



Florida Jurisprudence

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# **DISCLOSURE:**

 Joseph Sowka, OD, in the past 24-months, has been a Consultant/ Speaker Bureau/ Advisory Board member for Visus, Zeiss, and B&L. Dr. Sowka has no direct financial interest in any of the diseases, products or instrumentation mentioned in this presentation. All relevant relationships have been mitigated. He is a co-owner of Optometric Education Consultants (www.optometricedu.com)



The ideas, concepts, conclusions and perspectives presented herein reflect the opinions of the speaker; he has not been paid, coerced, extorted or otherwise influenced by any third party individual or entity to present information that conflicts with his professional viewpoints.

### Disclaimer

- Every attempt has been made to present actual and factual information
- Information presented here is based on opinion, knowledge and experience
- The presenter is not an attorney and one should seek professional legal advice and/or representation for final clarification

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- The objectives of this Association are to advance, improve, and enhance the vision care of the public
- To unite optometrists to encourage and assist in the improvement of the art and science of Optometry
- To elevate the standards and ethics of the profession of Optometry

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- To protect and defend the inalienable right of every person to freedom of choice of practitioner
- To restrict the practice of Optometry and any part of it to those who have been trained, qualified, and licensed to practice the profession
- To maintain an active affiliation with the AOA, and the Southern Council of Optometrists.







- Purpose: To protect the public and make Florida the healthiest state in the nation through health care licensure, enforcement, and information.
- Focus: To be the nation's leader in quality health care regulation.
- Values: I CARE (Innovation, Collaboration, Accountability, Responsiveness, Excellence)

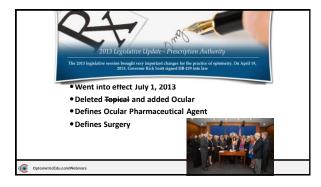


- The Florida Board of Optometry is composed of seven members appointed by the Governor and confirmed by the Senate.
- Five members of the board must be licensed practitioners actively practicing in this state.
- practitioners actively practicing in this state.

  The remaining two members must be citizens of the state who are not, and have never been, licensed practitioners.
- Additionally, the consumer members may not be connected with the practice of optometry or with any other vision-related profession or business.
- At least one member of the board must be 60 years of age or older.







### HB 239

### **Defines Ocular Pharmaceutical Agent**

"Ocular pharmaceutical agent" means a pharmaceutical agent that is administered topically or orally for the diagnosis or treatment of ocular conditions of the human eye and its appendages without the use of surgery or other invasive techniques.



## **HB 239**

#### **Defines Surgery**

"Surgery" means a procedure using an instrument, including a laser, scalpel, or needle, in which human tissue is cut, burned, scraped except as provided in s. 463.014(4), or vaporized, by incision, injection, ultrasound, laser, infusion, cryotherapy, or radiation. The term includes a procedure using an instrument which requires the closure of human tissue by suture, clamp, or other such device.



### HB 239

**Defines what is not Surgery** 



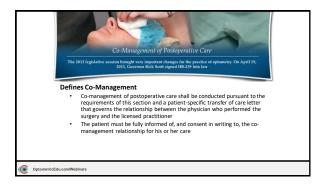
Surgery of any kind<del>, including the use of lasers</del>, is expressly prohibited. Certified optometrists may remove superficial foreign bodies. For the purposes of this subsection, the term "superficial foreign bodies" means any foreign matter that is embedded in the conjunctiva or cornea but that which has not penetrated the globe

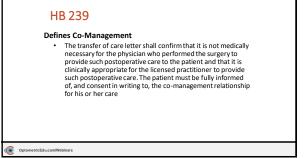
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 Notwithstanding the definition of surgery as provided in s. 463.002(6), a certified optometrist is not prohibited from providing any optometric care within the practice of optometry as defined in s. 463.002(7),

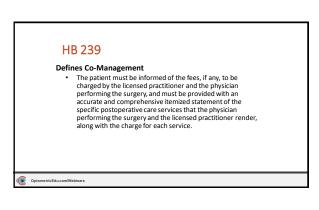
- such as removing an eyelash by epilation,
- probing an uninflamed tear duct in a patient 18 years of age or older.
- blocking the puncta by plug,
- or superficial scraping for the purpose of removing damaged epithelial tissue or superficial foreign bodies or taking a culture of the surface of the cornea or conjunctiva.

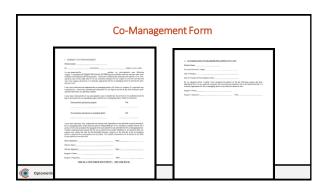


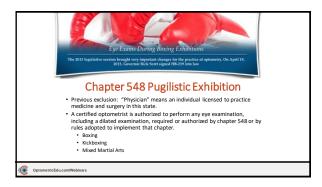


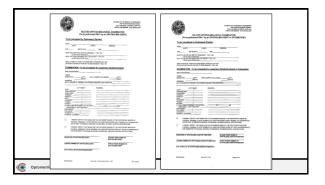


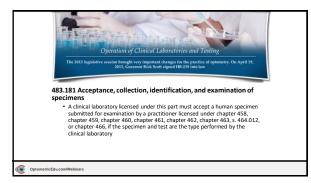


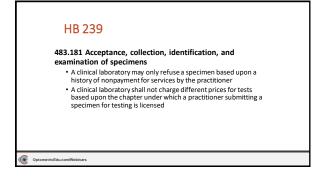














### **HB 239**

### **Defines Topical Formulary**

 The board shall establish a formulary of topical ocular pharmaceutical agents that may be prescribed and administered by a certified optometrist.

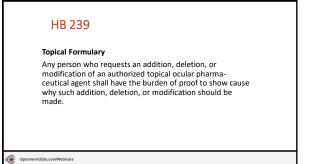


### HB 239

#### **Defines Topical Formulary**

The formulary shall consist of those topical ocular pharmaceutical agents that are appropriate to treat or diagnose ocular diseases and disorders and that which the certified optometrist is qualified to use in the practice of optometry. The board shall establish, add to, delete from, or modify the topical formulary by rule. Notwithstanding any provision of chapter 120 to the contrary, the topical formulary rule becomes shall become effective 60 days from the date it is filed with the Secretary of State.

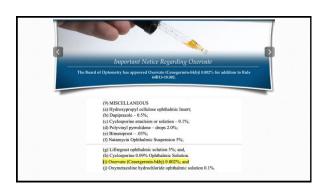












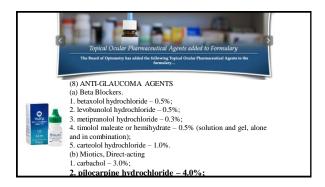


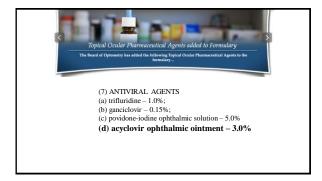














#### Fera Pharmaceuticals Announces FDA Approval of Avaclyr™ (acyclovir ophthalmic ointment)

NEW YORK—April 1, 2019—The US Food and Drug Administration (FDA) has approved Fera's New Drug Application (NDA) for Avaclyr<sub>w</sub>(acyclovir ophthalmic ointment) 3% for the treatment of herpetic keratitis. Orphan drug exclusivity was also granted, providing seven years of marketing exclusivity for the product.



- (a) hydroxypropyl cellulose ophthalmic insert;
   (b) dapiprazole 0.5%;
- (c) cyclosporine emulsion or solution 0.1%;
- (d) polyvinyl pyrrolidone solution 2.0%;
- (e) bimatoprost 0.03%; (f) natamycin ophthalmic suspension 5.0%;
- (g) lifitegrast ophthalmic solution 5.0%; and,
- (h) cenergermin-bkbj 0.002%;
- (i) oxymetazoline hydrochloride ophthalmic solution 0.1%; (j) hypochlorous acid 0.02%



The topical ocular pharmaceutical agents in the formulary include the following legend drugs alone or in combination in concentrations up to those specified, or any lesser concentration: (1) through (8) No change.

- (9) MISCELLANEOUS
- (a) through (j) No change.
- (k) varenicline solution 0.03mg



# Varenicline nasal spray approved as a treatment for dry eye

The FDA's approval of varenicline nasal spray 0.03 mg (Tyrvaya, Oyster Point Pharma) for the treatment of the signs and symptoms of dry eye disease (DED) brings to the management of this common condition a new therapeutic modality that is novel for both its mechanism of action and mode of administration. The new medication is recommended to be used twice daily, sprayed once into each nostril.



#### Do not spray too deep and avoid spraying into your sinuses

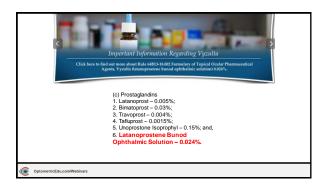
Insert the tip of the nasal spray just past the nasal opening. Aim the tip out towards your ear on the same side of the nostril you're spraying into.

### Ensure proper tongue placement

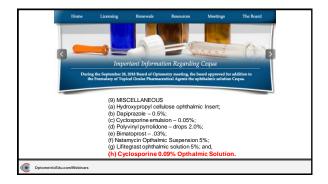
Press your tongue to the roof of your mouth.

#### Avoid inhaling deeply

Breathe gently as you press and release the applicator, just misting the inside of your nostril. The medication will absorb into the wall of the nose where the nerve is located.





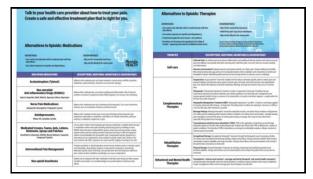












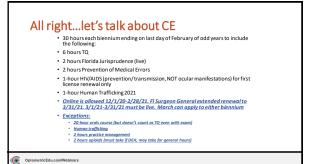




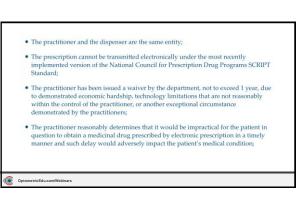


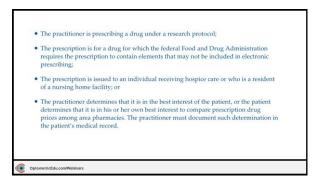


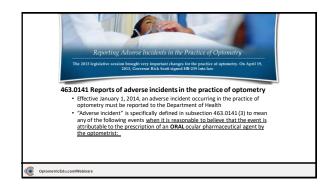












### **HB 239**

#### 463.0141 Reports of adverse incidents in the practice of optometry

- Any condition that requires transfer of the patient to a licensed hospital;
- Any condition that requires the patient to obtain care from a medical doctor or osteopathic doctor, other than a referral or a consultation required by Chapter 463;
- Permanent physical injury to the patient:
- Partial or complete permanent loss of sight by the patient; or
- · Death of the patient.



### HB 239

- 463.0141 Reports of adverse incidents in the practice of optometry
   If an "adverse incident" defined in subsection 463.0141 (3) occurs, the optometrist is required to provide written notice to the Florida Department of Health by certified mail.
  - If the incident takes place while the patient is in the optometrist's office, the notice must be postmarked within 15 days after occurrence.
  - If the incident occurs when the patient is not at the optometrist's office, the notification must be postmarked within 15 days after the optometrist discovers, or reasonably should have discovered, the occurrence of the adverse incident



### **Controlled Substances**

- To secure DOH approval, the counterfeit-proof pad or blank must contain certain security features (i.e., must be blue or green, printed on artificial watermarked paper, must resist erasures and alterations, and "void" or "illegal" must appear on any photocopy or other reproduction of the pad or blank]; and
- To secure DOH approval, the counterfeit-proof pad or blank must also contain the preprinted name, address and category of professional licensure, or a space for the prescriber's name if not preprinted, and a space for the practitioner's DEA registration number.



### **Controlled Substances**

- Tylenol w/Codeine Acetaminophen 300 mg with No. 3 codeine phosphate 30 mg.
  - Only for eye conditions.
  - Cannot be used for Chronic or nonmalignant pain
  - "Chronic nonmalignant pain" means pain unrelated to cancer which persists beyond the usual course of disease or the injury that is the cause of the pain or more than 90 days after surgery.



# **Analgesics**

- Tramadol hydrochloride
  - may not be administered or prescribed for more than 72 hours without consultation with a physician licensed under chapter 458 or chapter 459 who is skilled in diseases of the eye:



### **Controlled Substances**

• Florida Statutes, provides that a written prescription for a controlled substance listed in chapter 893 must be either written on a standardized counterfeit-proof prescription pad produced by a vendor approved by the Florida Department of Health (DOH) or electronically prescribed



## **Controlled Substances**

 Section 893.04 provides that a pharmacy may dispense a prescribed controlled substance only if the full name and address of the prescribing practitioner and the practitioner's DEA registration number is printed thereon.

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### **Controlled Substances**

- DEA Numbers
  - Applications submitted at http://www.deadiversion.usdoj.gov/drugreg/
  - \$731 every 3 years
  - 2 Controlled Substances Schedule 3
  - A certified optometrist licensed under chapter 463 may not administer or prescribe a controlled substance listed in Schedule I or Schedule II of s. 893.03.
  - Tylenol w/Codeine Acetaminophen 300 mg with No. 3 codeine phosphate 30 mg.
  - Tramadol hydrochloride



### **Antibiotics**

- The following antibiotics or their generic or therapeutic equivalents:
  - Amoxicillin with or without clavulanic acid.
  - Azithromycin.
  - Erythromycin.
  - Dicloxacillin.
  - Doxycycline/Tetracycline.
  - Keflex
  - Minocycline



### Antiviral

- The following antivirals or their generic or therapeutic equivalents:
  - Acyclovir
  - Famciclovir
  - Valacyclovir

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### Anti-Glaucoma

- The following oral anti-glaucoma agents or their generic or therapeutic equivalents, which may not be administered or prescribed for more than 72 hours:
- Acetazolamide
- Methazolamide



### 463.014 Certain acts prohibited

 (3) Prescribing, ordering, dispensing, administering, supplying, selling, or giving any drug for the purpose of treating a systemic disease by a licensed practitioner is prohibited. However, a certified optometrist is permitted to use commonly accepted means or methods to immediately address incidents of anaphylaxis.







# **Declaratory Statement**

#### Prokera<sup>©</sup>

The Florida Board of Optometry recently issued a declaratory statement finding that the non-surgical application of Prokera® (described by CPT code 65778 as the placement of amniotic membrane on the ocular surface without the use of sutures] by a Florida certified optometrist is authorized as being within the scope of optometric practice in Florida.





# It's a good thing you're here!

### Course must be live, no more affidavit

(6) As part of the thirty (30) clock hours, licensed practitioners shall be required to obtain two (2) hours in the area of Florida jurisprudence.

(a) No more than two (2) hours of continuing education in the area of Florida jurisprudence may be applied to the thirty (30) clock hour requirement in subsection (1).

(b) A licensed practitioner may earn two (2) hours in Florida jurisprudence by attending a meeting of the Board at which another licensee is disciplined for no less than four (4) continuous hours. Licensed practitioners will be required to sign-in and sign-out with board

staff. Those licensed practitioners present for disciplinary purposes are not eligible to earn the two (2) clock hours for the Board meeting.

DO NOT send in a signed affidavit stating that you read the laws and rules after October 2, 2018

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### 463.0135 Standards of practice

 A licensed practitioner shall provide that degree of care which conforms to that level of care provided by medical practitioners in the same or similar communities. A licensed practitioner shall advise or assist her or his patient in obtaining further care when the service of another health care practitioner is required

# Standards of practice

- 64B13-2.008 Probable Cause Panel.
- (1) The determination as to whether probable cause exists to believe that a violation of the provisions
  of Chapter 456, Part II, or 465, F.2, or of the rules promulgated thereunder, has occurred shall be
  made by the probable cause panel of the Board.
- (2) The probable cause panel shall be composed of at least two (2) present or former members of the Board of Optometry. At least one member of the panel must be a current Board member. At least one member shall be a present or former lay member, if available, willing to serve, and authorized by the Chair.



### 456

In determining what action is appropriate, the board, or department when there is no board, must first consider what sanctions are necessary to protect the public or to compensate the patient. Only after those sanctions have been imposed may the disciplining authority consider and include in the order requirements designed to rehabilitate the practitioner. All costs associated with compliance with orders issued under this subsection are the obligation of the practitioner.

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## What does this mean to you?

- · When in doubt, give the money back to the patient (within reason).
  - Leading complaint to Board: failure to refund money for glasses
  - Could then lead to investigation into file
     Take care Board doesn't overstep authority
- If a grievance is filed, you must defend yourself, preferably with the assistance of an
- · Malpractice insurance typically does not cover this. You must bear the costs personally. Check with carrier now



## Minimum Equipment

The following shall constitute the minimum equipment which a licensed practitioner must possess in each office in which he or she engages in the practice of optometry:

- (1) Ophthalmoscope;
- (2) Tonometer;
- (3) Retinoscope;
- (4) Ophthalmometer, keratometer or corneal topographer;

# Minimum Equipment

- (5) Biomicroscope:
- (6) Phoropter or trial frame, trial lenses and prisms;
- (7) Standard charts or other standard visual acuity test;
- (8) Field testing equipment (other than that used for a confrontation test).

Note: Pachymeter, fundus camera, OCT, etc., not part of the minimum

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### Minimum Exam

### 64B13-3.007 Minimum Procedures for Vision Analysis (comprehensive eye exam).

- (1) Vision analysis is defined as a comprehensive assessment of the patient's visual status and shall include those procedures specified in subsection (2) below.
- (2) An examination for vision analysis shall include the following minimum procedures, which shall be recorded on the patient's case record:
- (a) Patient's history (personal and family medical history, personal and family ocular history, and chief complaint);

### Minimum Exam

- (b) Visual acuity (unaided and with present correction at initial presentation; thereafter, unaided or with present correction);
- (c) External examination;
- (d) Pupillary examination;
- (e) Visual field testing (confrontation or other);
- (f) Internal examination (direct or indirect ophthalmoscopy recording cup disc ratio, blood vessel status and any abnormalities);



### Minimum Exam

- (g) Biomicroscopy (binocular or monocular);
- (h) Tonometry;
- (i) Refraction (with recorded visual acuity);
- (j) Extra ocular muscle balance assessment;

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### Minimum Exam

- (k) Other tests and procedures that may be indicated by case history or objective signs and symptoms discovered during the eye examination;
- (I) Diagnosis and treatment plan.
- (3) If because of the patient's age or physical limitations, one or more of the procedures specified herein or any part thereof, cannot be performed, or if the procedures or any part thereof are to be performed by reason of exemption from this rule, the reason or exemption shall be noted on the patient's case record.



### Minimum Exam

 Except as otherwise provided in this rule, the minimum procedures set forth in subsection (2) above shall be performed prior to providing optometric care during a patient's initial presentation, and thereafter at such appropriate intervals as shall be determined by the <u>optometrist's sound professional judgment</u>. Provided, however, that each optometric patient shall receive a complete vision analysis prior to the provision of further optometric care if the last complete vision analysis was performed more than two years before.

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### So what does this mean to you?

- Subjective:
- personal and family medical history, personal and family ocular history, and chief complaint
- Objective:
  - VA (with and without at initial; with afterwards); pupils, EOMs, screening fields (confrontation), ocular balance (Cover test), refraction, SLE, tonometry (some method), fundus (dilation at first-disc, vessels, abnormalities), any and all others as dictated by exam
- Assessment- detailed
- Plan-detailed



### Standards of Practice

(7)(a) To be in compliance with paragraph 64B13-3.007(2)(f), F.A.C., certified optometrists shall perform a <u>slitted fundus examination</u> during the patient's initial presentation, and thereafter, whenever medically indicated. If, in the certified optometrist's sound professional judgment, distint is not performed because of the patient's ageic, physical limitations, or conditions, the <u>reason(s) shall be</u> <u>noted in the patient's medical record</u>.

(b) Licensed optometrists who determine that a dilated fundus examination is medically indicated shall advise the patient that such examination is medically necessary and shall refer the patient to a qualified health care professional for such examination to be performed. The licensed optometrist shall document the advice and referral in the patient's medical record.

Imaging of the fundus does not count.

# What about non-Comprehensive exams?

- Whenever a patient presents to a licensed practitioner or certified optometrist with any of the following as the primary complaint, the performance of the minimum procedures set forth in subsection (2) above shall not be required.
- (a) Emergencies;
- (b) Trauma;
- (c) Infectious disease;
- · (d) Allergies;
- (e) Toxicities; or
- (f) Inflammations.
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- The minimum procedures set forth in subsection (2) above shall not be required in the following circumstances:
- (a) When a licensed practitioner or certified optometrist is providing specific
  optometric services on a secondary or tertiary basis in patient co-management with
  one or more health care practitioners skilled in the diagnosis and treatment of
  diseases of the human eye and licensed pursuant to Chapter 458, 459, or 463, Florida
  Statutes



# So what does this mean to you?

- If you can't do a required test, state the reason and the attempt.
- Reason for this statute is to protect and provide to public quality care
   Discourages 'refraction mills'
  - "There is no reason that you cannot do an eye exam in less than 5 minutes"



## **Branch License**

- 2014- you no longer need to apply for branch licenses for each office
- You must however have a copy of your Florida license displayed in each office

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# **Drug Dispensing-For Profit**

- A certified optometrist who dispenses medicinal drugs for a fee must register as a dispensing practitioner with the Florida Board of Optometry and pay a fee of \$100.00 at the time of registration and upon each biennial renewal of licensure.
- Subject to and must comply with all laws and rules applicable to pharmacists and pharmacies
- Department of Health is authorized to inspect in the same manner and same frequency as it inspects pharmacies



# **Drug Dispensing-Samples**

- Not required to register as a dispensing practitioner
- Must dispense the medicinal drugs in the manufacturer's labeled package with the practitioner's name, patient's name, and date dispensed.
- If not dispensed in the manufacturer's labeled package, they must bear the following information:
- Practitioner's name;
- Patient's name;
- Date dispensed;Name and strength of drug; and
- Directions for use.

What can get you sued for malpractice and what can get you sanctioned by the Board of Optometry are often two different things The Board of Optometry does not involve itself in malpractice suits. Getting sued for malpractice does not get reported to the Board. The patient or other entity must file a separate grievance with the Board.

# **Bad Outcome vs Malpractice**

- Florida OD
- 60 YOBF
- Routine exam
- IOP: Upper 40's OU
- Glaucoma suspect
- Begins topical treatment
- Manages for 2 years
- IOP low to mid 20's



# **Bad Outcome vs Malpractice**

- Seeks care from ophthalmologist
- On multiple meds
- IOP mid 20's
- Meds changed
- IOP low 20's
- Undergoes ALTP, then trabeculectomy OU
- Sues optometrist
- Retained by patient's attorney



### **Bad Outcome vs Malpractice**

- Allegations:
- $\bullet$  Detected elevated IOP and  $\underline{\textit{only}}$  used topical medications
- Diagnosed glaucoma, but failed to warn of serious nature
- · Failed to diagnose optic nerve injury
- Failed to properly treat optic nerve injury
- Failed to refer to ophthalmologist



### Bad Outcome vs Malpractice

- Files:
- Medications obviously added, notations unclear
- \* No C/D ratio recorded for 1  $\frac{1}{2}$  yrs
- Dilated exam performed, nothing recorded
- No gonio recorded
- No fields
- Frame style, bifocal style, seg height, PD, temple length, A/R coating, tint, all charges recorded
- Is this malpractice? Are allegations accurate?

### Failure to Warn

- · Consequences of contact lens use
- Infectious Keratitis, overwear
- · Consequences of spectacle wear
- Breakage, polycarbonate, safety lenses
- · Consequences of steroid use
- Glaucoma, cataracts, superinfection

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HB 1175; Chapter 2016-234
• Starting July 1, 2016, health care practitioners are required to provide a good faith estimate of anticipated charges to treat a condition if asked by the patient. The estimate must be provided to the patient or their proxy within 7 business days after receiving the request, however the practitioner is not required to adjust the estimate for any potential insurance coverage. Patients must contact their health insurer or health maintenance organization for any information relating to cost-sharing responsibilities.

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### HB 1175; Chapter 2016-234

 While the estimate does not preclude actual charges from exceeding the estimate, failure to provide it within the required time without good cause will result in discipline against the practitioner. This includes a daily fine of \$500 until the estimate is provided to the patient. Total fines may not exceed \$5,000.

# 463.009 **Supportive Personnel**

 No person other than a licensed practitioner may engage in the practice of optometry as defined in s. 463.002(7). Except as provided in this section, under no circumstances shall nonlicensed supportive personnel be delegated diagnosis or treatment duties; however, such personnel may perform data gathering, preliminary testing, prescribed visual therapy, and related duties under the direct supervision of the licensed practitioner. Nonlicensed personnel, who supervision of the licensed practitioner. Nonlicensed personnel, win need not be employees of the licensed practitioner, may perform ministerial duties, tasks, and functions assigned to them by and performed under the general supervision of a licensed practitioner, including obtaining information from consumers for the purpose of making appointments for the licensed practitioner. The licensed practitioner shall be responsible for all delegated acts performed by persons under her or his direct and general supervision.





# What happens when you get in trouble with the Board?

# Case: Running afoul of a crazy person

- Visit 1: Older female presents for CEE
  - checks off on a questionnaire that she has cataracts, floaters, and dry eyes
  - does not check off or otherwise indicate eye pain, vision blur, vision loss or other symptoms
- Pt 'friends' with OD's parents- feels entitled to 'special treatment'
  - No waiting room or copays for her!
- · OD flustered by pt 'barking' at her
- Performs IOP- normal, but not recorded



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# Case: Running afoul of a crazy person

 Successful dilation and stereoscopic evaluation of the optic nerves was performed and recorded as normal without suspicion of glaucoma. The patient was correctable to 20/20 in each eye following a thorough examination.



# Case: Running afoul of a crazy person

- Pt returns 1 year for annual exam
- The patient does not complain of ocular pain or vision loss.
- Intraocular pressure by applanation is normal at this visit.
- A dilated fundus examination is successfully performed without precipitating an angle closure attack. There is no evidence of abnormality other than advancing age-appropriate cataracts

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# Case: Running afoul of a crazy person

- PT RTC 1 mos later complaining of blurred vision that had occurred 2 days previously, but had since resolved.
- The patient appears to have mentioned elevated blood pressure at this time.
- The anterior chamber was judged to be deep and quiet and the patient was successfully dilated again without precipitating an angle closure attack. No signs consistent with glaucoma were found upon examination.



# Case: Running afoul of a crazy person

- Dr. diagnosed ocular surface abnormalities as a possible cause of the patient's transiently blurred vision and recommended lubrication as well as a referral to a primary care evaluation for a hypertension evaluation.
  - Pt diagnosed and now treated for HTN
- PCP orders MRI to determine the cause of the patient's transiently obscured vision
  - MRI norma

# Case: Running afoul of a crazy person

- 10 mos later, pt visits ophthalmologist who diagnoses 'narrow angle glaucoma'.
- MD examination details normal optic discs, normal retinal nerve fiber layer, and a normal GDx evaluation.
   Threshold perimetry done on this date also normal
  - Likely MD was using the antiquated term, "narrow angle glaucoma" to connote a potentially occludable angle.
    - Intraocular pressure at that visit was not in keeping with true angle closure.



# Case: Running afoul of a crazy person

- Gonioscopy indicated potentially occludable angles and MD appropriately recommended laser iridotomy
   Successful
- Interval of 10 months between the examinations
  - cataractogenesis process during this interval could easily increase pupil block and initiate narrowing of the anterior chamber angle, which may have not been present and observable to optometrist at the time of her last examination.

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# Case: Running afoul of a crazy person

- Pt quite agitated with optometrist for not 'diagnosing her glaucoma'
  - After all, pt needed surgery!
  - Prophylactic LPI
- Claims negligence against OD
  - Pain and suffering and mental anguish
    - Her life is 'ruined'
  - · Negligent care
  - Misdiagnosis leads to vision loss
    - Nothing documentable

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# Case: Running afoul of a crazy person

- Pt claims she has sought counsel of several lawyers but doesn't 'want to go that way'
   Translation:
- Pt send threatening letter to OD demanding refund of all fees, copays, and remuneration for 'pain and 'suffering' or she will 'avail herself of all legal means'
- Gives actual dollar amount for compensation
- Translation:
- OD seeks counsel
- Pt vindictively\* reports OD to Board
- \* Personal editoria



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# Case: Running afoul of a crazy person

- Pt dilated twice- Stereoscopic disc analysis, BIO
- Pt treated appropriately for OSD, refractive error
- Pt referred for evaluation and diagnosed with HTN and treated
- Sole issue: during 1 exam, under duress, OD did not record IOP
  - OD admission- knew IOP could have been added and none of this would have happened, but knew it wasn't right thing to do
  - Did perform dilation and BIO and disc analysis at visit

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# Case: Running afoul of a crazy person

- Charge: Violation of Chapter 463.005 Rule 64B13-3.007 Minimum Procedures for Vision Analysis
- Did not perform tonometry and 'specific glaucoma test'
- · Board retains expert
- OD and attorney retain me as expert

### The Facts as I See Them

- Tonometry is not, in fact, a "glaucoma test" or "specific glaucoma test", but merely the measurement of IOP
- Elevated intraocular pressure is a risk factor for glaucoma, but not in itself a diagnosis of glaucoma.
- Tonometry is not even an accepted screening test for glaucoma
   Tonometry is not specific enough a test to screen for glaucoma as many patients with the disease can be mis-labeled as normal
- Detailed stereoscopic evaluation of the optic disc is a more sensitive measurement for the determination of glaucoma
  - Ergo, the OD <u>did</u> do a 'specific glaucoma test'



### The Facts as I See Them

- No permanent damage sustained by the patient.
- No evidence that any of the patient's complaints were attributable to intermittent angle closure.
- The patient was determined to merely have potentially occludable angles.
- The patient successfully underwent laser iridotomy, which has presumably reduced the risk of future occlusion.

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### The Facts as I See Them

- The same procedure would have been necessary had the potentially occludable state been diagnosed by any other qualified doctor at any time.
- Thus, the patient has received the proper treatment.
- There is nothing in any records reviewed that indicate the actions or alleged inactions of optometrist negatively impacted the apparently positive outcome for this patient.

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## The Facts as I See Them

- OD delivered excellent care in face of adversity
- OD was professional in not altering record
- OD sought legal counsel

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### Final Outcome

· Case dismissed for no probable cause



# Case: Alleged Negligence

- Lawn/ tree service worker presents with corneal abrasion
  - No hx of vegetative matter given
- 3 days of FB sensation; no complaints of vision loss
- Geographic abrasion and edema without infiltration
  - Treated with Maxitrol and bandage CL- f/u 2 days
     RTC immediately if any changes
- Pt returns 2 days later with severe central corneal infiltration
- OD recognizes possibility of fungal infection- tries to refer immediately

# Case: Alleged Negligence

- · Pt wants to 'wait to see if it gets better'
- Workers comp-referral authorization will take 'at least a week'
- OD adamant- explains fungal infection and permanent vision loss
- Pt ultimately referred and seen next day and treated for bacterial keratitis despite OD note about fungus
- After 7-10 days of not improving, pt referred elsewhere and dx'ed with fungal keratitis



# Case: Alleged Negligence

- Pt initiates litigation against OD
- Referral center recognized issue and offered compensation in advance of litigation, so was not sued.
- Pt leaves country, not participating in legal processcase dies
- Pt's attorney vindictively\* reports OD to DOH for license sanctions

\*personal editorial

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## Case: Alleged Negligence

- · DOH Expert:
- OD violated Chapter 463.0135(1) by failing to provide the degree of medical care provided by similarly trained medical practitioners in the same or similar communities
  - Treated corneal abrasion with antibiotic-steroid combination
  - Use of antibiotics alone is standard of care
  - Using steroid for vegetative corneal injury
  - Failed to timely refer fungal keratitis



## The Facts as I See Them

- No hx of vegetative injury ever given by pt to anyone
- DOH broad speculation based upon employment and final diagnosis
- $\bullet \ \ \mathsf{Steroid}\text{-}\mathsf{antibiotic}\ \mathsf{combo}\ \mathsf{reasonable}\ \mathsf{for}\ \mathsf{corneal}\ \mathsf{abrasion}$
- No indication of fungal keratitis at first visit
- Prophylactic natamycin? Refer abrasion to corneal specialist? What more could OD do?
- OD was first to consider fungus, but nobody listened
- What would have happened if OD used standard of care treatment with topical antibiotics alone?

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### Final Outcome

· Case dismissed for no probable cause



### "There is no bad referral?"

- OD sees patient with progressive vision loss after solar eclipse
- 20/50 vision OS
- Pt told had to see ophthalmologist STAT due to potential for blindness for "large cups in nerve"
   0.7/0.7 C/D OU
- On call ophthalmologist for ER reports OD for 'patient dumping'.

# Do as I say...or else

- · Female presents to OD
- Demands 1 year refills on timolol
- · Refuses any additional testing or follow up
- Doctor declines...gets reported to DOH



### Another RD Case

- · Pt c/o floaters
- Examined by OD who dilates, performs BIO, finds retina intact, warns Si/Sx RD; RTC ASAP any changes
- Pt experiences vision reduction on a Thursday, somewhat worse on Friday- wants to see if it will 'clear up'
- Comes in Monday with macula off RD
- Sues OD
- Expert witness: "He didn't look well enough"
- Attorney invokes following statute:

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### Another RD Case

- (4) A licensed practitioner shall promptly advise a patient to seek evaluation by a
  physician skilled in diseases of the eye and licensed under chapter 458 or chapter
  459 for diagnosis and possible treatment whenever the licensed practitioner is
  informed by the patient of the sudden onset of spots or "floaters" with loss of all or
  part of the visual field.
- Defense attorney flustered by rule
- Retained to defend OD



# Why is this so?

- Do I have to refer every case of flashes and floaters?
- Difference between licensed practitioner (who cannot dilate) and certified practitioner (who can dilate).
- These patients need dilation- licensed practitioner can't and certified can.
  - If RD found- pt logically referred
  - If nothing seen but pt has vision loss- pt logically referred
- Why no statute regarding older patient with headache and jaw claudication, etc?

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### Standards of Practice

• (2) A licensed practitioner diagnosing angle closure, infantile, or congenital forms of glaucoma shall refer the patient to a physician skilled in diseases of the eye and licensed under chapter 458 or chapter 459.



# Why is this so?

- Acute angle closure, infantile, and congenital forms of glaucoma are primarily surgical diseases.
- Forces non-surgeons from "Forrest Gumping their way through" medically

# Responsibility

A licensed practitioner shall have an established procedure appropriate for the provision of eye care to his/her patients in the event of an emergency outside of normal professional hours, and when the licensed practitioner is not personally available. Since the licensed practitioner's continuing responsibility to the patient is of a personal professional hautre, no licensed practitioner shall primarily rely upon a hospital emergency room as a means of discharging this responsibility.



## So what does this mean to you?

- Unlike every other medical provider, your answering machine cannot say, "If this is a medical emergency, hang up and dial
- You must have an on-call system after hours; The system cannot direct patients to the ER.
- Options: your cell phone #, professional answering service with your cell phone #; a colleague or practice/ institution who will accept your emergencies
- Note: you have <u>no obligation</u> to provide after hours emergency care to any person who is **NOT** your patient
   Caveat: neither does your ophthalmology colleagues

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• (3) When an infectious corneal disease condition has not responded to standard methods of treatment within the scope of optometric practice, the certified optometrist shall consult with a physician skilled in diseases of the eye and licensed under chapter 458 or chapter 459.



# So what does this mean to you?

- Duh!
- Do we really have to explain it?

### 64B13-3.010 Standards of Practice.

(2) An optometrist shall not use or perform any technique, function, or mode of treatment which the optometrist is not professionally competent to perform. Professional competence as used in this rule may be acquired by formal education, supervised training and experience, continuing education programs which have been approved by the Board, or an appropriate combination of such means.



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# 64B13-3.010 Standards of Practice.

- (4) Certified optometrists employing the topical ocular pharmaceuticals listed in subsection 64B13-18.002(9), F.A.C., Anti-Glaucoma Agents, shall comply with the following:
- (a) Upon initial diagnosis of glaucoma of a type other than those specifically listed in Section 463.0135(2), F.S., the certified optometrist shall develop a plan of treatment and management.
- 1. The plan will be predicated upon the severity of the existing optic nerve damage, the intraocular pressure, and stability of the clinical course.
- In the event the certified optometrist cannot otherwise comply with the requirements of subsections 64B13-3.010(1)-(3), F.A.C., a co-management plan shall be established with a physician skilled in the diseases of the human eye and licensed under Chapter 458 or 459, F.S.

# So what does this mean to you?

- · Not much different than what you are already doing.
- If you diagnose glaucoma, make a treatment plan
- If glaucoma is bad, make it an aggressive plan.
- If you can't, send it to someone who can



### Standards of Practice

(b) Because <u>topical beta-blockers</u> have potential systemic side effects a certified optometrist employing beta-blockers shall, in a manner consistent with Section 463.0135(1), F.S., <u>ascertain the risk of ystemic side effects</u> through either a case history that complies with paragraph 68413-3.007(2)(a), F.A.C., or by <u>communicating with the patient's primary care physician</u>. The certified <u>optometrist shall</u> also <u>communicate with the patient's primary care physician</u>. The certified <u>optometrist shall</u> also <u>communicate with the patient's primary care physician</u>, over with a physician skilled in diseased of the eye and licensed under Chapter 458 or 459, F.S., when, in the professional judgment of the <u>certified optometrist</u>, it is medically <u>appropriate to do so</u>. This communication shall be noted in the patient's permanent record. The methodology of communication is left to the professional discretion of the certified optometrist.

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## So what does this mean to you?

- · When in doubt...ask
- You are not obligated to tell the PCP that you have prescribed a beta blocker... but it is good care and a courtesy
- Easy way- write the Rx and tell the patient to show to PCP before filling.

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# Standards of (Glaucoma) Practice

- (c) The certified optometrist shall have available, and be proficient in the use of, the following instrumentation:
- 1. Goldman-type <u>applanation</u> tonometer
- 2. Visual fields instrumentation capable of  $\underline{\text{threshold perimetry.}}$
- 3. Gonioscope.
- Fundus Camera or detailed sketch of optic nerve head.
- 5. Biomicroscope.
- 6. A device to provide <u>stereoscopic view of optic nerve</u>.

Hmmm... still no pachymeter, camera, or OCT

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 (9) A licensed practitioner who believes a patient may have glaucoma shall promptly advise the patient of the serious nature of glaucoma. The licensed practitioner shall place in the patient's permanent record that the practitioner provided such advice to the patient.

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 (4) A licensed practitioner shall promptly advise a patient to seek evaluation by a physician skilled in diseases of the eye and licensed under chapter 458 or chapter 459 for diagnosis and possible treatment whenever the licensed practitioner is informed by the patient of the sudden onset of spots or "floaters" with loss of all or part of the visual field

# Why is this so?

- Do I have to refer every case of flashes and floaters?
- Difference between licensed practitioner (who cannot dilate) and certified practitioner (who can dilate).
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  - If RD found- pt logically referred
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- Why no statute regarding older patient with headache and jaw claudication, etc?

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# 463.0135 Standards of practice.—

 (1) A licensed practitioner shall provide that degree of care which conforms to that level of care provided by medical practitioners in the same or similar communities. A licensed practitioner shall advise or assist her or his patient in obtaining further care when the service of another health care practitioner is required.

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- (5) The licensed practitioner shall routinely advise a patient to immediately contact the licensed practitioner if the patient experiences an adverse drug reaction.
- (6) The licensed practitioner shall, when appropriate, refer to medical specialists or facilities patients who notify a licensed practitioner of an adverse drug reaction.
- (7) The licensed practitioner shall place in a patient's permanent record information describing any adverse drug reaction experienced by the patient, the date of such reaction, and whether any referral was made.

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(8) The licensed practitioner shall maintain the names of at least three
physicians, physician clinics, or hospitals to whom the licensed
practitioner will refer patients who experience an adverse drug reaction.
At least one of these physicians shall be a physician skilled in the
diagnosis and treatment of diseases of the eye and licensed under
chapter 458 or chapter 459.

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### Responsibility

A licensed practitioner shall **give notice** to the patient when he or she relocates his or her practice or withdraws his or her services so that the patient may make arrangements for his or her eye care. Notice to the patient shall specifically identify the new location of the licensed practitioner's practice or the location at which the patient may obtain his or her patient record, and shall be in compliance with Rule 64B13-3.003, F.A.C.



### So what does this mean to you?

- You have to let them know when you and your practice cease
- Caveat:
  - Covering offices of "Dr. Smith and associates"
    - The practice remains open
    - Pt records are still at that practice
    - Can post notice of departure

## Responsibility

Patient records shall clearly identify the optometrist who examined or treated the patient on each separate occasion.



# So what does this mean to you?

- · Sign the chart
- · Make sure EHR drops signature correctly
- This has been an issue in Board cases and malpractice litigation

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### **Patient Records**

64B13-3.003 Patient Records; Transfer or Death of Licensed Practitioner.

- (1) The licensed practitioner must legibly sign the entry in his or her records for each patient encounter. If the practitioner maintains electronic patient records, the practitioner may affix an electronic signature which can be generated by using either public key infrastructure or signature dynamics technology, and meets the following criteria:
- (a) The electronic signature is unique to the person using it;
- (b) The electronic signature is capable of verification;
- (c) The electronic signature is under the sole control of the person using it;
- (d) The electronic signature is linked to the record in such a manner that the electronic signature is invalidated if any data in the record are changed.

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### **Patient Records**

(2) A licensed practitioner shall maintain full and independent responsibility and control over all records relating to his or her patients and his or her optometric practice. All such records shall remain confidential with Rule Balla 23.00 i.F.A.C. For the purposes of this rule, "maintain full and independent responsibility and control" means that the records shall be maintained in the licensed practitioner's office or solely in the possession of the licensed practitioner shall not share, delegate, or relainquish either possession of the records or his or her responsibility or control over those records with or to any entity which is not listefal licensed practitioner.

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### **Patient Records**

(3) The records relating to the patients of a multidisciplinary group of licensed health care professionals as provided in Section 463.014(1)(a), F.S., or relating to the patients of a partnership or professional association as provided in Section 463.014(1)(b), F.S., may be maintained by the group practice, partnership, or professional association on behalf of all licensed practitioners employed by the group practice, partnership, or professional association.

(4) For the purposes of this rule, "entity which itself is not a licensed practitioner" shall refer to any corporation, lay body, organization, individual, or commercial or mercantile establishment which is not a licensed practitioner or which is not comprised solely of licensed health care professionals, the primary objective of whom is the diagnosis and treatment of the human body.

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### **Patient Records**

(5) For the purposes of this rule, "commercial or mercantile establishment" shall include an establishment in which the practice of opticianny is conducted pursuant to Chapter 484, Part I, Florida Statutes, and an establishment in which optical goods are sold.

(6) A licensed practitioner shall keep patient records for a period of at least <u>five years</u> after the last entry. Upon the discontinuance of his or her practice, the licensed practitioner shall either transfer all patient records which are less than five years old to an eye care practitioner licensed pursuant to Chapter 463, 488, or 459, F.S., where they may be obtained by patients, or he or she shall keep them in his or her possession for at least five years and make them available to be obtained by patients.

# So what does this mean to you?

- The records are yours, not the optician's, not Lenscrafters, etc.
- · Keep them for 5 years after last visit
- Hand them off to a colleague if pt active and records less than 5 years old



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### Records at Death

(7) A licensed practitioner who retires or otherwise discontinues his or her practice shall cause to be published in the newspaper of greatest general circulation in each county where the licensed practitioner practiced, a notice indicating to his or her patients that the licensed practitioner system records are eval able from a specified eye care practitioner licensed pursuant to Chapter 458, 459, or 463, FS., at a certain location. The notice shall be published once during each week for four (4) consecutive weeks. A copy of the published notice shall be delivered to the Board office for filing.



### Records at Death

(8)(a) The executor, administrator, personal representative, or survivor of a deceased licensed practitioner shall retain patient records concerning any patient of the deceased licensed practitioner for at least five years from the date of death of the licensed practitioner.

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# So what does this mean to you?

- If you are retiring, you should make patients aware as soon as plans are
- · Additionally, you have to make patients aware after retirement that they can get their records and how
- After your death, does it really matter? What exactly can be done to you? You can't be brought up on charges and the Board and DOH have no governance over your spouse.



### **Entrance Sign**

- · Whenever a licensed practitioner is actively engaged in the practice of optometry, or actively holding himself or herself out as a practitioner, he or she shall cause to be placed or kept in a conspicuous place at each entrance to each office a sign which lists each licensed practitioner's name and words of proper abbreviation or intelligible lettering clearly denoting that the practitioner is engaged in the practice of
- · 'Practice Limited to the Eye" is not acceptable

