseases, including laser procedures; optometrists often provide pre and post care for these procedures. Nearly every program has a course on ophthalmic lasers, typically featuring simulated training of laser procedures.³⁹ For schools in post-expansion states, like Oklahoma and Kentucky, laser and surgical training is emphasized, with programs offering both lab/simulated and clinical experience for laser procedures.^{40,41} For optometrists whose pre-graduation coursework does not satisfy laser certification requirements in their state, continuing education programs are available that allow practitioners to complete the relevant training.⁴²

³⁶ As of the writing of this report, Virginia is still finalizing administrative rulemaking related to scope expansion.

³⁷ Mississippi requires an additional 8 hours working under an ophthalmologist or licensed credentialed optometrist. <u>Miss. Code Ann. § 73-19-191</u>

³⁸ https://optometriceducation.org/about-asco/asco-member-schools-and-colleges/

³⁹ OPLR reviewed the curriculum of all 23 ASCO accredited Doctor of Optometry programs. Only 4 schools did not explicitly have a course with laser/surgical procedures in the title.

⁴⁰ Northeastern State University Oklahoma College of Optometry, 2023

⁴¹ University of Pikeville, 2022

⁴² For example, Northeastern State University in Oklahoma offers an "Ophthalmic Procedures" continuing education course. This course is offered on an ongoing basis and is one of the longest-running training

United Kingdom

Licensure

The regulatory frameworks that govern healthcare practitioners' activities differ substantially between the US and the UK. To practice in the US, an optometrist must meet a set of entry qualifications to hold an active license that permits them to legally engage in a set of protected activities, or scope of practice. In contrast, the limits of UK health professionals' scopes of practice are "defined by their knowledge, skills and experience on an individual level...clinicians in the UK have no restriction except those functions which are regulated and the legal frameworks associated with a particular activity (i.e. prescription of medication)."43 As such, the UK's Optometry Act protects only a few functions specific to the practice of optometry (e.g., performing a sight test, fitting contact lenses, selling optical lenses, or falsely advertising oneself as a registered optometrist/optician).⁴⁴ Rather than legislating scope of practice, this law largely serves to protect optometrists' title as well as provide a means to discipline registrants deemed unfit to practice. Instead of legislating specific training and education gualifications that a practitioner must meet, the UK has set up competencies for practitioners to meet and the standards for certification at the entity (educational institution) level. As long as the educators ensure their curriculum enables students to demonstrate their competency in the necessary areas, the specificity of training is left up to them.⁴⁵

Entry level qualifications

To practice in the UK as a registered optometrist, one must register with the General Optical Council (GOC). To enter the GOC registry, an applicant must have a degree in Optometry from a certified educational institution and complete various experiential requirements, including a work-based assessment of graded patient visits, a Hospital Eye Service experience with a minimum patient encounter quota, and an additional direct assessment by a doctor of optometry.⁴⁶

One may also decide to complete higher qualifications in a specific area, like glaucoma. The highest levels of specialization allow for community optometrists to run specialized clinics independently and for hospital optometrists to work with greater autonomy in a hospital glaucoma clinic. Registered optometrists may also gain an independent prescribing qualification after working as a registered optometrist for 2 years and completing the necessary training.⁴⁷

Expanded scope-laser privileges

The UK's approach to regulating health professionals' activities means that, for any health professional working in a hospital setting, there are few restrictions on what activities they can perform, given they have the necessary knowledge, skills, experience, insurance, and

programs in the country, as Oklahoma was the first state to authorize optometric scope to include laser procedures. See https://optometry.nsuok.edu/continuingeducation/Ophthalmic_Procedures.aspx

⁴³ Vallabh, N.A., 2023. [Email]

⁴⁴ Opticians Act 1989

⁴⁵ College of Optometrists. 2023

⁴⁶ Ibid.

⁴⁷ Ibid.

supervision if necessary.⁴⁸ It is largely left to the local Trust or employer (i.e. hospital) to set standards of practice and determine which professionals may carry out specific activities.

Therefore, laser surgery privileges are also decided at the entity or hospital level. Optometrists are not restricted from engaging in laser surgery, as long as their knowledge, skills, and experience allows them to engage in the practice safely and the hospital's standards do not explicitly prohibit them. This is not to say, however, that the UK has not experienced challenges related to optometrist-delivered laser surgery procedures—as researchers have noted, one of the greatest perceived challenges in non-physician deliverance of laser procedures, in this case SLT, is related to the current lack of standardized training and governance.⁴⁹

Moorfield Eye Hospital in the UK is one of the hospitals that allows non-physician health specialists to engage in laser surgery, and they offer a laser course for ophthalmic healthcare professionals to engage in three laser procedures: SLT, YAG peripheral iridotomy (PI) and YAG capsulotomy.⁵⁰ The training combines didactic lectures with workshops and all enrolled are expected to find placement within a clinic to engage in in-vivo training. To enroll in the training, health specialists must: 1) possess a minimum of a BSc in Optometry, Orthoptics or Nursing or equivalent, 2) hold a College of Optometrists Glaucoma Higher Certificate or an equivalent qualification, 3) must be or must be working toward becoming an independent prescriber or be able to prescribe as part of a PGD in their Trust. It is also recommended that applicants have experience working in a glaucoma clinical setting. As part of training, applicants must engage in supervised practice of these laser procedures.

Chadwick et al. noted a similar process for allied health professionals (AHP) in a Scottish NHS Hospital Eye Service to perform SLT. "A system of accreditation requiring attendance at didactic teaching, laser safety training, and directly supervised practice under the direct supervision of an experienced consultant ophthalmologist with a specialist interest in glaucoma, was developed in order to complete a skills matrix designed specifically for this service by consultant ophthalmologists specializing in glaucoma before being signed off for independent practice." The researchers found that, although only 5 supervised SLT procedures were initially considered adequate for a sign-off, the AHPs performed around 23 supervised SLT procedures before sign-off.⁵¹

Qualifications for laser privileges clearly vary by hospital in the UK, but the required training typically consists of both didactic lecture and direct supervised practice under a specialized ophthalmologist, who must sign off on a number of procedures.

Additionally, optometrists performing clinical care (i.e., laser procedures) must work within an ophthalmologic clinic and consult with ophthalmologists. The degree of supervision may vary between optometrists and hospitals, depending on the qualifications and training of the

⁴⁸ Vallabh, N.A., 2023. [Email]

⁴⁹ Konstantakopoulou et al., 2021

⁵⁰ Moorfields Education, 2023

⁵¹ Chadwick et al., 2019

optometrist and the standards set by the hospital. OPLR was unable to determine the exact parameters of this supervision, but experienced optometrists who perform many of these procedures seem to work with a fairly high degree of autonomy within the hospital center.⁵²

3. Findings: Safety

Analysis of Patient Safety Outcomes in Post-Expansion States

OPLR contacted both the boards of optometry and the medical boards in all nine post-expansion states to request data on safety outcomes in these states. All nine boards of optometry responded to OPLR's inquiries and provided the requested data, where available.⁵³ In total, post-expansion states reported that optometrists have performed an estimate of at least 195,000 laser procedures in total. Only Oklahoma and Missouri reported that negative outcomes had been recorded. While the exact count of negative outcomes in Oklahoma was not available, the Oklahoma optometry board executive director stated to OPLR that these events were the result of cystoid macular edema, which in each case "was successfully managed by the optometrist without harm" using anti-inflammatory topical eye drops.⁵⁴ Missouri reported one negative outcome and one disciplinary action, both of which were associated with the same incident.⁵⁵ A total of four malpractice cases were reported, all of which occurred in Oklahoma and were settled out of court.⁵⁶ Under any method of calculation, these represent near-zero incident rates.⁵⁷

As of the writing of this report, four state medical boards have responded to OPLR's inquiries (AR, OK, VA, and WY). Of these states, none require ophthalmologists to report similar metrics on procedures performed or negative outcomes. These states reported zero disciplinary actions or malpractice claims against physicians related to these procedures, and none are aware of

⁵² Harper et al., 2015

⁵³ The data available from each state varied due to differing reporting requirements. State reporting requirements ranged from requiring ODs to report both the number of laser procedures performed and the number of negative outcomes, to no related reporting requirements. Some states' requirements fell in the middle of this spectrum–for example, Colorado does not require ODs to report the number of procedures performed, but does require any negative outcomes to be reported. Louisiana reporting requirements include both the number of procedures and negative outcomes, but only "visually significant" outcomes must be reported. Oklahoma previously required procedure count and outcomes reporting for a 5-year period at the beginning of the scope expansion, but has since discontinued those requirements.

⁵⁵ This disciplinary action resulted in the suspension of the licensee's privileges to perform laser surgery procedure, the assessment of a fine, and reinstatement conditional on additional board supervision.
⁵⁶ Only one of these cases has been confirmed to be related specifically to one of the three laser procedures within the scope of this review. The OK optometry board stated to OPLR that this malpractice case was the result of an optometrist "not making the proper adjustment in a YAG laser procedure."
⁵⁷ If calculated as a percentage of all procedures reported in post-expansion states, these five incidents represent a safety incident rate of 0.003%; if reported as a percentage of procedures in only those states in which incidents occurred or that require negative outcome reporting, this rate is 0.004%.# Measured another way, over the 55 total post-expansion state-years, these states have reported an average of 0.1 patient safety incidents annually.

any complaints made by physicians against optometrists to the state optometry boards in relation to the performance of these procedures.

This regulatory data comes with significant limitations and should be interpreted with caution. First, the lack of standardized reporting requirements (both across states and across the medical and optometric professions) and the lack of any centralized system for reporting and storing the data that is reported makes it difficult both to draw direct comparisons between states and to determine whether the values reported by each state are in fact measuring the same variable in the same manner. Differing reporting thresholds and definitions of "negative outcomes" or "adverse events" also make rigorous comparison difficult–an incident that an optometrist is legally required to report in one state may not meet reporting thresholds in another state. (For instance, Arkansas requires optometrists to report "any outcome that is not desirable," whereas neighboring Louisiana only requires "visually significant" negative outcomes to be reported.) Additionally, it is possible that even in states with more rigorous reporting requirements, these oversight systems may have failed to identify some patient safety incidents (e.g., due to falsified reports, purposeful or accidental failure to report incidents that meet reporting thresholds, practitioners being unaware of negative outcomes experienced by their patients, or patients not making complaints to regulators).

Methodology. Each optometry board was asked to provide any available information on 1) the reported number of procedures performed by optometrists, 2) the reported number of negative outcomes or adverse events associated with procedures performed by optometrists, and 3) the volume and nature of any related disciplinary actions or malpractice cases against optometrists. Each medical board was asked to provide information on 1) whether ophthalmologists in their state are required to report the number and outcome of procedures performed, 2) the volume and nature of any related disciplinary actions or malpractice cases against ophthalmologists, and 3) whether the board was aware of any complaints made by physicians to the state optometric board against optometrists related to these procedures.

Table 7. Administrative Data from Post-Expansion States: Certifications, Procedures, and Outcomes								
State	Count of ODs certified	% of all ODs certified	Procedure reports required	Outcome reports required	Count of Procedures	Count of Negative Outcomes	Count of Disciplinary Actions	Count of Malpractice Claims
Alaska	54	21.86%	-	-	-	-	0	0
Arkansas	171	30.54%	~	~	2,956	0	0	0
Colorado	Certification not required	-	-	~	-	0	0	0
Kentucky	498	56.33%	-	-	~60,000	0	0	0
Louisiana	362	57.64%	~	~	25,807	0	0	0
Mississippi	187	40.74%	~	~	~2,000	1	1	0
Oklahoma	908	~100%	-	-	~105,000	≥1 ⁵⁸	0	4
Virginia	No certifications yet issued, reporting rules not finalized				-	-	-	-
Wyoming	Certification not required ⁵⁹	-	-	-	-	-	0	0

⁵⁸ The OK optometry board's response to OPLR only specified that "very few adverse outcomes" were recorded during the initial 5-year period (previous to 1998) in which OK optometrists were required to report laser surgery outcomes. In response to OPLR's follow-up, the executive director stated that details on these adverse outcomes 'are not available at this time," but that "each outcome was successfully managed by the optometrist without harm," and that the cases reported were associated with cystoid macular edema and treated with anti-inflammatory topical eye drops.

⁵⁹ Wyoming does not require that optometrists hold a state-issued certification, but optometrists performing laser procedures must maintain documentation of the required training outlined in state statute and rule.

Table 8. Optometric and Medical Regulators Contacted in Post-Expansion States						
Optometry Boards						
State	Contact(s)	Response				
Alaska	Ashley Carabajal, Occupational Licensing Examiner, Board of Examiners in Optometry9/12/20					
Arkansas	Tanya Ford, Executive Director, State Board of Optometry	9/13/2023				
Colorado	Karen Phelan, Program Director, State Board of Optometry	9/13/2023				
Kentucky	Christi LeMay, Executive Director, Kentucky Board of Optometric Examiners	9/14/2023				
Louisiana	Gary Avallone, Secretary, State Board of Optometry Examiners	9/13/2023				
Mississippi	Beverly Limbaugh , Executive Director, Mississippi State Board of Optometry	9/26/2023				
Oklahoma	Russell Laverty, Executive Director, Board of Examiners in Optometry	9/25/2023				
Virginia	Leslie Knachel, Executive Director, Board of Optometry9/12/2023					
Wyoming	Emily Cronbaugh, Executive Director, Board of Examiners in Optometry	9/15/2023				
	Medical Boards					
Alaska	Natalie Norberg, Executive Administrator, Alaska State Medical Board	9/28/2023				
Arkansas	Juli Carlson, Regulatory Manager, Arkansas State Medical Board	9/25/2023				
Colorado	Colorado Medical Board	None				
Kentucky	Kentucky Board of Medical Licensure	None				
Louisiana	Louisiana State Board of Medical Examiners	None				
Mississippi	Mississippi State Board of Medical Licensure	None				
Oklahoma	Lyle Kelsey, Director, Oklahoma Medical Board	9/28/2023				
Virginia	Jennie Wood, Case Manager, Discipline & Compliance, Virginia Board of Medicine	9/25/2023				
Wyoming	Kevin Bohnenblust, Executive Director, Wyoming Board of Medicine	9/25/2023				

Literature Review on Patient Safety

OPLR's review of the academic literature on patient safety focused primarily on locating findings related to the outcomes of laser surgery procedures performed by optometrists. Emphasis was placed on locating any available studies that compared ophthalmologists' and optometrists' performance of the procedures and related patient safety outcomes. Studies that examined optometrists' abilities to accurately diagnose and make appropriate treatment management decisions were also prioritized.

OPLR found that the literature on these topics is still limited. Significant research gaps exist (e.g., no studies related to optometrists' performance of LPI were identified), and the literature on YAG and SLT procedures is often limited by the lack of direct comparisons between ophthalmologists' and optometrists' performance of these procedures in a controlled clinical setting. To the best of OPLR's knowledge, researchers have yet to conduct randomized controlled trials that directly compare the two provider groups' performance on any of the three procedures within the scope of this review, which would be the ideal standard of evidence upon which to base either affirmative or negative scope expansion recommendations. Many studies are also limited by small sample sizes or retrospective (rather than prospective) designs.

The following summary of relevant research identified in OPLR's review is not meant to be exhaustive. Additionally, as our team are not medical professionals or experts in the medical fields described below, this summary will be primarily descriptive rather than interpretive. Summary tables of highlighted literature relevant to the following five topics are provided below.

Diagnosis & Clinical Decision-Making. Much of the research evaluating optometrists' diagnostic accuracy and their levels of agreement with ophthalmologists in terms of treatment planning has been conducted in the United Kingdom's Hospital Eye Service (see *Annoh et al. 2019, Marks et al. 2012, Ho & Vernon et al. 2011*). The effectiveness of both experiential and didactic training methods for upskilling optometrists have also been studied (*Myint et al. 2014, Azuara-Blanco et al. 2007*). However, many of these studies examined very small groups of providers, or sometimes only an individual provider, and not all findings may be generalizable to the eye care landscape in the U.S. Whereas many U.S. optometrists practice independently, many of the UK studies evaluated the performance of hospital optometrists working in larger clinic settings and under the supervision of an ophthalmologist consultant

Overall, research in this area has found that optometrists who receive additional training and practical experience (such as working in glaucoma clinics) can achieve high levels of diagnostic concurrence with ophthalmologists, with some studies finding that optometrists could display diagnostic and decision-making skills related to the treatment of glaucoma similar to those of junior ophthalmologists. Again, however, many of these studies are low-powered and additional research is needed in this area.

YAG Capsulotomy. The most relevant research on the safety of optometrist-performed YAG capsulotomy procedures is a 2023 prospective study (Lighthizer et al., 2023). This study

examined the effectiveness and complication rates of 91 YAG procedures performed by optometrists in Oklahoma and Louisiana. Other than this study, however, the existing literature seems to be sparse. Lighthizer et al. found that optometrist-delivered YAG procedures were highly effective in improving subjects' vision, and of the 69 patients whose outcomes were tracked for three months, the only adverse event reported was lens pitting with no impact on vision. Additionally, while findings from Moussa et al. (2022) examined the outcomes of YAG delivered by an advanced nurse practitioner rather than optometrists, that study also provides early evidence that non-physician HCPs can be satisfactorily trained to deliver laser surgery procedures.

Selective Laser Trabeculoplasty (SLT). Of the three procedures under review, SLT is the most studied when it comes to outcomes of optometrist-performed procedures. However, as noted in a 2021 review of the existing literature, "There has yet to be a randomised controlled clinical trial evaluating outcomes" (Jones et al., 2021). Chadwick et al. (2019) conducted a prospective study of SLT delivered by allied health professionals, including optometrists, finding low rates of minor complications comparable to those of ophthalmologists, but the treated patient populations were not randomized between provider groups. Stein et al. (2016), examined the rates of repeat SLT needed by patients who had undergone an initial procedure by either optometrists or ophthalmologists. The available academic research provides early indications that the efficacy and safety outcomes of optometrist-delivered SLT may be comparable to that of ophthalmologist-delivered SLT (Lee et al., 2023). While Stein et al. found a higher rate of repeat procedures for patients of optometrists, this was a retrospective study using Medicare claims data that did not include any clinical data on safety outcomes and did not control for differences in clinical techniques. Studies incorporating clinical data have not demonstrated significant differences in safety outcomes, but these studies may not be fully generalizable to the U.S., as the majority of SLT research comes out of the U.K., where laser-trained optometrists are practicing in hospital settings with access to ophthalmologists.

Laser Peripheral Iridotomy (LPI). The gap in the patient safety literature is most significant when it comes to optometrist-performed LPI. As of the writing of this report, OPLR has not yet located any literature discussing the patient outcomes of optometrist-performed procedures.

General Research on Expansion of Optometric Scope. Chodnicki et al. (2018) described the national landscape of optometric scopes and found some associations between workforce-to-population ratios and states' scope of practice policies. Several studies from the United Kingdom also describe the trends in optometric scope expansion in the UK, including the mechanisms through which these scope expansions have occurred in hospital contexts. This literature shows that the U.K. has seen an increased emphasis on training optometrists to deliver laser surgery procedures to enhance the efficiency of eye care delivery, as a growing number of Hospital Eye Service sites report utilizing optometrists in this expanded scope. (Gunn et al., 2022) U.S. researchers have also identified optometric scope expansion as a potential solution to the growing mismatch between demand for eye care services and the declining ophthalmic workforce (Browning, 2018).

	Table 9. Highlighted Literature on Diagnostic Accuracy & Clinical Decision-Making							
Study	Study Scope/Aims	Procedures/ Conditions/Patient Populations	Practitioners	Key Findings/Conclusions				
<u>Annoh</u> et al. (2019)	"To examine the accuracy of referrals by community optometrists for suspected primary angle closure, including primary angle closure suspects, primary angle closure and primary angle closure glaucoma."	Glaucoma patients (n = 715)	Optometrists	"Community optometrists had good ability to detect eyes at risk of angle closure. There was also greater accuracy of referrals for suspected angle closure than for other glaucoma referrals."				
<u>Myint et</u> <u>al.</u> (2014)	"To investigate the impact of a postgraduate training module on optometrists' clinical decision-making in relation to the diagnosis and management of primary open-angle glaucoma."	Glaucoma	Optometrists (n = 73)	"The results of the present study suggest that a traditional didactic approach, in isolation, is unlikely to be suited to training optometrists to achieve or develop the clinical competencies required for glaucoma detection and management. Consideration should be given to the development of specialist postgraduate training that is more practice-based, provides opportunities for active learning and includes strategies for feedback and reinforcement."				
<u>Hadwin</u> et al. (2013)	"To assess the ability of UK optometrists to accurately discriminate between stereoscopic photographs of healthy and glaucomatous optic discs."	Glaucoma	Optometrists (n = 208)	"On average, UK optometrists display high sensitivity and moderate specificity when examining optic discs for glaucoma in this study."				
<u>Marks</u> <u>et al.</u> (2012)	"The aim of this study was to assess the agreement between specially trained optometrists and glaucoma-specialist consultant ophthalmologists in their management of glaucoma patients."	Glaucoma patients (n = 96)	Ophthalmologists (n = 2) Optometrists (n = 4)	"the optometrists in our study achieved an 81% level of agreement with the glaucoma-specialist consultant ophthalmologists when making clinical management decisions about the timing of follow-up, the suitability for discharge, and the need to discuss or refer the patient back for a consultant's opinion and/or intervention. This level of agreement increased to 90% when qualified agreements were included and decisions regarding medical management reached agreement levels of 96–97%."				
<u>Ho &</u> Vernon (2011)	"Our aim was to audit the appropriateness of optometrists' decision-making when working	Glaucoma patients (n = 140)	Ophthalmologists (n = 2) Optometrists	"It has been demonstrated that community optometrists with additional training in glaucoma can make management decisions concerning diagnosis and initial therapy at least as well as junior ophthalmologists				

	in an in-house shared care glaucoma scheme."		(n = 3)	and with a weighted Kappa score of 85% in comparison with a consultant ophthalmologist. Our study suggests that, with appropriate training and experience, community optometrists can perform at a similar or higher level when making management decisions on patients with established diagnoses of glaucoma and glaucoma related conditions."
<u>Azuara-</u> <u>Blanco</u> <u>et al.</u> (2007)	"To compare the diagnostic performance of accredited glaucoma optometrists (AGO) for both the diagnosis of glaucoma and the decision to treat with that of routine hospital eye care, against a reference standard of expert opinion (a consultant ophthalmologist with a special interest in glaucoma)."	Glaucoma patients (n = 100)	Ophthalmologists Optometrists	"Community optometrists trained in glaucoma provided satisfactory decisions regarding diagnosis and initiation of treatment for glaucoma. With such additional training in glaucoma, optometrists are at least as accurate as junior ophthalmologists but some cases of glaucoma are missed."
<u>Hau et</u> <u>al.</u> (2006)	"To assess optometrists' ability to correctly identify and manage patients with different ocular conditions seen in the accident and emergency (A&E) department of an eye hospital."	Diagnosis of multiple conditions (n = 150)	Ophthalmologists (n = 1) Optometrists (n = 2)	"There was good agreement in both the diagnosis and management plan between optometrists and the ophthalmologist. This study has shown that optometrists can potentially work safely in an A&E [accident and emergency] department of a busy eye hospital."
<u>Menon</u> <u>et al.</u> (2004)	"To study referrals of posterior capsular opacification (PCO) for laser capsulotomy by optometrists and compare direct referral with that via the general practitioner (GP)."	YAG referrals (n = 222)	General practitioners Optometrists	"Diagnostic concurrence was 99% (211/213 patients). The rate of laser capsulotomy was 98.2% (215/219)Direct optometrist referral is effective, accurate and reduces patient waiting time and GP workload."
<u>Oster</u> <u>et al.</u> (<u>1999</u>)	"At Moorfields Eye Hospital, we attempted to develop the role of the hospital optometrist by establishing a study to evaluate the clinical appraisal of new referrals in a busy out-patient clinic."	Multiple	Optometrists (n = 1)	"The results showed a high level of diagnostic accuracy which suggests that the role of hospital optometrists may be successfully extended to include some aspects of patient evaluation not typically undertaken."

Table 10. Highlighted Literature on YAG Capsulotomy				
Study	Study Scope/Aims	Procedures/ Conditions	Practitioners	Key Findings/Conclusions
Safety of Optome	etrist-Performed Procedures			
Lighthizer et al. (2023)	"This study aims to assess the efficacy and safety of capsulotomy procedures performed by optometrists."	YAG capsulotomy (n = 92)	Optometrists	"99% of subjects in this study who responded reported subjective improvement in vision and 95% of subjects showed objective visual improvement which allowed for a better quality of life. No significant adverse events were noted in any subject. This study demonstrates that capsulotomies can be effectively and safely performed by doctors of optometry with minimal risk to patients and significant benefit to visual function and provides evidence to support the use of YAG capsulotomy in optometric practice."
<u>Moussa et al.</u> (2022)	"To primarily report the baseline characteristics and visual acuity (VA) outcomes of advanced nurse practitioners (ANP) compared to ophthalmologists following YAG posterior capsulotomy (YAGPC)."	YAG capsulotomy (n = 6,308)	Ophthalmologists (n = 111) Advanced nurse practitioners (n = 1)	"While we detected no difference in visual outcomes between different operator grades, we found that a lower proportion of patients in the ANP group required further YAGPC compared to the ophthalmologists' group (p<0.001 in both instances)."
Baseline - Safety	Rates and Complications			
<u>Dot et al.</u> (2023)	"To estimate the incidence and assess the risk factors associated with 3 adverse events (AEs) after neodymium:yttrium-aluminu m-garnet posterior capsulotomy (Nd:YAG-caps): ocular hypertension (OHT), macular edema (ME), and retinal detachment (RD)."	YAG capsulotomy (n = 7,958)	Ophthalmologists	"The 3-month and 12-month overall AE [adverse event] rates (≥ 1 AE of interest) were 8.6% and 13.3%, respectively Three-month rates were ≈5% for OHT [ocular hypertension] and ME [macular edema]. Retinal detachment remained ≤ 0.5% over follow-upOHT and ME were the most frequent AEs of interest post–Nd:YAG-caps, mainly observed within 3 months post procedure, highlighting the need for a close follow-up during this period or a delayed capsulotomy. Diabetes and an early Nd:YAG-caps after cataract surgery were among the main drivers for AE occurrence."
<u>Liu et al. (2022)</u>	"This study aimed to evaluate the impact of Nd:YAG laser capsulotomy	YAG capsulotomy (n = 8,232)	Ophthalmologists	"This analysis demonstrated an increased risk for RD with Nd:YAG laser capsulotomy (relative risk [RR], 1.57; 95% CI, 1.17-2.12; P = .003; hazard ratio, 1.64; 95% CI, 1.03-2.62; P = .04)."

DRAFT on the incidence of pseudophakic retinal detachment (RD). " Burg & Tagui YAG capsulotomy Ophthalmologists "To document the frequency "The incidence of retinal detachment after Nd:Yag laser capsulotomy (2008)in our institution was 1.9% which is similar to incidence rates of retinal detachment and (n = 104) other complications worldwide. However, that of cystoid macular oedema was markedly associated with Nd:Yag laser higher at 9.6% when compared to incidence rates worldwide." capsulotomy." Billotte & "To evaluate the clinical YAG capsulotomy Ophthalmologists "Over 9 years in a 70-year-old population, switching from an IOL with Berdeaux (n = 3,335)a 20% Nd:YAG capsulotomy rate at 3 years to an IOL with a 5% rate consequences of (2004) complications from would avoid 1 chronic intraocular pressure increase requiring neodymium:YAG (Nd:YAG) medical follow-up in every 54 surgeries, 1 case of glaucoma in every 237 surgeries, 1 case of cystoid macular edema in every 265 laser capsulotomy for surgeries, and 1 retinal detachment in every 265 surgeries." posterior capsule opacification (PCO) over the lives of cataract patients."

	Table 11. Highlighted Literature on Selective Laser Trabeculoplasty (SLT)					
Study	Study Scope/Aims	Procedures/ Conditions	Practitioners	Key Findings/Conclusions		
Safety of Optome	etrist-Performed Procedures					
<u>Lee et al.</u> (2023)	"SLT in the UK national health service (NHS) is increasingly undertaken by optometrists (OPTs) but studies comparing outcomes of SLT delivered by OPTs to ophthalmologists (OPHs) are lacking. We have undertaken a multi-centre observational study to evaluate this."	SLT (n = 194)	Ophthalmologists Optometrists	"Efficacy outcomes of SLT are comparable between eyes treated by OPTs compared to OPHs. There was a higher risk of raised IOP in eyes treated by OPHs - this may be due to differences in baseline case mix with OPHs opting to treat patients at higher risk of complications or progression."		
<u>Jones et al.</u> (2021)	"We conducted a scoping review to identify the current global landscape of HCP [health care professional]-delivered SLT and describe training features, clinical effectiveness and safety."	SLT		"Although limited, published results indicate HCP outcomes are comparable to ophthalmologists. The level of evidence was low as outcomes have only been assessed among a small number of HCPs without optimising study design. There has yet to be a randomised controlled clinical trial evaluating outcomes, such as clinical efficacy, safety profile, legal framework and patient experience in HCP-delivered SLT. Further research into stakeholders' views of changes in the delivery infrastructure of SLT (already underway by the review authors) and into clinical effectiveness and cost-effectiveness and safety, with suitable outcome measures and larger sample sizes, may help consolidate evidence in this area."		
<u>Konstantakopo</u> <u>ulou et al.</u> (2021)	"To explore the acceptability, training requirements, enablers and barriers of optometrist-delivered SLT."	SLT	Optometrists	"Certain clinical pre-requisites, such as gonioscopy and independent prescribing rights, were perceived as necessary for undertaking SLT training. An optometrist-delivered SLT service was expected to benefit the NHS, but there was an identified need of a standardised training scheme and robust governance. Patients were accepting of an optometrist-delivered SLT service in the hospital eye service."		
<u>Chadwick et al.</u> (2019)	"To describe the process of establishing a selective laser trabeculoplasty (SLT) service delivered by experienced allied health professionals (AHP) in a	SLT (n=325)	Ophthalmologists Optometrists Other allied health professionals	"the outcomes of this study demonstrate that the AHP delivered SLT service is at least as safe as the previous ophthalmologist delivered SLT service. The data demonstrate a similar efficacy between AHP and ophthalmologist delivered SLT."		

	Scottish NHS Hospital Eye Service, and assess the safety and efficacy in comparison with SLT performed by ophthalmologists."		(AHPs)	
<u>Stein et al.</u> (2016)	"To compare outcomes of LTPs performed by ophthalmologists with those performed by optometrists to determine whether differences exist in the need for additional LTPs."	SLT (n = 1,384)	Ophthalmologists Optometrists	"Considerable differences exist among the proportions of patients requiring additional LTPs comparing those who were initially treated by ophthalmologists with those initially treated by optometrists."
Fingeret (2016)	Invited commentary on Stein et al. (2016)	SLT	Ophthalmologists Optometrists	"Using Medicare claims data as their only resource, [Stein et al.] did not have access to LTP outcomes—the goal of their study—and hence, only reported procedure utilization rates Without the aforementioned information, the number of LTP sessions cannot be a substitute for the quality of the procedure."
Baseline - Safety	Rates and Complications			
<u>Landers (2021)</u>	"SLT is equally effective as ALT and topical medication in lowering IOP. It is simple to perform, with a well described side-effect profile, and is long-lasting and repeatable. This review will summarise the current literature on SLT for each of these topics."	SLT	-	"After 20 years, SLT has established itself as an effective and safe modality for managing glaucoma. It is simple to perform, with a well described side-effect profile, is long-lasting, and repeatable. It is comparable to topical medication in its IOP lowering effect, without any of the side-effects commonly seen with the eye drops."

Table 12. Highlighted Literature on Laser Peripheral Iridotomy (LPI)					
Study	Study Scope/Aims	Procedures/C onditions	Practitioners	Key Findings/Conclusions	
Safety of Optome	etrist-Performed Procedures				
No literature ider	ntified				
Baseline - Safety	Rates and Complications				
Radhakrishnan et al. (2018)	"To examine the efficacy and complications of laser peripheral iridotomy (LPI) in subjects with primary angle closure (PAC)."	LPI, Glaucoma	-	"Laser peripheral iridotomy increases angle width in all stages of primary angle closure and has a good safety profileThere were relatively few studies on complications after LPI, which included IOP spikes, dysphotopsia, anterior chamber bleeding, and cataract progression. Subjects included in 4 of 5 studies on IOP spikes after LPI were exclusively or predominantly PACS, but this complication is of higher concern in PACG eyes that are more vulnerable to IOP elevations. Although the issue of cataract progression remains of concern when considering prophylactic LPI in a population-based setting, it may be less relevant in the clinic-based setting, especially with the current trend toward early cataract or clear lens removal for angle closure."	

	Table 13. Highlighted Literature on the General Trend of Optometric Scope Expansion					
Study	Study Scope/Aims	Key Findings/Conclusions				
<u>Gunn et al.</u> (2022)	"We aim to establish if the skills or services delivered by optometrists [working in hospital settings in the UK] have changed to meet varying demands."	"Optometrists' scope of practice continues to develop in the HES with an increased variety of roles and an apparent increase in the number of units employing optometrists, often working in roles historically performed by medical practitioners. Such changes appear necessary in recovery and transformation within ophthalmology, alongside wider optometry changes arising at the interface of primary and secondary care."				
Browning (2018)	Editorial on approaches to addressing decreasing ophthalmologic workforce availability	"The gap between demand for physician services in the United States and the supply is increasingIn ophthalmology, the mismatch is amplifiedThere are several ways the gap can be addressed. One response is to increase the supply of optometrists and change their scope of practice so that they assume more of the duties previously carried out by ophthalmologistsAnother option is for ophthalmologists to use physician assistants (PAs) to supplement their effortsAn advantage of PAs from the perspective of the ophthalmologist is that they work as part of a physician-led team, a feature not associated with optometrists, who can practice independently if they care to do so."				
<u>Chodnicki et al.</u> (2018)	"To describe state laws that govern the optometric practice of glaucoma management in the United States and to correlate those laws with state demographics up to 2015."	"Optometrists in all states, except for Massachusetts, and the District of Columbia are allowed to manage glaucoma; 16 states have defined comanagement guidelines. Therapeutic lasers are allowed in 3 states: Kentucky, Louisiana, and Oklahoma There is a diversity of regulations that govern optometric management of glaucoma in each of the 50 states and the District of Columbia. The number of optometrists and ophthalmologists in a state may influence state regulations governing optometric practice and referral guidelines."				
<u>Harper et al.</u> (2015)	"In this report, we present the findings from a national survey of the scope of practice of optometrists working in the UK HES."	"A substantial majority of respondents (N = 67/70, 96%) indicated that optometrists undertook extended rolesA wide variety of clinical procedures or interventions are undertaken as part of these services, which for a small number of optometrists now also includes the undertaking of specific laser procedures. There is evidence for a significant degree of autonomy within these extended roles. The primary mode of training is an 'apprentice' model, incorporating sessions worked under supervision in ophthalmology clinics."				
<u>Creer et al.</u> (2014)	"The primary purpose of this paper is to describe the evolving role and scope of practice of the optometrist working in hospital practice, working at the interface with ophthalmology, while also focusing on the potential training and accreditation requirements that go hand in hand with such roles."	"The evolving role for hospital optometry [in the NHS] demonstrates an emphasis on clinical roles traditionally undertaken by ophthalmologists and, while the term 'medical' optometry might be used to describe such services, this work is now part of the scope of practice of modern hospital optometryEntry-level competencies of the newly qualified optometrist should be augmented through local training and accreditation and/or undertaking national training programmes where available. It is vital that extended-role clinicians, in particular those with more autonomous decision-making responsibilities, are fully supported by appropriate extended-role competency-based assessments."				

Analysis of State and Federal Disciplinary Action Data

OPLR also attempted to corroborate and supplement the safety findings discussed above by analyzing data available from the Utah Division of Professional Licensing (DOPL) and the National Practitioner Data Bank (NPDB). This included examining records of closed complaints against Utah-licensed physicians who appeared on a public registry of board-certified ophthalmologists, contacting the DOPL bureau head responsible for physician investigations, and accessing NPDB data on adverse action reports and malpractice claims against optometrists in post-expansion states.

DOPL Records. DOPL staff confirmed that the division has not taken any disciplinary actions against physicians in relation to ophthalmic laser surgery procedures since at least 2000, which is the earliest year available for physician complaints in the current database.⁶⁰ OPLR analysis of this data identified a total of three substantiated complaints of incompetence or negligence against individuals currently listed as board-certified ophthalmologists⁶¹ prior to 2015 (all of which were resolved with verbal warnings), but none of these were related to laser surgery procedures.

NPDB Data. OPLR examined publicly available data on all adverse actions and malpractice claims against optometrists reported to the NPDB between 1990 and 2023 in all post-expansion states.⁶² It is important to note that this data does not include information as to the nature of the incidents or procedures involved, so it is unknown whether these reports made to the NPDB in each state were related to optometrists' performance of laser procedures or not. However, when examining general patterns in the volume of reports made, this data showed no systematic increases in adverse action or malpractice reports after scope expansion in each state; with the exception of Kentucky, all other post-expansion states have in fact seen decreased reports post-expansion. However, the total volume of these reports is very small and OPLR was unable to determine whether the patterns described have any statistical significance or correlation with the enactment of scope expansion legislation.

⁶⁰ Marx, L., 2023. [Email]

⁶¹ It is possible that OPLR's search did not identify all complaints against ophthalmologists, as board certifications had to be manually crosswalked with licensing records. This was necessary because DOPL data does not maintain records of physicians' specialty areas or board certifications. This may have resulted in missing complaints against those who are no longer board certified, or whose primary practice address listed on their board certification is outside of Utah.

⁶² 2023 NPDB data only includes reports made as of June 30, 2023.

4. Findings: Access

To understand the proposed scope expansion's potential impacts on consumers' access to care, OPLR analyzed data and information from 1) the existing academic literature, 2) Medicare datasets, 3) national board certification registries, 4) federal health workforce datasets, 5) administrative data from post-expansion states, and 6) Utah licensing records. (See appendix).

Current Access to Laser Eye Surgery in Utah

Service Utilization. According to 2021 Medicare claims data, YAG is the most commonly delivered procedure in the state in terms of overall volume, followed by SLT and LPI procedures. While Medicare does not cover all laser procedures performed in the state, it is estimated that 80% of YAG procedures are covered by Medicare.⁶³ This analysis also assumes that a similar proportion of SLT and LPI procedures are covered by Medicare, as most cases of cataracts (in which YAG is used to treat postoperative lens clouding) occur in populations over 65 years of age⁶⁴ and the prevalence of glaucoma (treated by SLT and LPI) also increases with age.^{65,66}

To OPLR's knowledge, reliable data on unmet need for these three procedures (such as unmet need due to underinsurance or uninsurance) is not currently available. Such data would give a clearer picture of whether the utilization data displayed below represents sufficient levels of access for Utahns. According to Medicare claims data, YAG is the most frequently delivered procedure, with over 6,000 procedures performed in 2021. YAG is followed in frequency by SLT (680 procedures in 2021) and LPI (none recorded in 2021 and averaging 26 procedures per year between 2013-2021).

Table 14. Medicare Claims Data for YAG, SLT, and LPI Procedures				
Measure	YAG (2021)	SLT (2021)	LPI (2013-2021 annual averages) ⁶⁷	
Medicare Services Provided	6,380	680	26	
Beneficiaries Served	5,295	471	15	
Unique Individual Providers	92	18	<1	
Unique Entity Providers	11	5	<1	

⁶³ French et al., 2017

⁶⁴ Hashemi et al., 2020

⁶⁵ Rudnicka et al., 2006

⁶⁶ The documented typical age of onset for glaucoma is earlier than that for cataracts (sometimes as early as individuals in their 40s) so this estimate may be overlooking some portion of the population that is not yet eligible for Medicare.

⁶⁷ Very little claims data was available for LPI; between 2013-2021, only 6 years had recorded Medicare claims for this procedure in Utah. These numbers are annual averages across 9 years.

Average Services per Individual Provider	49.6	24.0	-
Average Services per Entity Provider	138.4	44.8	-
Average Services per Beneficiary	1.2	1.4	1.7
Estimated Procedures Statewide, Including Non-Medicare ⁶⁸	~7,975	~850	~32

Geographic Access. As of September 2023, a public registry of board-certified ophthalmologists listed 190 ophthalmologists based in Utah and holding current certifications. The majority of these individuals (70.5%) listed addresses in Salt Lake and Utah counties. The remainder were distributed among other urban counties (Weber, Davis, and Cache), rural counties (such as Washington, Summit, and Iron counties) and one frontier county (Grand), for a total of 14 counties covered. The remaining 15 counties, all of which were rural or frontier counties, had no ophthalmologist coverage as measured by providers' addresses. However, while ophthalmologist-to-population ratios vary by county and many counties lack any coverage, the state's aggregate ratio is virtually identical to the national average ratio (as measured in 2017),⁶⁹ at 5.68 providers per 100,000 residents.

This distribution of providers is also supported by data from the Medicare National Downloadable File,⁷⁰ which lists 199 unique ophthalmologists. Of these providers, 80% practice exclusively in urban counties, 20% list at least one rural or frontier practice location, and 12% practice exclusively in rural or frontier counties. If we exclude Park City, which is close to large urban centers, and St. George, which is one of the state's densest rural communities, the proportion of rural and frontier ophthalmologists drops to 5%.⁷¹ This data shows 104 unique facilities listed by these ophthalmologists as a practice location. These facilities cover 17 counties, with 73% of facilities in urban counties, 25% in rural counties and 2% in frontier counties. The remaining 12 uncovered counties are all either rural or frontier counties. Anecdotal reports from rural patients and providers do suggest that rural Utahns face scheduling delays and longer travel to laser surgery providers.

 ⁶⁸ Assuming that 80% of services are covered by Medicare; see <u>French et al., 2017</u>
 ⁶⁹ Feng et al., 2020

⁷⁰ Centers for Medicare and Medicaid Services, 2023b

⁷¹ Medicare National Downloadable File, 2023



Figure 2. Ophthalmologist Density by County as of Sep. 202372

The geographic patterns of laser surgery procedure sites as recorded in the 2021 Medicare claims data referenced above correspond with the licensing and board certification address data used to map ophthalmologist practice locations. The majority of YAG (66%) and SLT (56%) procedures were performed in urban counties, with the remainder delivered in six rural counties (Iron, Washington, Box Elder, Tooele, Summit, and Sevier). All LPI procedures for which claims were submitted between 2013-2021 were performed in Washington County (St. George), and no claims originated from frontier counties. This suggests that although some providers visit rural sites on rotation, these visiting providers have yet to deliver services to Medicare beneficiaries at locations in half of Utah's rural counties or all of Utah's frontier counties. However, overall, the rural availability of these procedures were performed in the urban counties that account for 79% of the population. This may be correlated with demographic differences between counties, as higher proportions of the population are on Medicare in frontier counties (22%) and rural counties (17%) as compared to urban counties (12%).⁷³

Provider Availability. While Utah's ophthalmologist-to-population ratio is currently in line with the national average, and national workforce adequacy is estimated at 91%,⁷⁴ workforce availability is trending downward and is projected to decline to 70% nationwide by 2035.⁷⁵ This is thought to be due in part to an aging workforce⁷⁶ and training bottlenecks resulting from limited residency positions.⁷⁷ Additionally, one analysis found that "rural counties had the highest

⁷² Created using addresses listed on board certification registry (see <u>American Board of Ophthalmology</u>, <u>2023</u>)

⁷³ Centers for Medicare and Medicaid Services, 2023a

⁷⁴ Calculated as estimated supply over estimated demand.

⁷⁵ National Center for Health Workforce Analysis, 2016

⁷⁶ Feng et al., 2020

⁷⁷ Berkowitz et al., 2023

proportion of older ophthalmologists and experienced the greatest increase in the ratio of older to younger ophthalmologists," and that "the retirement of currently practicing ophthalmologists may disproportionally impact rural residents' access to ophthalmic care."⁷⁸ Nationwide, ophthalmologist availability in non metro areas is estimated at 37% and is projected to decline to 29% by 2035.⁷⁹

This downward trend in ophthalmologist workforce availability, combined with projections that the proportion of Utahns above the age of 65 will continue to increase over the coming decades,⁸⁰ may result in reduced access to eye care in the long term, including access to the three laser surgery procedures reviewed here. Regardless of the policies or methods used to expand access to these procedures, Utah policymakers should take proactive steps to ensure that access to vision-saving care remains available and hopefully improves in the long term.

Potential Impacts of Scope Expansion on Access in Utah

Provider Availability. Scope expansion would likely have a significant impact on the number of Utah providers authorized to perform laser surgery procedures. The proportion of licensed optometrists who are certified to perform these procedures in post-expansion stats is moderately positively associated⁸¹ with the number of years since scope expansion legislation was enacted. The percent of laser-certified optometrists ranges from 22% - 40% in states that have passed scope expansion legislation within the last six years (AK, AR, MS, WY), and increases to over 50% in states that are 9-12 years post-expansion (KY, LA).⁸² In Oklahoma, which is 19 years post-expansion, it is assumed that 100% of licensees are certified, as the state now requires all optometrists to meet the requirements for laser certification in order to hold an Oklahoma optometry license.

If Utah were to pass scope expansion legislation and follow a similar trend in certification rates, the state could expect to see around 42% of the optometric workforce certified to perform these procedures by 2030, for a total of approximately 500 certified providers (assuming that the optometric workforce continues to follow previous growth trends as seen in DOPL licensing data).⁸³ This may reduce wait times and make access to care more convenient, but OPLR has not located any systematic research on the impact of optometric scope expansion on wait times. National workforce projections also anticipate a general increase in optometrist workforce adequacy between now and 2035,⁸⁴ corroborating the growth trend seen in Utah's optometric workforce.

⁸³ Between 2014-2023, Utah's licensed optometric workforce grew by an average of 2.2% annually.

⁷⁸ Feng et al., 2020

⁷⁹ Health Resources & Services Administration, 2023

⁸⁰ Kem C. Gardner Policy Institute, 2019

⁸¹ R² = 0.775

⁸² Virginia and Colorado are excluded from this portion of the analysis. Virginia has not begun certifying optometrists to perform these procedures, and data from Colorado was unavailable.

⁸⁴ Health Resources & Services Administration, 2023

However, as one analysis of procedures performed in Oklahoma and Kentucky suggests, the majority of optometrist-performed laser procedures would likely be performed by a small subset of those who become certified. That analysis found that in both states, 5% of optometrists (between 32-35 individuals in each state) performed ~45-50% of advanced procedures.⁸⁵ Thus, Utah may also expect to see a smaller proportion of optometrists actually performing these procedures than may be suggested by the numbers of providers who become certified.

Assertions about potential negative workforce impacts have been made on both sides of this scope expansion debate. OPLR has found no data to support the contention that optometrists would avoid Utah without scope expansion, nor that scope expansion for optometrists would hinder Utah in attracting and retaining ophthalmologists, except in one limited case related to training ophthalmology residents on LPI. (See section below titled "Workforce Training"). OPLR's initial analysis of data from the Area Health Resources Files (AHRF), a federal dataset maintained by HRSA, did not find that optometric scope expansion had any measurable effect on changes in ophthalmologist workforce counts in post-expansion states, whether positive or negative (see section below titled "Ophthalmologist Population in Post-Expansion States: Analysis of Area Health Resources Files").

Geographic Access. As opposed to overall provider availability, scope expansion seems to have had a smaller impact, if any, on access to laser surgery procedures in rural areas of post-expansion states. A study of driving times to laser procedures performed by both ophthalmologists and optometrists in five post-expansion states (OK, KY, LA, AR, MS) found that "with the exception of YAG and SLT in Oklahoma, the percentage of the population within 30 minutes of only an optometrist for laser eye surgery procedures was less than 5% in the states with expanded scope...Most optometrists performing laser eye surgery are doing so where ophthalmologists already practice."⁸⁶

However, impacts on eye care access studied in New Mexico may be more generalizable to potential effects in Utah, due to the two states' more comparable sizes, geographical features, and population density distributions. A 2018 study comparing travel times to optometrist and ophthalmologist offices found that in New Mexico, where optometrists are authorized to perform an expanded set of non-laser surgeries, 34.8% of expanded scope procedures performed by optometrists occurred "in locations where the [estimated travel time] exceeded 1 hour," compared to 12.2% and 0.5% in Oklahoma and Kentucky, respectively.⁸⁷

Utah's current geographic distribution of optometrists, as measured by DOPL licensing address data, does show that optometric coverage is better in rural and frontier counties as compared to ophthalmic coverage, and in the majority of those counties with at least one optometrist, the provider-to-population ratios meet or exceed the targets for developed countries of 1:10,000.⁸⁸ While ophthalmologists are only located in 14 counties, actively licensed optometrists are

⁸⁵ Sanders et al., 2017

⁸⁶ Shaffer et al., 2023

⁸⁷ Stein et al., 2018

⁸⁸ Holden and Resnikoff, 2002

present in 23 of Utah's 29 counties. Those additional nine counties (which include three rural and six frontier counties) would be the areas most likely to see improved access in terms of travel times if this scope expansion were to occur in Utah.



Figure 3. Ophthalmologist and Optometrist Density by County as of Sep. 2023⁸⁹

However, urban-rural disparities still exist in the statewide distribution of optometrists, though not to the extent seen in the distribution of ophthalmologists. Six of the counties with any optometrist coverage only have one provider with a listed address in that county, and this data also does not account for providers who may have moved since last renewing their license or those who live and work in different counties. A study of national trends in the eye care workforce identified this same pattern, stating that "while the mean optometrist density increased in rural counties [over the last decade], there remained a significant rural/urban disparity similar to that seen in the distribution of ophthalmologists. It is possible that optometrists may be dissuaded from practicing in rural areas for similar reasons as ophthalmologists. Furthermore, rural counties not only had a lower density of practicing optometrists but also experienced the smallest growth in the supply of optometrists over the study period."⁹⁰

Workforce Training. Scope expansion for LPI would be the most likely have a measurable negative impact on training opportunities for ophthalmology residents training in the state, as the Moran Eye Center (Utah's sole ophthalmology residency site) reports that a large majority of all LPI procedures are already used for resident training purposes, either as observation opportunities or as opportunities for residents to perform procedures themselves and reach minimum procedure quotas mandated by the ACGME.⁹¹ This assertion is supported by the

⁸⁹ Based on address data available on the ABOP website and DOPL licensing data.

⁹⁰ Feng et al., 2020

⁹¹ John A. Moran Eye Center, 2023. [Meeting]

available data on annual LPI procedure volumes—Medicare data from 2013-2021 showed that an average of only 26 claims were submitted each year for this procedure in Utah. Simultaneously, the Moran Eye Center reported to OPLR that its ophthalmology residents perform a combined average of 18 procedures per year and often still fall well below national medians in terms of resident training procedure volume. In the case of LPI, any diversion of this limited patient pool could very well impact Moran Center residents' abilities to meet ACGME training standards within a timely manner, thus potentially having a direct impact on provider availability.

Literature Review: Access

While much of the key literature on access has been discussed above, the summary tables beginning on the following page provide an overview of the literature that informed OPLR's research and analysis of access to care. The studies listed below include research on general eye care workforce trends, geographic access to eye care (including laser eye surgery procedures in post-expansion states), the incidence of laser procedures and the prevalence of related conditions, and relationships between population-level vision outcomes and workforce availability.

	Table 15. Highlighted Literature on Access to Care					
Study	Scope & Aims	Populations & Measures	Key Findings & Conclusions			
<u>Berkowitz</u> <u>et al.</u> (2023)	"To analyze ophthalmology workforce supply and demand projections from 2020 to 2035."	<i>Population:</i> U.S. ophthalmologists <i>Measure:</i> Workforce supply & demand	"From 2020 to 2035, the total ophthalmology supply is projected to decrease by 2,650 full-time equivalent ophthalmologists (FTE) (12% decline), and total demand projected to increase by 5,150 FTE (24% increase), representing a supply and demand mismatch of 30% workforce inadequacy. The level of inadequacy was markedly different based on rurality by year 2035 with 77% compared to 29% workforce adequacy in metro and nonmetro geographies, respectively. By year 2035, ophthalmology is projected to have the second lowest rate of workforce adequacy (70%) out of 38 medical and surgical specialties studied."			
<u>Shaffer et</u> <u>al. (2023)</u>	"To address concerns about regional variation in access to eye care, several states allow optometrists to perform laser procedures previously limited to ophthalmologists, including selective laser trabeculoplasty (SLT) and Nd:YAG laser procedures. We evaluated access to care for residents of three such states by comparing driving distances to optometrists versus ophthalmologists."	<i>Population:</i> Medicare claims (N=1,564,307) for YAG, SLT, and LPI in OK, KY, LA, AR, MS between 2016 and 2020 <i>Measure:</i> Population and patient travel times to ophthalmologist and optometrist locations	"found insufficient evidence to assert that optometric scope expansion increases geographical access and reduces driving times for laser procedures."			
<u>Lu & Lee</u> (<u>2022)</u>	"To examine associations between the geographic distribution of eye care clinicians and visual impairment in California."	<i>Populations:</i> Ophthalmologists and optometrists licensed in California in 2018 and 2020; respondents to the 2014 to 2018 American Community Survey (ACS) <i>Measure:</i> Prevalence of visual impairment	"For every increase of 1 eye care clinician per 100 000 residents, there was a mean (SE) decrease of 3.90 (1.39) persons with visual impairment per 100 000 residents in adjusted analyses[A] higher number of eye care clinicians was potentially associated with lower prevalence of visual impairment in California. Additional studies are needed to assess eye care clinician availability on a national and global scale and strategies to improve access to eye care."			
Feng et al.	"To describe temporal and	Populations: Ophthalmologists and	"[The] national density of ophthalmologists in the United States has			

<u>(2020)</u>	geographic trends in the US eye care workforce."	optometrists participating in patient care between 1990 and 2017 <i>Measure:</i> Ophthalmologist and optometrist density; ratio of ophthalmologists ≥55 years of age to those <55 years of age; county characteristics associated with the availability of an ophthalmologist	decreased over the past 2 decades, while the density of optometrists has increased. In addition, we found that the ophthalmologist workforce has aged. Rural/urban disparities in ophthalmologist and optometrist availability have persisted, and the rural ophthalmologist workforce is aging more than its urban counterparts Future work should examine how the increasing demands on the shrinking and aging ophthalmologist workforce are impacting the quality of patient care as well as physician well-being. Further efforts should also determine how to leverage the expanding optometrist workforce to best complement the predicted ophthalmologist shortage, particularly in areas with lower ophthalmologist availability."
<u>Hashemi</u> <u>et al.</u> (2020)	"The aim of our study was to estimate regional and global cataract prevalence, its prevalence in different age groups, and the determinants of heterogeneity and its prevalence."	<i>Population:</i> Meta-analysis of 45 studies of age-related cataract	"In general, the prevalence of cataract not only varies by region but also by age group, and most cases are over the age of 60 years."
<u>Ling et al.</u> (2020 <u>)</u>	"The objective of this study was to assess the rate of posterior capsule opacification (PCO), under "real-life" conditions, as measured by rates of Nd:YAG laser intervention, rather than from a controlled study from which patients with conditions predisposing to PCO have been excluded."	<i>Population:</i> Post-operative patients who had undergone senile cataract surgery (n = 200). <i>Measure:</i> Rates of YAG capsulotomies performed for posterior capsule opacification (PCO) at 1, 2, and 3 years	"Laser capsulotomy rates were 4.5% at 1 year and 10% by year 2 and 12% by year 3It is critical to ensure that Nd:YAG capsulotomies are being performed only for the correct clinical reason. Carrying out unnecessary procedures places the patient at risk of adverse events, is a cost to the healthcare system, and is likely to have no direct visual benefit for the patient."
<u>Stein et al.</u> (2018)	"To determine the estimated travel time (ETT) to the nearest ophthalmologist office for persons residing in states that have expanded scope of practice for optometrists, and to quantify ETT to the nearest ophthalmologist for Medicare	<i>Population:</i> Random sample of 20% of beneficiaries enrolled in Medicare nationwide from 2008 to 2014 (n=14,063,725). <i>Measure:</i> ETT to the nearest ophthalmologist office	"In the states where optometrists have expanded scope of practice, most residents lived within an ETT of 30 minutes of the nearest ophthalmologist office, as do half of Medicare beneficiaries who received surgical care from optometrists."

	beneficiaries who received surgical care from optometrists in those states between 2008 and 2014."		
<u>Mahr &</u> <u>Erie</u> (2017)	"To quantify Medicare beneficiary proximity to his or her yttrium–aluminum–garnet (YAG) laser capsulotomy–providing ophthalmologist and optometrist in Oklahoma by calculating driving distances and times."	Populations: Oklahoma ophthalmologists (n = 90) and optometrists (n = 65) who submitted claims to Medicare for a YAG laser capsulotomy; Medicare beneficiaries who underwent YAG capsulotomy in OK in 2014 (n of procedures = 11,272) Measure: Beneficiary driving distances and times to the office locations of their YAG laser capsulotomy-providing Oklahoma ophthalmologists and optometrists	"For Medicare beneficiaries, there was no difference in geographic access to YAG laser capsulotomy whether performed by an Oklahoma ophthalmologist or optometrist as determined by calculated driving distances and times."
Sanders et al. (2017) (Annual Meeting Abstract and Poster Presentati on)	"To determine numbers, types and geographic distribution of ophthalmic procedures performed by optometrists and ophthalmologists in OK, KY and NM."	Populations: 20% sample of Medicare claims of beneficiaries undergoing multiple ophthalmic procedures between 2008-2014 <i>Measures:</i> Beneficiary characteristics, number or procedures performed, percentage of procedures performed by most active providers, and odds of receiving procedures by an optometrist versus an ophthalmologist	"Factors associated with higher odds of receipt of procedures by optometrists rather than ophthalmologists include younger age, better overall health, and residence in rural parts of the stateOphthalmologists perform the large majority (76-94%) of procedures for patients residing in rural areas of these statesBased on these results, policy makers should reassess whether the purported benefits of expansion in surgical scope of practice outweigh the potential downsides. Additional research is needed to explore whether differences exist in surgical outcomes between the 2 groups."
<u>Gibson</u> (2016)	"To examine whether the local availabilities of ophthalmologists and optometrists were associated with outcomes related to the	<i>Populations:</i> County-level information on the numbers of ophthalmologists and optometrists per capita from the Area Health Resources File; data on adults from	"Among individuals in the perceived lower-risk sample, greater local ophthalmologist and optometrist availability were both associated with an increased likelihood of having had a dilated eye exam in the previous 2 years or ever having had a dilated eye examThe findings suggest that the overall availability of eye care providers influenced whether individuals likely

	prevention and timely treatment of vision conditions."	the 2008 National Health Interview Survey <i>Measures:</i> county-level availabilities of ophthalmologists and optometrists; rates of dilated eye exams and vision loss	to perceive themselves as being at lower risk for vision conditions decided to seek preventive eye care."
<u>Lee et al.</u> (2016)	"To quantify the proximity to eye care in the contiguous United States by calculating driving routes and driving time using a census-based approach."	Populations: 2010 US census survey respondents older than 65 years; addresses of all practicing ophthalmologists and optometrists from the 2012 Medicare Provider Utilization and Payment Data Measures: Driving time and driving distance to the nearest optometrist and ophthalmologist per state.	"While there are regional variations, overall more than 90% of the US Medicare beneficiary population lives within a 30-minute drive of an ophthalmologist and within 15 minutes of an optometrist."
<u>Arora et</u> <u>al. (2015)</u>	"Determine how procedural treatments for glaucoma have changed between 1994–2012."	<i>Population:</i> Medicare fee-for-service paid claims data between 1994-2012 <i>Measure:</i> Number of glaucoma-related procedures performed between 1994-2012	"From 2001 to 2005, the number of trabeculoplasties more than doubled from 75,647 in 2001 to 176,476 in 2005, but since 2005 the number of trabeculoplasties decreased 19% to 142,682 in 2012. The number of laser iridotomies was fairly consistent between 1994-2012, increasing 9% over this period and ranging from 63,773 to 85,426trend. The continued movement away from trabeculectomy and toward alternative intraocular pressure-lowering procedures highlights the need for well-designed clinical trials comparing these procedures."
<u>Gibson</u> (<u>2015)</u>	"To describe the patterns of local eye care provider availability in the US."	Population: Number of ophthalmologists and optometrists in each US county from the 2011 Area Health Resources File Measure: Rates of ophthalmologist and optometrist availability, by county	"24.0% of US counties had no ophthalmologists or optometrists. 60.7% of counties in the US were in one of the lower two quartiles of both ophthalmologist availability and optometrist availability, and 24.1% of counties were in one of the lower two quartiles of ophthalmologist availability but in one of the upper two quartiles of optometrist availabilityPublic health interventions that are effective in a context of limited local eye care provider availability or that are able to leverage optometrist availability effectively in areas with limited ophthalmologist availability could be of widespread use in the US."

<u>Tham et</u> <u>al. (2014)</u>	"We systematically examined the global prevalence of primary open-angle glaucoma (POAG) and primary angle-closure glaucoma (PACG), and projected the number of affected people in 2020 and 2040."	<i>Population:</i> Meta-analysis of 50 population-based studies of POAG and PACG <i>Measures:</i> Prevalence and projection numbers of glaucoma cases	"The global prevalence of glaucoma for population aged 40-80 years is 3.54% (95% Crl, 2.09-5.82) In 2013, the number of people (aged 40-80 years) with glaucoma worldwide was estimated to be 64.3 million, increasing to 76.0 million in 2020 and 111.8 million in 2040."
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Analysis of Medicare Datasets

Medicare National Downloadable File. Data on Utah ophthalmologists was downloaded from the Medicare National Downloadable File in October of 2023 and used to confirm the geographic distribution of ophthalmologists' practice locations in conjunction with DOPL licensing data and ABO registry data. This data, which allows for analysis of multiple practice locations associated with a single provider, was used to 1) identify the city, county, and county type (urban, rural, or frontier) associated with each practice location, 2) determine the geographic distribution of those locations, and 3) analyze the proportions of ophthalmologists with multiple practice locations and those listing rural or frontier practice locations.

- Of 104 unique ophthalmology practice locations, 73% percent were located in urban counties, followed by 25% and 2% located in rural and frontier counties, respectively. Salt Lake City accounted for 16% of all practice locations, followed by Provo (10%) and Murray (7%).
- Similarly, of 199 unique ophthalmologists, 83% were associated with at least one urban practice location, followed by 16% and 1% associated with rural and frontier counties, respectively. 41% of all ophthalmologists were associated with a Salt Lake City practice location, followed by Provo (8%) and Murray (5%).
- 30% of ophthalmologists listed multiple practice locations, and 20% listed a rural or frontier practice location. 12% listed only a rural or frontier location.

Medicare Physician & Other Practitioners - by Provider and Service. Medicare data was queried to identify claims submitted in UT for YAG, SLT, and LPI procedures.^{92,93} For the YAG and SLT procedures, only data from the most recent year available (2021) was examined; for LPI procedures, because no claims were recorded in 2021 and the overall volume of claims was low, the analysis looked at all available years to find annual averages. For YAG and SLT, this analysis only considered data from the most recent available year (2021); for LPI, due to few claims per year and some years having no claims, this analysis included all available years (2013-2021). The Medicare database was filtered for records matching the relevant CPT procedure codes (YAG: 66821, SLT: 65855, LPI: 66761) and the UT state abbreviation. With the exception of LPI data, these figures are all a snapshot in time as of 2021 and do not account for year-to-year trends/changes.

YAG. In 2021, a total of 6,380 services were provided to 5,295 individuals by 109 providers (including 11 entities). On average, each individual ophthalmologist provided 49.6 services and each entity provided 138.4 services. On average, beneficiaries underwent 1.2 procedures. Assuming that 80% of YAG services are covered by Medicare,⁹⁴ estimated total procedures in the state in 2021 were ~7,975. This volume was comparable to OPLR estimate of procedure volume calculated using March 2023

⁹² Centers for Medicare & Medicaid Services, 2021

⁹³ Claims data were filtered by each procedure's respective CPT code (YAG - 66821, SLT - 65855, LPI - 66761) and state ("UT").

⁹⁴ French et al., 2017

Medicare enrollment numbers and the average rate of routine cataract surgery for Medicare beneficiaries in the Western U.S.

- SLT. In 2021, a total of 680 services were provided to 471 beneficiaries by 24 providers (including 5 entities). On average, each ophthalmologist provided 24 services and each entity provided 44.8 services. On average, beneficiaries underwent 1.4 procedures. Assuming that 80% of SLT services are covered by Medicare,⁹⁵ estimated total procedures in the state were ~850.
- LPI. Very little claims data was available for LPI procedures. Between 2013-2021, only 6 years had recorded Medicare claims for this procedure in Utah, for an annual average of 25.6 procedures per year by 3 unique individuals and 1 unique entity. On average, beneficiaries underwent 1.7 procedures. Assuming that 80% of LPI services are covered by Medicare,⁹⁶ estimated annual total procedures in the state between 2013-2021 were ~32.

Analysis of Area Health Resources Files: Ophthalmologist Population in Post-Expansion States

To determine the effect of optometrist scope expansion on the number of ophthalmologists in a state, we applied a difference-in-differences (DiD) model⁹⁷ to ophthalmologist population data sourced from the Area Health Resource Files (AHRF).⁹⁸ To estimate the average treatment effect (ATT) of optometrist scope expansion on ophthalmologist populations, we used the Calloway and Sant'Anna estimation method and R package, as they "provide a unified framework for average treatment effects in DiD setups with multiple time periods, variation in treatment timing, and when the parallel trends assumption holds potentially only after conditioning on observed covariates."⁹⁹

AHRF's estimated ophthalmologist counts were aggregated to the state level, and these estimates served as the dependent variable in our model. We then used the Calloway and Sant'Anna method to determine the effect of the scope expansion by comparing the number of

⁹⁸ The Area Health Resources Files (ÅHRF) is a federal database that tracks the number of ophthalmologists in each FIPS state and county code each year from 2001-2020.

⁹⁵ Ibid.

⁹⁶ Ibid.

⁹⁷ DiD is a common method used to evaluate the effects of a policy intervention. In its most basic form, a DiD model compares two groups (e.g., county, state, country) in two time periods, before and after a policy intervention, where only one group adopted the new policy. As long as the parallel trends assumption (that absent treatment, the average outcomes of both groups would have followed similar trends over time) is met, the average treatment effect for the treated group (ATT) can be estimated by comparing the average change in outcomes experienced by the treated group and the average change in outcomes experienced by the treated group and the average change in outcomes experienced by the control group. This basic model can be expanded to cover many groups over many periods of time, where policy interventions may occur in different time periods. A model that could handle this nuance was necessary to us, as each state that has expanded laser privileges to optometrists has done so in different years.

⁹⁹ Callaway and Sant'Anna, 2020

ophthalmologists in states who did adopt the scope expansion to those who did not, in periods before and after each state adopted the new policy. The five states we considered were Oklahoma, Kentucky, Louisiana, Alaska, and Arkansas, which adopted their scope expansion policies in 2004, 2011, 2014, 2017, and 2019 respectively. We could only include states that adopted the policy between 2001-2020. States with more recent scope expansion (Colorado, Wyoming, Virginia, and Mississippi) were excluded from this analysis.

Overall, we found no significant difference in the number of ophthalmologists before and after this scope expansion. The figure below illustrates this finding, as the average effect post policy intervention follows a very similar trend to the average effect pre policy intervention. Additionally, there is not a year for which any effect could be differentiated from 0, as each point on the figure has a confidence interval that contains zero.



Figure 4. Change in State Ophthalmologist Populations Pre and Post Scope Expansion

In Figure 4 above, the X-axis represents the number of years pre and post scope expansion legislation, centered on 0 (the year that legislation was enacted in each state). The Y-axis represents the average change in the estimated count of ophthalmologists in post-expansion states, with the vertical bars representing the confidence interval for each year's average.

It is important to note that we cannot confidently conclude that there is zero causal effect present between scope expansion and ophthalmologist populations. Our data was very limited, as we included no variables beyond population, year, and when policy implementation occurred. Although the DiD model inherently controls for state-invariant and time-invariant variables, there may be omitted variables that differ by time and state which could ultimately bias the estimate. These results do not indicate a conclusive finding; rather, this analysis provides further evidence that the connection between the policy (scope expansion) and the outcome (changes in the ophthalmologist population) is unclear at best.

5. Additional Materials

A. UK Training Policies

In 2018, the Moorfields Eye Hospital, which is an NHS facility that has produced much of the research on non-physicians delivering laser surgery procedures, published "N:d YAG Laser Capsulotomy by Nurses and Optometrists: Policy and Procedure." This policy handbook outlines requirements such as outcomes measurement, qualifications and training, and the responsibilities of all stakeholders involved, including practitioners and employers. The document is available on the UK Ophthalmology Alliance website here: https://uk-oa.co.uk/wp-content/uploads/2018/07/UKOA_Worksteams_Extended_Roles_nd_yag_laser_capsulotomy_by_nurses_and_optometrists_v3_0.pdf

B. Vermont Scope Expansion Review

The Vermont Office of Professional Regulation conducted a review of a similar proposal for optometric scope of practice in 2020. The text of Vermont's report, which recommended against expanding optometric scope of practice, is available here:

https://sos.vermont.gov/media/dhlgd0ve/optometry-advanceed-proceedures-report-january-202 0.pdf

C. Nebraska Scope Expansion Review

The Nebraska Division of Public Health conducted a review of a similar proposal for optometric scope of practice in 2020. The text of Nebraska's report, which recommended against scope expansion, is available here:

https://dhhs.ne.gov/licensure/Credentialing%20Review%20Docs/OptDirReport2023.pdf

A detailed overview of findings and discussion by the Nebraska Optometry Technical Review Committee is also available here:

https://dhhs.ne.gov/licensure/Credentialing%20Review%20Docs/OptTRCReportSep2022.pdf

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7. Stakeholder Outreach

Table 16. Stakeholder Engagement Summary	
Utah State Government	
Legislative Leadership	Sen. Stuart Adams, President
Utah House of Representatives	Rep. James Dunnigan Rep. Stephen Whyte
Business and Labor Interim Committee	Sen. Curtis Bramble, Chair
Department of Commerce	Robert Woolridge, DOPL Optometry Advisory Board Chair
Industry Stakeholders (e.g., employers, professional associations)	
Utah Medical Association	Michelle McOmber, CEO
Utah Ophthalmology Society	Dr. Bradley Katz, President Dr. Rachel Simpson, Legislative Advocacy Co-Chair
Utah Optometric Association	Dr. Mark Taylor
Moran Eye Center	Dr. Bradley Katz Dr. Rachel Simpson Dr. Katherine Hu Dr. Brian Stagg
Rocky Mountain University	Cameron K. Martin, President Adam Hickenbotham, Dean, College of Optometry Dr. Donnie Akers, Associate Dean, College of Optometry Dr. Court Wilkins, Assistant Dean of Clinical Affairs, College of Optometry Dr. Spencer Johnson, Lead Instructor Stephen Whyte, Vice President of Communications, Marketing & Enrollment
Subject-Matter Experts (e.g., academics, analysts)	
University of Liverpool	Dr. Neeru Vallabh, Clinical Senior Lecturer, Ophthalmologist

*Individuals who interacted with OPLR's review in multiple capacities may be listed more than once.

Statement from the Utah Ophthalmology Society (UOS)



Bradley J Katz, MD, PhD President Utah Ophthalmology Society Salt Lake City, Utah <u>drkatzenjammer@gmail.com</u>

8 December 2023

Jeff Shumway Director Office of Professional Licensure Review Heber M Wells Building Salt Lake City, Utah

RE: Legislative Inquiry Report: Optometrist Laser Surgery Privileges

Dear Mr. Shumway,

Thank you for the opportunity for the Utah Ophthalmology Society to comment on the draft report prepared by your office, "Legislative Inquiry Report: Optometrist Laser Surgery Privileges." The UOS appreciates the work OPLR has done to better understand the issues surrounding scope expansion and the technical aspects of ophthalmic laser surgery. For reasons described in this letter, the Society strongly objects to the final conclusions set forth in the report that recommend pathways for optometrists to perform neodinium:yttrium-aluminum garnet ("YAG") laser capsulotomy and selective laser trabeculoplasty ("SLT") surgeries in Utah.

The Report suggests three paths forward: a clinical trial where the safety of scope expansion in Utah could be investigated, expansion of scope with "guardrails" in place to track adverse outcomes, and continuing the *status quo*. In this letter we summarize why we oppose these proposals and instead suggest other paths forward that would meet the objective of improving access to eye care services without compromising public safety.

Clinical Trial

The Report suggests executing a clinical trial where patients requiring YAG or SLT would be randomized to be treated by an optometrist or an ophthalmologist. This proposal is modeled on a trial conducted in New Zealand. The pilot program in New Zealand involved only two optometrists, both of whom were trained to perform YAG laser surgery under the supervision

of an ophthalmologist in a government health care facility. The pilot program was quickly discontinued when it was clear that it was both unsafe and unnecessary for optometrists to perform this surgery. Despite the outcome of this small pilot program, The New Zealand Optometrist and Dispensing Opticians Board concluded that it was safe for *all* optometrists to perform laser surgery in New Zealand.

The proposed trial would need to be conducted in a setting where optometrists and ophthalmologists practice side by side. This setting would ensure that optometrists are properly trained and that adverse outcomes could be rapidly identified and treated. The Report acknowledges that most optometrists in Utah do not practice under the supervision of an ophthalmologist. The vast majority of our state's optometrists practice independently, making the conduct a clinical trial impractical. In addition, the report does not consider the ethical and financial aspects of conducting a clinical trial. The proposed trial would require that the protocol be approved by an institutional review board and that all patients participating in the trial provide informed consent. Conducting a clinical trial is notoriously expensive and requires a staff to maintain the study documents, to report outcomes including any adverse outcomes, to collect the data, and properly analyze the data. The report does not address what state institution would be responsible for the conduct of the trial, how the trial would be funded, or what criteria would be used to determine under what circumstances scope expansion might be deemed to be safe and effective. For these reasons, this proposal is impractical unless these issues can be clearly addressed.

Expansion of Scope with "Guardrails"

This proposal would forego the clinical trial and instead allow expansion of scope to allow optometrists to perform YAG capsulotomy SLT while monitoring for adverse outcomes. This recommendation relies heavily on experience in the United Kingdom where some optometrists have been allowed to perform some laser surgeries (Harper et al., 2016; Gunn et al., 2022). This proposal does not acknowledge that practice patterns in the UK differ substantially from practice patterns in the US. In the UK, many optometrists practice under the direct supervision of an ophthalmologist, while in Utah and the US, most optometrists are properly trained, constantly evaluate their work, and are present to quickly address complications or adverse outcomes. Because most optometrists in Utah work independently, there would be no way to independently confirm that an individual optometrist is performing these laser surgeries appropriately, safely, and effectively, and that complications are avoided, recognized, and promptly addressed.

UOS contacted one of the authors of the UK studies cited in the Report and the author was "horrified" to learn that their research was being used to justify scope expansion in the US. They said to do so was like "comparing apples to oranges."

This proposal also relies on the manuscript, "Nd:YAG Laser Capsulotomy: Efficacy and Outcomes Performed by Optometrists" (Lighthizer et al., 2023). The authors of this manuscript

have significant conflicts of interest with regard to the expansion of optometric scope. Optometrists Nathan Lighthizer and Jeffrey Miller both conduct 32-hour courses for optometrists in states that have not expanded scope of practice. Optometrists David Cockrell (President of the Oklahoma Board of Optometry) and Christopher Wroten (a member serving a 5-year term on the Louisiana Board of Optometry) have vested interests in expanding scope of practice in their states.

This study also reports that there were no complications in the patients who underwent YAG capsulotomy surgery by optometrists. The Lighthizer study followed less than 100 eyes for three months. A much larger study conducted by Dot et al. (2023) involved almost 8,000 YAG capsulotomy procedures by ophthalmologists followed for 12 months and found a 13% incidence of adverse events. It is difficult to square the conclusions of the Lighthizer study with the much larger and more carefully executed Dot study. It is possible that the Lighthizer study was too small to detect complications, that the follow-up period was too short to detect complications, that the authors were inexperienced in detecting complications, or some combination.

The UOS contends that the Report does not fully appreciate the conclusions of the research by Stein et al. (2016). This study clearly demonstrated that SLT performed by ophthalmologists is safer and more effective than when it's performed by optometrists. Drawing from the available data and peer-reviewed research, one can only infer that either optometrists lack a comprehensive understanding of the proper execution of this laser surgery, or they are intentionally overutilizing the procedure, both of which pose safety risks for patients and increase costs.

Guardrails for the safe performance of eye surgery already exist within ophthalmology, while no such guardrails exist within optometry. Utilizing medical experts in clinical and surgical education and training, the Accreditation Council for Graduate Medical Education ("ACGME") sets minimum standards for the performance of all ophthalmic surgeries. The standards for the performance of YAG and SLT do not exist in a vacuum, but in the context of years of education, training, and supervised performance of scores of surgeries on live patients that serve as the foundation for safe performance of all ophthalmic surgeries. It's inappropriate to expand scope to a group of professionals who lack this foundation in the clinical and surgical care of patients.

The Report acknowledges the potential risks that this option presents to the safe performance of laser eye surgery with the insistence on requiring reporting of all complications and adverse events. However, putting in place an effective reporting process is no small task. In states where scope has been expanded, reporting of adverse events is voluntary and neither the optometric boards nor the professional licensing boards track adverse events. By comparison, if an ophthalmologist is sued for malpractice, that information is readily available in the National Practitioner Database. <u>No such database exists for optometry</u>. It is not clear what government entity would have the funding and expertise necessary to implement these guardrails in Utah. As data documenting adverse outcomes accumulates, it is not clear from the Report what entity would analyze these data or if this entity would have any authority to roll back scope. In

addition, the guardrails do not address the topic of effectiveness nor appropriateness of performing the surgery, both key determinants in the decision to allow expansion of scope.

Status Quo

The report states that demand for eye care services is expected to expand and that the available supply of eye care professionals is not keeping pace. For this reason, the report concludes that maintaining the *status quo* is an unacceptable choice. The report may be correct to forecast that the availability of *comprehensive eye care services* will not keep pace with demand in the coming decade but extrapolating that forecast to conclude that the availability of two very specific surgeries, YAG capsulotomy and SLT, will not keep pace is likely incorrect. Were an optometric office to contact an ophthalmologist's office requesting a YAG capsulotomy or SLT for a patient, it's likely that patient could be scheduled within 2-4 weeks, a very acceptable window. There is no reason to believe that the availability of ophthalmologists are willing to accommodate the request of another professional if they have a patient in need. It would be far more appropriate and of no additional risk, to have optometrists expanding their availability to conduct routine comprehensive eye care visits in Utah, thereby freeing ophthalmologists to perform more complex evaluations and surgeries.

The Report concludes that even if scope is expanded, the number of optometrists performing these surgeries in Utah will be small. Indeed, in states in which scope has been expanded, few optometrists are interested in performing surgeries with only 7.6% of optometrists filing Medicare fee for service claims in 2021. In states where scope has expanded, optometrists performing these surgeries are not practicing in underserved areas. Taken together, expansion of scope is not going to have the desired effect of improving access to YAG and SLT, especially in underserved areas of Utah.

Instead of expanding scope with its unproven track record of effectiveness and safety, and its inability to address the growing demand for eye care services, UOS would instead encourage the State to work together with other partners, including the Utah Medical Association, University of Utah Health, and the State's flagship tertiary eye care center, the John Moran Eye Center, to find other solutions to meeting the State's eye care and health care needs. This partnership could consider innovative solutions such as:

- 1. Increasing the number of ophthalmology residency training slots at the Moran Eye Center. This expansion would increase the number of qualified experts available to perform YAG and SLT.
- Provide financial incentives for ophthalmologists to stay in Utah or relocate to Utah, specifically to practice in underserved areas. The State was recently awarded a \$1.7 million federal grant to expand telehealth services to underserved areas. Similar grant support may be available to expand eye care services to these areas.

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- 3. Address the shortage of ophthalmic nurses and technicians in our state. Many ophthalmic practices, public and private, are being strained by the lack of trained staff following the pandemic. The partnership proposed above could incentivize nurses and technicians to stay in our state or relocate to our state to make our existing pool of ophthalmologists more efficient and increase patient volume.
- 4. This partnership could find other innovative ways to make ophthalmologists more efficient. As an example, the Moran Eye Center is already working on a virtual technician platform to help ophthalmologists gather critical patient data in advance of the patient's appointment, thereby making visits more focused and efficient, and allowing the ophthalmologist to see more patients. Other researchers are finding ways to leverage artificial intelligence to screen patients for diabetic eye disease, again allowing ophthalmologists to concentrate their efforts on patients in immediate need of specialized care.

In summary, it is the position of the UOS that allowing optometrists to perform these delicate and intricate laser surgical procedures poses significant risks to patient safety without any concomitant benefits in terms of effectiveness, cost, or access to care. If the State wishes to address concerns about access to eye care services as the population of our state ages, the UOS would recommend innovation over deregulation. Our state is fortunate to already have the researchers, clinicians and teachers who can safely and in a cost-effective manner address these issues. Let's use these resources collaboratively in a manner that maintains the standard of care that our citizens expect and deserve.

The UOS sincerely appreciates your dedication to upholding the highest standards of patient care in Utah. We look forward to continuing to work with the Office of Professional Licensure Review and the Department of Professional Licensing to ensure that all Utahns have access to the best eye care.

Sincerely,

Bradley Katz

Bradley J Katz, MD, PhD

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OPLR Response to UOS Statement

OPLR would like to thank the Utah Ophthalmology Society for their thoughtful review of and statement on an earlier version of this report. Based on the UOA's feedback, we have made factual corrections, explanatory additions, and slight changes to one recommendation. We have also prepared a detailed response to several items raised in the UOS statement appended above. Contact <u>haupt@utah.gov</u> for more information.

Statement from the Utah Optometric Association (UOA)

Provided to OPLR by Dr. Mark Taylor, Dr. Ross Chatwin, and Dr. Weston Barney of the UOA.

Official Response of the Utah Optometric Association to the Legislative Inquiry Report Optometrist Laser Surgery Privileges

The Utah Optometric Association would like to commend the OPLR board for their efforts in producing an objective review of the current outdated Utah Optometry Practice Act. This review will assist in bringing the Utah Optometry Practice Act in line with the current level of advanced laser training provided by all doctor of optometry programs in the United States. We wholly agree with the OPLR recommendation that as any profession increases in knowledge and competence, standards and mechanisms are needed to allow for this growth without having to constantly legislate. In the case of Optometry, the current practice act does not allow for this growth and specifically disallows optometrists from performing the minor, in office procedures we have been trained to perform. These include YAG Capsulotomy, SLT, and LPI procedures.

The Utah Optometric Association would like to offer a response to the Optometry Laser Surgery Privileges Review with the intention to offer clarification on a few points addressed therein.

- 1. Throughout the report Optometrists are often referred to as "non-physician" and "allied health professionals."
 - a. Optometrists have been considered physicians by the Federal government since 1986 when the Social Security Act was amended. Section 1861 states (*r*) The term "physician", when used in connection with the performance of any function or action, means.. (4) a doctor of optometry, ("Social Security Act §1861(r)(4)")
 - b. As physicians, optometrists are specifically excluded from the definition of "Allied Health Professional" as indicated by the Federal Public Service Commission Title 42 ("42 USC CHAPTER 6A, SUBCHAPTER V: Part G(295p)(definitions")
- 2. The review references optometrists in the United Kingdom and New Zealand as a comparison for training requirements and supervision. However, the reference clearly states in the Literature Review on Patient Safety section that *"not all findings may be generalizable to the eye care landscape in the U.S."* We would like to add the following clarification: Optometrists in those countries are trained to a Baccalaureate or Masters level, whereas all optometrists in the US must obtain a doctorate degree. Additionally, US optometrists have performed these laser procedures for over two decades without direct ophthalmology oversight.
- 3. The specific laser procedure of Laser Peripheral Iridotomy (LPI) is discussed in the review as having limited data available stating "OPLR does not recommend scope expansion for optometrist-performed LPI procedures, due to the lack of clinical safety evidence and potential negative impacts on access to care." The Utah Optometric Association would like to contend that a lack of published safety data should not warrant a negative endorsement. Additionally, optometrists have been performing LPI procedures in the US for over 30 years with no reported negative outcomes. This indicates an extensive safety record, even if no formal studies have been published. We feel that a neutral recommendation would be more appropriate.
- 4. Currently, optometrists in eleven states are performing laser procedures. The OPLR report mentions nine of the eleven including Alaska, Arkansas, Colorado, Kentucky, Louisiana, Mississippi, Oklahoma, Virginia, Wyoming. However, Indiana and Wisconsin optometrists have also been performing these laser procedures for several years.

OPLR Response to UOA Statement

OPLR would like to thank the Utah Optometric Association for their review of and statement on an earlier version of this report. Based on the UOA's feedback, we have made factual corrections and explanatory additions to our report content. We have also prepared a response to several items raised in the UOS statement appended above. Contact https://www.lhaupt.com for more information.

Statement from the Utah Physicians Licensing Board



State of Utah Physicians Licensing Board

Response to the Office of Professional License Review Report on Optometrist Laser Surgery Privileges Report

To Whom It May Concern:

On January 18, 2024, the Physicians Licensing Board, (the Board), of the Utah Division of Professional Licensing (DOPL) met during a regularly scheduled public meeting. One of the items on the agenda for discussion was the Report from the Office of Professional Licensure Review, OPLR, entitled "Optometrist Laser Surgery Privileges." This report was prepared in response to the legislative inquiry from a member of the Utah State Legislature.

A lively and comprehensive discussion resulted, with participation from members of the Board and other witnesses.

There appeared to be agreement that the 55-page report was thorough and competently prepared. The Board agreed that the Office of Professional License Review made a good faith attempt to live up to its statutory mandate "to balance protecting the health, safety, and financial welfare of the public with minimizing the burden for qualified individuals to practice in their chosen occupations."

The Report outlined three options regarding Optometrist Laser Surgery Privileges:

- 1. Conduct a clinical study, using Utah's regulatory "sandbox program," to collect improved patient safety data and draw direct comparisons between ophthalmologist- and optometrist-performed YAG and SLT laser surgery procedures, and then base future expansion decisions upon the results of this trial and pilot program.
- 2. Expand optometrists' scope of practice to include YAG and SLT laser surgical procedures, conditional on additional training and certification requirements, along with requirements for collaborative practice agreements, data collection, and outcomes reporting.
- 3. Maintain the status quo. No action taken to expand the scope of practice relating to optometrists' privileges to include laser surgery.

OPLR did not recommend option #3 due to concern regarding access issues, especially in rural areas of Utah, and the projected demand for laser and other advanced eye care services.

In spite of OPLR's recommendation, the Board voted to support option #3 (to maintain the status quo). This decision was based on the overwhelming testimony of the physician members of the

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Board as well as expert witnesses from the Utah Ophthalmology Society and other written testimony.

A brief summary of the testimony and concerns follows:

- 1. Access: The Board heard from ophthalmology that access to the YAG and SLT laser surgeries was not a serious problem in Utah. It was stated that expansion of optometry laser surgery privileges "was a solution to a problem that doesn't exist." Testimony was heard that in most cases a referral to an ophthalmologist for this type of surgery today can be scheduled in less than a week. It was stated that this type of surgery is elective and not an emergency. A study published in JAMA Ophthalmology, in 2023, using Medicare data from 5 states where optometrists have been granted laser surgery privileges concluded that it did not lead to shorter travel times to receive care or to a meaningful increase in the percentage of the population with nearby health care professionals. jamaophthalmol.2023,3061
- 2. Quality and Cost: The Board heard testimony that the training differences between ophthalmologists and optometrists varies considerably in type and length of training. Whereas ophthalmologists, (medical doctors) attend 4 years of medical school and one year of internship, followed by 3 to 5 years of residency/fellowship training (12,000 to 16,000 hours of total patient care hours), optometrists, on the other hand, spend only 4 years in optometry school with no requirement for residency training. In addition, ophthalmologist training includes extensive experience in the diagnosis of eye disease, and years of hands-on, live patient experience learning surgical techniques in the treatment of eye conditions. The current requirement for optometrists to become "trained" and certified in laser surgery is often a weekend (4 day) course at a hotel ballroom with four hours of "lab rotations" using lasers with plastic models, followed by written exam. (example available upon request). A study in JAMA Ophthalmology in 2016 containing more than 1,000 eyes of Medicare enrollees in Oklahoma with glaucoma who underwent laser trabeculoplasty (LTP) surgery by ophthalmologists and optometrists concluded that there were significant differences between those patients requiring additional LTP laser surgery performed by optometrists compared to those performed by ophthalmologists, thereby increasing cost and potential morbidity. jamaophthalmol.2016.2495
- 3. Precedence and Examples from Other States: Only nine U.S. states allow some form of optometrist laser surgery. One of OPLR's responsibilities in reviewing licensing requirements is to look at "the regulation of the occupation in other states." Since 2015 optometry has failed 64 out of 70 times to pass legislation to expand their scope of practice. Most recently the State of Nebraska in 2023 considered expanding optometry practice to include laser surgery. The bill failed to pass. There was concern regarding "scope creep" where optometrists will continue to expand their scope of practice to procedures beyond their training and competence.
- 4. **Public Misunderstanding**: It has been shown that many members of the public do not understand the difference between an optometrist and an ophthalmologist. In a recent

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AMA survey, patients were asked if optometrists were physicians; 47% said yes and 43% correctly said no. (reference available upon request). Many members of the public are confused by the term "eye doctor." The public trusts that state legislative and regulatory bodies will make correct decisions to assure that only highly trained surgeons are allowed to perform laser surgery.

5. **Patient Safety**: The Division of Professional Licensing is charged with granting licenses in health care to ensure that only those practitioners who can safely deliver care are legally authorized to do so. Several of the surgeons noted that a surgeon not only must be able to diagnose and treat complications of their procedure, but also know when to refer to a higher level of care. There was concern expressed that optometrists with limited training in an independent and isolated practice may not be able to recognize their limitations.

Sincerely,

Utah Physicians Licensing Board

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