Illinois Society of Eye Physicians & Surgeons Comments on Proposed Amendments Illinois Department of Financial & Professional Regulation Optometric Practice Act Rules Published in the *Illinois Register* on December 29, 2017

February 9, 2018

The Illinois Society of Eye Physicians & Surgeons (ISEPS) is grateful for this opportunity to submit comments concerning the proposed amendments to the rules associated with the Optometric Practice Act of 1987 (the "Act") published in the *Illinois Register* on December 29, 2017.

We strongly object to adoption of these proposed Rules that would, for the first time in the State's history, permit people who are not licensed to practice medicine to perform surgery on Illinois citizens.

This Rule Must Be Rejected

The Department is proposing a Rule that would allow that which the General Assembly already has rejected. The proposed Rule should be overruled by the Joint Committee on Administrative Rules because:

- The Department lacks legislative authority to propose this Rule.
- By adding surgical procedures and injections by Rule, which are prohibited by the Optometric Practice Act, the Department is circumventing the General Assembly.
- The Department failed to follow the requirements of the legislation which created the Collaborative Optometric/Ophthalmological Task Force.
- The Department did not rely on any published studies, reports or sources of underlying data in developing this Rule as referenced in the Illinois Administrative Code.
- The surgical procedures that would be added to the optometric scope of practice by this Rule are overly broad, use incorrect terminology and fail to take into account proper surgical methods.
- The proposed training requirements are grossly inadequate for the surgical procedures listed and create a substantial danger to the public.
- There is no stated public benefit that would result from reducing the current educational and training standards for becoming an eye surgeon.

Introduction and Background

The Optometric Practice Act currently prohibits surgery by optometrists.ⁱ The Act also authorizes optometrists to give only one type of medication by injection: for treatment of anaphylaxis.ⁱⁱ

Optometrists first sought to remove the prohibition of surgery in 2016. After extensive debate among legislators and discussion with interested parties, the General Assembly passed the renewal of the optometry practice act *without* permitting optometrists to perform surgical procedures. In conjunction with the 2016 renewal legislation, the legislature created a Task Forceiii "In order to protect the public and provide quality care..." which included representatives from optometry, ophthalmology and the state medical society. The purpose was to consider what educational standards would apply to procedures it identified as "advanced optometric procedures." The Department was to propose – by January 1, 2018 -- rules "that are consistent with the Task Force's recommendations," or recommend legislation to the General Assembly, providing educational

requirements that must be met for an optometrist to obtain certification to perform advanced optometric procedures. The Task Force members reached no agreements and made no recommendations before the panel adjourned.

Lack of Legislative Authority

Surgery is prohibited by statute. Section 3, subsection (a) of the Optometric Practice Act of 1987 specifically prohibits surgery for practicing optometrists. Although the Act states that the practice of optometry includes "any other procedures taught in schools and colleges of optometry approved by the Department," the very next phrase offers the following limitation: "and not specifically restricted in this Act..." Accordingly, the Department clearly lacks the legislative authority to add any surgical procedure to the practice of optometry absent specific action by the General Assembly to grant an exception to the ban on surgery. No such authority has been passed by the legislature.

IFDPR is legislating. The Department attempts to circumvent the prohibition on surgery by creating a wholly new term: "Advanced Optometric Procedures." However, this term is not defined anywhere in the Illinois statutes. Since the General Assembly has not seen fit to define the term or to state what specific procedures – or even what *type* of procedures – should be considered to be "Advanced Optometric Procedures," the Department is taking on a responsibility reserved for the legislature.

The General Assembly gave no guidance. In the language creating the Collaborative Optometric/Ophthalmological Task Force, the General Assembly stated the Task Force was to recommend educational standards that would apply to "advanced optometric procedures." However, no definition or guidance of any kind was given to the Task Force members as to what these procedures should be, nor were "advanced optometric procedures" exempted from the statutory prohibition of surgery. Thus, determining the procedures and related educational standards was completely left up to the Task Force, which adjourned without adopting any definitions for the term and did not make recommendations for educational standards. In any event, even if the Task Force had adopted educational standards for particular "advanced optometric procedures," in the event any of these were surgery, action by the General Assembly would have been required because of the statutory prohibition of surgery for optometrists.

Surgical procedures would be added by this Rule. The Department's proposed definition of "advanced optometric procedures" in the Rule, in fact, includes seven types of surgery which are prohibited by the Act. These are:

- 1. Excision, removal or destruction of chalazion.
- 2. Excision, removal or destruction of benign, superficial lesions.
- 3. Removal of skin tags.
- 4. Incision and drainage of cysts.
- 5. Epilation by means other than forceps.
- 6. Corneal debridement, other than dead tissue, not including removal of pterygium or corneal neoplasias.
- 7. Biopsy, excluding corneal biopsy.

All of these are surgical procedures. These procedures appear in the surgery section of the CPT^{iv} codes. <u>Attachment A</u> includes several items which document the surgical nature of these procedures. In the absence of a definition of surgery enacted by the General Assembly, one must look to other reliable sources for a definition of what constitutes surgery. The CPT codes published by the American Medical Association are used widely throughout our healthcare system, including the Federal Medicare program and by Illinois Public Aid. All of the codes that pertain to the seven procedures contained in the Rule are listed in the surgery section of CPT. Furthermore, both the

American Medical Association and the American College of Surgeons have adopted definitions of surgery which clearly would include all seven of the procedures (*Attachment B*).

We also can look to the Federal Centers for Medicare & Medicaid Services for guidance which has published the following definition of surgery in the *Federal Register* pertaining to a rule affecting ambulatory surgery centers: "Under the current ASC payment system, we define as a surgical procedure any procedure described within the range of CPT Category I codes that the AMA defines as 'surgery' (CPT codes 10000-69999) for purposes of the ASC payment system." This same definition is referred to in conjunction with other postings in the *Federal Register* as recently as December 14, 2017. The seven procedures contain in the proposed Rule fit within this definition.

The Department itself identified some of these procedures as surgery. The Department's own fact sheet ($\underbrace{Attachment\ C}$) describing the content and purpose of SB 2899 in the 99th General Assembly (2016) identified the following "surgical procedures" that would have been added to the practice of optometry had that bill passed. These include:

- Removal, destruction or drainage of superficial lesions and conjunctival cysts (#2 and #4 in the list above)
- Removal of Chalazia (#1 above)
- Corneal debridement (#6 above)

The Department in 2016 recognized these procedures were not authorized in the Act. The fact that the Department sought legislation to add these to the optometric scope of practice as recently as 2016 clearly demonstrates that these surgical procedures were not seen as currently authorized by the Act. Thus, by the Department's own words, these fall under the prohibition of surgery, and the General Assembly's decision *not* to add them in 2016 or since then means the Department does not now have authority to bypass the legislature and add them by Rule.

The injections listed in the Rule are not authorized by law. The Department includes in its new definition of "advanced optometric procedures" three different types of administering medications by injection. However, the Act does not specify these types of injections in Section 15.1 which defines the types of drugs and the method of administration permitted for use by optometrists. Subsection (a-5) states: "Ocular pharmaceutical agents administered by injection may be used only for the treatment of anaphylaxis." This typically would be an intramuscular injection of epinephrine (such as with an "Epi-Pen") to counteract a severe allergic reaction. If it was the intent of the General Assembly to allow other ocular pharmaceutical agents to be given by injection, it would not have specified this *one* type of injection as being permitted, but no others. Moreover, subsection (a) limits anesthetic medications to topical application. The General Assembly has not enacted any exceptions or expansion to the single injectable medication currently permitted.

The Department has acknowledged optometrists do not now have the authority to give injections. The 2016 fact sheet published by the Department for SB 2899 stated that the bill would *add* subcutaneous and subconjunctival injections to the Act. However, the General Assembly <u>did not enact these provisions</u>, so the Department cannot now claim it has authority to permit them.

Requirements of the Task Force

Public Act 99-909 which created the Collaborative Optometric/Ophthalmological Task Force requires the Department to propose rules "in direct consultation with the Task Force" that are "consistent with the Task Force's recommendations." The Department did not consult with the Task Force before publishing the proposed Rule. Equally important, the Task Force adjourned without adopting any recommendations. The Department's proposed Rule cannot be "consistent with recommendations" that do not exist.

No Reliance on Studies, Reports or Data

The Department did not rely on any published studies, reports or sources of underlying data in developing this rule, as referenced in the Illinois Administrative Code. The Department does not cite any references or data to support its proposal to add these surgical procedures and injections to the practice of optometry. Thus, it is impossible to ascertain the validity of its assumptions regarding the amount or setting of training that would be required for an optometrist to safely perform these functions as stated in the proposed Rule. For instance, without referencing clinical studies, the Department has no way of knowing how often a "benign" lesion actually is a malignant cancerous tumor or what risks would be associated. (Under the Rule, optometrists would not be allowed to remove a malignant tumor.) Likewise, the Department cites no comparisons of its proposed 32 hours of instruction (only 16 of which must be "clinical") to any other disciplines which currently are permitted to perform the surgical procedures listed in the Rule. Moreover, the Department has not referenced any sort of risk/benefit to be gained by Illinois citizens as a result of this significant reduction of licensing standards for eye surgeons.

Flawed Definition of Advanced Optometric Procedures

The descriptions of the procedures allowed by the Rule is overly broad. In the list of "advanced optometric procedures," at least seven different types of biopsy, including *orbital* biopsies, would be permitted. (The "orbit" is the structure in the head that houses the eyeball and related anatomy.) Biopsy is a surgical procedure in which tissue is cut from the patient using a scalpel, scissors or a needle for pathology analysis. Depending on the anatomy to be biopsied and the purpose, substantial risks could be associated with this procedure. Incidentally, optometrists would not be allowed to remove a malignant lesion. Performing a biopsy on a malignant tumor has the same potentially fatal risks as actually removing it.

Also, there is no limitation on the location of cysts that could be incised or drained. Thus, a scleral cyst – on the surface of the eyeball itself – could be treated by an optometrist. Epilation (removal of eyelashes) "by means other than forceps" could include any number of techniques such as electrolysis (using an electric current), cryotherapy (freezing) or photoablation (destroying the follicle with a laser). The use of lasers is excluded in the legislation creating the Task Force.

Correct medical terminology is not utilized. By failing to be precise in the terminology used to describe medical and surgical procedures, the Department potentially is leaving much to the discretion of a provider. There are multiple types of skin tags, and not all are found on or near the structures of the eye. Likewise, there are *many* different types of "superficial" lesions, among these:

- Nevus, a benign eve lesion which can also be found anywhere else in the body
- Corneal lesions caused by the herpes simplex virus
- Molluscum Contagiosum which affects immunocompromised individuals (must be removed by cryotherapy – freezing)
- Actinic keratosis, a pre-cancerous lesion affecting different parts of the body and may be also develop on the eyelids. This growth requires surgical excision because if left untreated or treated improperly, it eventually progresses into squamous cell carcinoma.
- Seborrheic keratosis which is a benign lesion affecting the eyelid
- Hydrocystoma is a lesion associated with a blockage of sweat glands

Is it the intent of the Department that an optometrist be permitted to remove any or all of these lesions... with only 32 hours of training?

The Rule opens the door to treatment that is not allowed by the Rule itself. It is not possible to know if a lesion is "benign" until it is actually removed and studied in the pathology lab. A lesion thought to be benign might actually be a malignant tumor which, according to the language of the Rule, an optometrist would be prohibited from removing.

Malignant lesions require a more complex approach and treatment. The area of the eye may be affected by three types of malignant tumors: squamous cell carcinoma, basal cell carcinoma, and melanoma, all of which may appear to be a benign lesion or a chalazion. Squamous cell carcinoma is rather aggressive and develops in a form of raised, scaly lesion usually on the upper lid. Basal cell carcinoma is also a malignant tumor, but it progresses very slowly. Malignant melanoma is one of the most aggressive tumors and even in early stages it can give satellite metastases in the surrounding tissue. The eyelids also may be affected by sebaceous carcinoma. This is an aggressive tumor which, if left untreated or inadequately removed, easily may spread to distant organs such as the lungs, liver and bones.

Inadequate Training Requirements

The 32 hours of training – only 16 hours of which must be "clinical" – is grossly inadequate for the significant level practice that would be allowed by the Rule. During the Task Force discussions, the optometry representatives suggested a 30 hour course to support training for their proposed list of "advanced optometric procedures," all of which were surgical. This proposal was rejected by the other two Task Force members and was not adopted.

All surgical procedures carry an element of risk to the patient, and there is a direct correlation between risk, and the training received by and competence of the surgeon. In addition to learning the mechanical technique associated with a particular procedure, the surgeon must:

- Correctly diagnose the condition (e.g., benign lesion vs. carcinoma).
- Determine if surgery is necessary. None of the conditions listed in the Rule are urgent or emergencies. For example, the correct treatment for a chalazion before surgical excision is four weeks of warm compresses. (Most of the time, a chalazion goes away on its own.)
- Determine the indications and contraindications for surgery, including the patient's overall medical condition.
- Be prepared to manage any and all complications that present during the operation, such as bleeding or trauma to the globe (eyeball).
- Be able to immediately convert to a more extensive procedure if, for instance, a suspected chalazion turns out to be a cancerous tumor that has spread to other structures of the eyelid or face
- Maintain proficiency by performing a sufficient number of surgeries over a given period of time.

An ophthalmology resident in training develops all of these skills over a period of more than 6,000 hours of hands-on training and performing hundreds of surgeries under the supervision of expert faculty. We are baffled that the Department believes that the many different types of operations represented by the proposed list of "advanced optometric procedures" could be learned and competence achieved in only 16 hours of clinical experience.

Of particular note, many comprehensive ophthalmologists – who themselves are qualified eye surgeons – choose not to perform the oculoplastic procedures included in the list of "advanced optometric procedures" because of the delicate nature of the affected structures of the eye, the precise nature of the operation, and the number of cases available for a comprehensive ophthalmologist to maintain proficiency.

No Demonstrated Public Benefit

The Department has failed to provide any evidence that there would be a benefit to the public as a result of reducing the current training requirements for eye surgeons. No data has been presented that Illinois citizens are unable to find a qualified physician if surgical intervention is needed for any of the conditions that could be treated using the so-called "advanced optometric procedures." No information is provided to support the notion that the substantial reduction in training would not create an unacceptable risk to patients.

Ophthalmological care is available to every Illinois citizen within a reasonable distance. Moreover, there is no reduction in cost in allowing optometrists to perform these operations since there is no difference in fees paid by private insurance, Medicare or Medicaid based on a provider's professional degree. None of the conditions listed as "advanced optometric procedures" are urgent or emergencies. Thus, there is no reason whatsoever that a patient could not be scheduled for treatment with a qualified surgeon.

Optometry advocates claim that rural areas in the state need this expansion so residents there can receive care. However, the Department has provided no evidence that optometrists who practice in rural areas would qualify to provide "advanced optometric procedures." Similarly, the Department has not produced any studies in the few other states where optometrists have been granted limited surgical privileges that rural optometrists are any more likely to provide surgical care than those who practice in cities.

Conclusion

This proposed Rule is fatally flawed. The Department does not have the legislative authority to unilaterally expand the scope of practice for optometry, especially into an area that has been prohibited specifically by the General Assembly as recently as 2016. The Department was required, but failed, to consult with the Collaborative Optometric/ Ophthalmological Task Force and to base its proposal for a Rule on the recommendations of the Task Force, which do not exist. The proposed training requirements in the Rule are grossly inadequate, especially when compared to the current standards in Illinois for becoming an eye surgeon. As a result, the potential risk to the public is significant if this Rule is adopted.

The Joint Committee on Administrative Rules must reject this Rule.

Footnotes

¹ The Illinois Optometric Practice Act of 1987 (225 ILCS 80/3) Sec. 3, subsection (a) defines the practice of optometry and includes "without the use of surgery . . . or any other procedures taught in schools and colleges of optometry approved by the Department, **and not specifically restricted in this Act**..."

order to protect the public and provide quality care, a Collaborative Optometric/Ophthalmological Task Force is established. This Task Force shall collaboratively develop minimum educational requirements for an optometrist to perform advanced optometric procedures. Advanced optometric procedures do not include the use of lasers. . . No later than January 1, 2018, the Department, in direct consultation with the Collaborative Optometric/Ophthalmological Task Force, shall propose rules for adoption that are consistent with the Task Force's recommendations, or recommend legislation to the General Assembly, providing educational requirements that must be met for an optometrist to obtain certification from a school of optometry approved by the Department to perform advanced optometric procedures as taught (1) at an accredited, private 4-year school of optometry that is located in a city in Illinois with a population in excess of 1,500,000, or (2) at a school of optometry with a curriculum that is substantially similar to the curriculum taught at the school of optometry described in item (1) of this paragraph."

iv CPT®, or "Common Procedural Terminology" is a code set published and maintained by the American Medical Association. CPT codes are used to describe tests, surgeries, evaluations, and any other medical procedure performed by a healthcare provider on a patient. CPT codes are used widely throughout the healthcare system, and by the Federal and state governments (including Illinois) in the Medicare and Medicaid programs. More information about how CPT codes are developed through the CPT Editorial Panel can be viewed at: https://www.ama-assn.org/practice-management/cpt-purpose-mission

v *Federal Register* - 8/23/2006; Centers for Medicare & Medicaid Services; Document Citation: 71 FR 49505; Page: 49505-49977 (473 pages)

vi Types of injections proposed in the Rule are: subcutaneous, intradermal and subconjunctival injections, but excluding retrobulbar, intraocular and botulinum injections.

vii 1 Ill. Adm. Code 100.355

ⁱⁱ Section 15.1 of the Act specifies what "ocular pharmaceutical agents" may be prescribed or employed by optometrists. Subsection (a-5) permits administering medication by injection only for treatment of anaphylaxis, which is a severe allergic reaction. This typically would be an intramuscular injection of epinephrine, and would *not* be given anywhere near the eye.

ISEPS - Attachment A

- ISEPS Review of items listed in the IDFPR definition of "advanced optometric procedures," including description of the procedure, structures involved, associated CPT codes, and potential complications
- Detailed description of chalazion surgery (with photos)
- Sample of chalazion surgery patient consent form
- Example of operative notes for chalazion surgery

<u>NAME</u>	<u>DEFINITION</u>	OCULAR STRUCTURES INVOLVED	<u>CPT</u> <u>CODES</u>	SURGICAL PROCESS	COMPLICATIONS
Excision, removal, destruction of chalazion	Excision of a chalazion (single, multiple same lid, multiple different lids). A chalazion is an inflammation in a meibomian gland. Inflammation usually subsides without surgical treatment, but may need surgical removal if standard therapy fails.	Eyelid Conjunctiva	67805 67801 67800	Creating an incision by cutting into the chalazion with the use of a scalpel. Removing the contents.	 Vision threatening Sudden permanent loss of vision by perforating a blood vessel which connects to the back of the eye. Bleeding/hemorrhaging Infection Ruptured globe (puncturing the eyeball) with potential permanent vision loss Double vision Eyelid droop Eyelid disfigurement Systemic complications from anesthetic injection OBreathing problems, Nerve trauma, Seizures Misdiagnosing a cancerous lesion as
Excision, removal or destruction of benign, superficial lesions	Excision is full-thickness removal of a lesion, including margins, and includes simple closure when performed. The closure of defects created by incision or excision may require closure.	Eyelid Conjunctiva	11440 11401 11402 11403 11404 11406 11420 11421 11422 11423 11424 11426 11440 11441 11442 11443	Measure the greatest clinical diameter of the lesion plus the margin needed for complete excision (lesion diameter plus the most narrow margins required equals the excised diameter.) The margins refer to the most narrow margin required to adequately excise the lesion based on individual judgment.	benign—and then injecting it—can result in the cancer spreading which can be life threatening. • Vision threatening • Sudden permanent loss of vision by perforating a blood vessel which connects to the back of the eye. • Bleeding/hemorrhaging • Infection • Ruptured globe (puncturing the eyeball) with potential permanent vision loss • Double vision • Eyelid droop • Eyelid disfigurement

<u>NAME</u>	<u>DEFINITION</u>	OCULAR STRUCTURES INVOLVED	<u>CPT</u> <u>CODES</u>	SURGICAL PROCESS	COMPLICATIONS
			11444 11446		Systemic complications from anesthetic injection OBreathing problems, Nerve trauma, Seizures Misdiagnosing a cancerous lesion as benign—and then injecting it—can result in the cancer spreading which can be life threatening.
Removal of skin tags	Removal by scissoring or any sharp method, ligature strangulation, electrosurgical destruction or combination of treatment modalities, including chemical destruction or electrocauterization of wound, with or without local anesthesia	Eyelid Skin	11200 11201		 Vision threatening Sudden permanent loss of vision by perforating a blood vessel which connects to the back of the eye. Bleeding/hemorrhaging Infection Ruptured globe (puncturing the eyeball) with potential permanent vision loss Double vision Eyelid droop Eyelid disfigurement Systemic complications from anesthetic injection oBreathing problems, Nerve trauma, Seizures Misdiagnosing a cancerous lesion as benign—and then injecting it—can result in the cancer spreading which can be life threatening.

<u>NAME</u>	<u>DEFINITION</u>	OCULAR STRUCTURES INVOLVED	<u>CPT</u> <u>CODES</u>	SURGICAL PROCESS	• <u>COMPLICATIONS</u>
Incision and drainage of cysts	A cyst is a thin-walled sac, usually containing a liquid or semisolid. The conjunctiva is a transparent mucous membrane covering the outer surface of the eye and lining the inner surface of the eyelid.	Conjunctiva Sclera	68020 68110 68115 68130	Creating an incision by cutting into the cyst with the use of a scalpel or scissors.	 Vision threatening Sudden permanent loss of vision by perforating a blood vessel which connects to the back of the eye. Bleeding/hemorrhaging Infection Ruptured globe (puncturing the eyeball) with potential permanent vision loss Double vision Systemic complications from anesthetic injection Breathing problems, Nerve trauma, Seizures Misdiagnosing a cancerous lesion as benign—and then injecting it—can result in the cancer spreading which can be life-threatening.
Epilation by means other than forceps (not including use of laser)	Correction of trichiasis. Trichiasis is the misdirected upper or lower eyelashes that turn inward toward the eye.	Eyelid	67825* 67830 67835*	Removal of misdirected eyelashes with the use of forceps or through incision of the eyelid margin using a scalpel.	 Vision threatening Bleeding/hemorrhaging Infection Ruptured globe (puncturing the eyeball) with potential permanent vision loss Eyelid droop Eyelid disfigurement
Corneal debridement, other than dead tissues (not including removal of pterygium or corneal neoplasias)	Removal of corneal epithelium in an attempt to stimulate new growth of healthy epithelium	Cornea	65435* 65436*	Removal of the front surface of the cornea (epithelium) with the use of scalpel, chemocauterization or application of a chelating agent (EDTA)	 Vision threatening Corneal abrasion Corneal infection Corneal scarring Ruptured globe Bleeding Could allow for "refractive surgery" as can be interpreted as PRK

<u>NAME</u>	<u>DEFINITION</u>	OCULAR STRUCTURES INVOLVED	<u>CPT</u> <u>CODES</u>	SURGICAL PROCESS	• <u>COMPLICATIONS</u>
Biopsy (excluding corneal)	During certain surgeries such as excision, destruction or other removals, the removed tissue is sent for pathologic examination.	Conjunctiva Extraocular muscle Eyelid Lacrimal gland Lacrimal sac Skin Fine needle aspirate	68100 67346 67810 68510 68525 11100 67415	Removal of tissue with the use of a needle, scalpel, scissors and/or forceps. The tissue is placed in an appropriate chemical agent to preserve the tissue for surgical pathologic review. The tissue is sent to a pathologist for final diagnosis.	 Vision threatening Sudden permanent loss of vision by perforating a blood vessel which connects to the back of the eye. Bleeding/hemorrhaging Infection Ruptured globe (puncturing the eyeball) with potential permanent vision loss Double vision Eyelid droop Eyelid disfigurement Systemic complications from anesthetic injection Breathing problems, Nerve trauma, Seizures
Injection, subcutaneous	Therapeutic, prophylactic, or diagnostic injection. A subcutaneous injection is a method of administering medication. Subcutaneous means under the skin. Subcutaneous injection of filling material (i.e. collagen).	Skin Eyelid Conjunctiva	96372 11950* 11951* 11952* 11953* 11954*	A needle is used to inject a drug into the tissue layer between the skin and the muscle.	 Vision threatening Sudden permanent loss of vision by perforating a blood vessel which connects to the back of the eye. Bleeding/hemorrhaging Infection Ruptured globe (puncturing the eyeball) with potential permanent vision loss Double vision Eyelid droop Eyelid disfigurement Systemic complications from anesthetic injection Breathing problems, Nerve trauma, Seizures

<u>NAME</u>	<u>DEFINITION</u>	OCULAR STRUCTURES INVOLVED	<u>CPT</u> <u>CODES</u>	SURGICAL PROCESS	• <u>COMPLICATIONS</u>
Injection, intradermal	Intradermal injection is the injection of a substance into the dermis, just below the epidermis. Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation.	Skin Eyelid	11900 11901 11920* 11921* 11922*	A needle is used to inject into the dermis.	 Vision threatening Sudden permanent loss of vision by perforating a blood vessel which connects to the back of the eye. Bleeding/hemorrhaging Infection Ruptured globe (puncturing the eyeball) with potential permanent vision loss Double vision Eyelid droop Eyelid disfigurement Systemic complications from anesthetic injection Breathing problems, Nerve trauma, Seizures
Injection, sub- conjunctival	An injection is given between the conjunctiva and Tenon's capsule	Conjunctiva Sub- conjunctival space	68200	A needle is used to inject into the subconjunctival space.	 Vision threatening Sudden permanent loss of vision by perforating a blood vessel which connects to the back of the eye. Bleeding/hemorrhaging Infection Ruptured globe (puncturing the eyeball) with potential permanent vision loss Double vision Eyelid droop Eyelid disfigurement Systemic complications from anesthetic injection Breathing problems, Nerve trauma, Seizures

Epilation –

67825: correction of trichiasis: epilation by other than forceps (i.e. electrosurgery, cryotherapy, laser surgery)

67835: correction of trichiasis, incision of lid margin, with free mucous membrane graft

Corneal debridement

- There is no code for this! Using the code for "epithelium removal"
- The 36 code is with use of EDTA (a chelating agent)

Injection, Subcutaneous

- 11950 - 11954 – subcutaneous injection of filling material (i.e. collagen)

Injection, intradermal

- 11920, 21, 22 – tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation

Chalazion Eyelid Surgery

The technique is as follows:

- After adequate anesthesia, (injection of lidocaine with epinephrine) the skin is prepared and draped.
- A chalazion clamp is inserted so that its circular opening surrounds the conjunctival aspect of the chalazion while its other blade lies against the skin surface.



- Chalazion clamp is applied to the everted lower lid.
- The clamp is tightened and used to evert and expose the conjunctival aspect of the eyelid. The clamp aid controls bleeding during the procedure and helps in fair localization of the lesion.
- No. 11 Bard-Parker blade or radiofrequency cautery tip in "cut/coag" or "hemo" mode is used to incise the tarsus vertically up to 3 mm over the area of the chalazion (see image below).
- Incision perpendicular to the lid margin is placed. Chalazion contents are seen popping out.



- Care is taken to avoid inadvertent extension of incision to the lid margin. This can cause a permanent notching and scarring in the lid margin which may be cosmetically unacceptable.
- The curette enters the tarsal incision and scrapes the cyst, tarsus, and orbicularis surfaces until the entire contents and wall of the cyst are removed from the internal lid (see image below). The curetted material is always sent for histopathological examination to rule of malignancy because sebaceous gland carcinoma is known to present as a chalazion-like lesion.



- Contents of the cyst are being scooped with a chalazion scoop.
- The wound is opened and inspected, and any remaining tags of tissue are picked up with the forceps and severed until the wound is free of any chalazion content or cyst wall (see image below). Meticulous excision of the entire cyst wall reduces the rate of recurrence.



Cyst is excised with radiofrequency cautery probe.

- The clamp is removed and pressure is applied over the site until the bleeding is controlled. The marginal artery of the eyelid can bleed profusely and may bring the patient back to the office for control. Careful inspection is used to ensure bleeding is controlled. A cautery is recommended. A hot cautery can go through the eyelid and perforate the eyeball. A pressure patch is commonly used to help prevent post operative bleeding.
- Clots are wiped from the wound with cotton-tipped applicators, and an antibiotic ointment is applied to the eyelids for 1 day.
- When the chalazion points externally, it may also be removed through the
 cutaneous route. The procedure is essentially the same as that described for
 surgical treatment of chalazion by the internal route, but for the direct excision of
 the cyst and the skin incision. The skin incisions are performed parallel to the lid
 margin. Small incisions can be left unsutured. Gentle digital massage at the site 2
 weeks after the procedure helps to smooth the scar surface and provides good
 cosmesis.

Possible Complications

Potential complications of chalazion procedures are as follows:

- Bleeding
- Lid notching due to incision to lid margin
- Tarsal plate instability due to too large incisions
- Recurrences
- Inadvertent ocular trauma and blindness
- Blindness from steroid injection and central retinal vein occlusion

Local intralesional injection of triamcinolone may result in hypopigmentation at the site of injection, atrophy of the tarsal plate, visible depot of the medication, and/or a raise in intraocular pressure.

CONDITION AND PROPOSED TREATMENT

You have been diagnosed with a chalazion, which is a localized inflammatory response involving sebaceous glands of the eyelid that occurs when the gland duct is obstructed. A chalazion may resolve spontaneously or with warm compresses, lid scrubs, and lid massage. When there is no improvement, the chalazion may be incised and drained. After local anesthesia, a chalazion instrument is put in place and an incision is made in the inner aspect of the eyelid. The contents of the chalazion are then carefully drained with a curette followed by gentle pressure or heat to control any bleeding.

ALTERNATIVES TO SURGERY

- 1 Lid Hygiene Warm compresses, lid massage and scrubs; may not improve chalazion if deep.
- 2 Steroid Injection May require more than one injection. Can result in depigmentation of the eyelid, steroid deposits at the injection site, or in rare instances occlusion of retinal and choroidal blood vessels with possible loss of vision
- 3 No Treatment I may choose no treatment and tolerate the chalazion.

RISKS AND COPMLICATIONS

No procedure is entirely risk free. Adverse effects from incision and drainage of chalazion may include:

- 1 Infection Infections can be treated with topical or oral antibiotics
- 2 Bleeding Normally controlled with gentle pressure or heat cautery at the incision site.
- 3 Pain Minimal and resolves with healing of incision.
- 4 Recurrence Chalazion may recur if incomplete excision.
- 5 Loss of lashes in the involved area
- 6 Eyelid notching in the area of the inflammation
- 7 Damage to the globe from the scalpel, needle used to inject the anesthetic, or cautery instrument.
- 8 Vision loss, including blindness.

CONSENT FOR TREATMENT

CONSENT FOR TREATMENT
By signing below I acknowledge that I have read and understand the above, and have had my
questions answered by the surgeon to my satisfaction.
I consent to the incision and drainage of the chalazion on my
Right upper lid
Right lower lid
Left upper lid
Left lower lid

Patient	signature
Date	

CHALAZION EXCISION

PREOPERATIVE DIAGNOSIS:

Eyelid chalazion, left lower lid

POSTOPERATIVE DIAGNOSIS:

Eyelid chalazion, left lower lid

OPERATION PERFORMED:

Eyelid chalazion excision, left lower lid, interior

ANESTHESIA:

Local, topical and by injection

COMPLICATIONS:

Minor bleeding

ESTIMATED BLOOD LOSS:

Less than 5 mL.

SPECIMENS REMOVED:

Eyelid chalazion, left lower lid

OPERATIVE FINDINGS:

As below.

INDICATIONS FOR SURGERY:

Drainage of chalazion that has not responded satisfactorily to medical management, including: Applying warm compresses 4 times per day for 4 weeks.

INSTRUMENTATION:

Scleral shell

Chalazion clamp

Chalazion curette

Scalpel (#11 Bard-Parker blade)

Toothed forceps (Bishop-Harmon)

Scissors (Wescott)

OPERATIVE PROCEDURE:

After informed consent was obtained, the left eye was marked for surgery. The patient was brought into the operative/procedure suite. One drop of topical anesthetic (tetracaine) was placed in the eye. One mL of 1% lidocaine with epinephrine (to decrease risk of bleeding) was injected into the left lower eyelid subcutaneously and subconjunctivally near the planned incision site, avoiding direct injection into the chalazion.

The patient was prepped and draped in the usual sterile fashion for oculofacial surgery. A scleral shell was placed in the eye to protect from a ruptured globe.

A Chalazion clamp was placed and the lower eyelid everted. Then the chalazion was incised vertically with an 11 blade scalpel through the conjunctiva and into the tarsus. The incision was oriented parallel to the meibomian glands to avoid excessive damage to the glands. The lipogranulomatous material was removed with the chalazion curette. The capsule was loosened up with a curette and then excised with Westcott scissors. The specimen was sent for biopsy. The chalazion clamp was removed and hemostasis was achieved with cautery. The scleral shell was removed. Antibiotic ointment was applied. The eye was patched.

The patient tolerated the procedure well, and was in stable condition upon completion of the surgery.

POST-OPERATIVE PROCEDURE:

Remove the patch 6 - 24 hours after the drainage has stopped. Apply antibiotic ointment 4 times per day for 1 week.

Apply warm compresses 4 times per day for 1 week.

FOLLOW UP:

The patient was instructed to follow up in one week or sooner if there are any changes including: loss of vision, persistent bleeding, swelling of the lid, double vision, or other symptoms.

ISEPS - Attachment B

- American College of Surgeons definition of surgery
- American Medical Association definition of surgery adopted by the AMA House of Delegates in 2007



Definition of Surgery Background

Legislation that defines surgery and its scope is a proactive means for ACS state chapters to ensure that patients are protected and treated with the highest level of surgical care. State regulatory bodies have established high standards for surgeons by setting minimum requirements for education and training for the purpose of ensuring patient safety and quality outcomes.

To ensure that these high standards of patient safety and quality are clearly understood in the rapidly changing medical profession, the American College of Surgeons adopted the following definition for surgery:

Surgery is performed for the purpose of structurally altering the human body by incision or destruction of tissues and is part of the practice of medicine. Surgery also is the diagnostic or therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or transportation of live human tissue, which include lasers, ultrasound, ionizing radiation, scalpels, probes, and needles. The tissue can be cut, burned, vaporized, frozen, sutured, probed, or manipulated by closed reduction for major dislocations and fractures, or otherwise altered by any mechanical, thermal, light-based, electromagnetic, or chemical means. Injection of diagnostic or therapeutic substances into body cavities, internal organs, joints, sensory organs, and the central nervous system is also considered to be surgery (this does not include administration by nursing personnel of some injections, such as subcutaneous, intramuscular, and intravenous when ordered by a physician). All of these surgical procedures are invasive, including those that are performed with lasers, and the risks of any surgical intervention are not eliminated by using a light knife or laser in place of a metal knife or scalpel. Patient safety and quality of care are paramount, and the College therefore believes that patients should be assured that individuals who perform these types of surgery are licensed physicians (defined as doctors of medicine or osteopathy) who meet appropriate professional standards.

The American Medical Association House of Delegates adopted the definition of surgery created by the College in 2007, providing uniformity within the house of medicine and surgery.



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H-475.983 Definition of Surgery

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Our AMA adopts the following definition of "surgery" from American College of Surgeons Statement ST-11:

Surgery is performed for the purpose of structurally altering the human body by the incision or destruction of tissues and is part of the practice of medicine. Surgery also is the diagnostic or therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or transposition of live human tissue which include lasers, ultrasound, ionizing radiation, scalpels, probes, and needles. The tissue can be cut, burned, vaporized, frozen, sutured, probed, or manipulated by closed reductions for major dislocations or fractures, or otherwise altered by mechanical, thermal, light-based, electromagnetic, or chemical means. Injection of diagnostic or therapeutic substances into body cavities, internal organs, joints, sensory organs, and the central nervous system also is considered to be surgery (this does not include the administration by nursing personnel of some injections, subcutaneous, intramuscular, and intravenous, when ordered by a physician). All of these surgical procedures are invasive, including those that are performed with lasers, and the risks of any surgical procedure are not eliminated by using a light knife or laser in place of a metal knife, or scalpel.

Patient safety and quality of care are paramount and, therefore, patients should be assured that individuals who perform these types of surgery are licensed physicians (defined as doctors of medicine or osteopathy) who meet appropriate professional standards. (Res. 212; A-07; Reaffirmed: BOT Rep. 16, A-13)

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ISEPS - Attachment C

•	Fact Sheet distributed by the Illinois Department of Financial and Professional Regulation -
	SB 2899 (2016-99th General Assembly)

SB 2899 - OPTOMETRIC PRACTICE ACT-SUNSET

The Illinois Optometric Practice Act expires on January 1, 2017 and must be renewed so that the practice of optometry continues as a regulated profession. Includes a minor scope of expansion to allow Illinois optometrists to utilize more effective treatments to provide timely and more convenient access to care for patients.

Surgical Procedures Optometrists Currently Permitted To Perform:

- Dilation and irrigation of the lacrimal ducts.
- Insertion and removal of lacrimal plugs
- · Removal of superficial foreign body and rust ring
- Epilation (removal of eyelashes)
- Corneal debridement dead tissue
- Culture
- Corneal shaping with external devices like contact lenses
- Application of human or other tissue without suture

<u>Additional Surgical Procedures Proposed By the Bill with Educational Training:</u>

- **SB 2899** maintains the blanket prohibition on surgery but specifies which surgeries are permitted, thereby allowing additional minor surgical procedures that may be performed by Doctors of Optometry.
 - 1. Suture removal (removal of stitches)
 - 2. Removal, destruction or drainage of superficial lesions and conjunctival cysts (the conjunctiva lines the inside of the eyelids and covers the white part of the eye).
 - 3. Removal of Chalazia (a pea-shaped swelling in the eyelid)
 - 4. Corneal debridement, scrape or anterior puncture not including removal of pterygium (a corneal growth), corneal biopsy or removal of corneal neoplasias (an abnormal growth of tissue).

Treatment by Injection Optometrists Currently Permitted to Perform:

• Intramuscular for the treatment of anaphylaxis

<u>Additional Treatment by Injection Proposed By The Bill with Educational Training:</u>

• **SB 2899** allows Doctors of Optometry to use injectable pharmaceuticals with limitations. Below is the list of each injection and its use:

1. Subcutaneous (just under the skin)

Use: Eyelids -local anesthetics, chalazia (a pea-shaped swelling in the eyelid)

2. Subconjunctival (mucus membrane of the eye)

Use: Inflammation

Note: Retrobulbar (behind the eyeball), intraocular (into the globe), and botulinum (botox) are not permitted.

<u>Narrowing the Scope of the Introduced Bill Regarding Surgical Procedures and Treatment by Injection that Optometrists Permitted to Perform</u>

No longer repeals the blanket prohibition on surgery. No longer enumerates the procedures that may NOT be performed by Doctors of Optometry.

Removes intravenous (into the veins) injections

Use: Fluorescein angiography to detect and manage eye disorders. Fluorescein angiography – fluorescent dye is injected into the bloodstream to highlight the blood vessels in the back of the eye so they can be photographed

Removes intramuscular (into the muscles) injections