

Jurisprudence 2020 Outline Part 2
Chapter 465
PHARMACY

465.0276 Dispensing practitioner.—

So, can you sell drugs in your practice?

Yes you can!

You just have to follow a few simple rules...

(2) A practitioner who dispenses medicinal drugs for human consumption for fee or remuneration of any kind, whether direct or indirect, must:

Register

(a) Register with her or his licensing board as a dispensing practitioner and pay a fee not to exceed \$100 at the time of registration and upon each renewal of her or his license.

Comply

(b) Comply with and be subject to all laws and rules applicable to pharmacists and pharmacies, including, but not limited to, this chapter and chapters 499 and 893 and all federal laws and regulations.

Advise

(c) Before dispensing any drug, give the patient a written prescription and orally or in writing advise the patient that the prescription may be filled in the practitioner's office or at any pharmacy.

Inspection

(3) The department shall inspect any facility where a practitioner dispenses medicinal drugs... in the same manner and with the same frequency as it inspects pharmacies for the purpose of determining whether the practitioner is in compliance with all statutes and rules

Guilty

(4) The registration of any practitioner who has been found by her or his respective board to have dispensed medicinal drugs in violation of this chapter shall be subject to suspension or revocation.

So, how you solve this dilemma?

No Charge

5) A practitioner who confines her or his activities to the dispensing of complimentary packages of medicinal drugs to the practitioner's own patients..., without the payment of fee or remuneration of any kind, ..., and who herself or himself dispenses such drugs is not required to register

So if you give away free samples do you have any requirements?

Of course you do!

What are the requirements for giving away free samples in your practice?

Label

The practitioner must dispense such drugs in the manufacturer's labeled package with the practitioner's name, patient's name, and date dispensed, or, if such drugs are not dispensed in the manufacturer's labeled package, they must be dispensed in a container which bears the following information:

- (a) Practitioner's name;
- (b) Patient's name;
- (c) Date dispensed;
- (d) Name & strength;
- (e) Directions for use.

Highway? in Canyonlands

Canyonlands National Park

Everything we discussed previously applied to all physicians
Now we will start talking about Optometry.

Specifically Chapter 463:

Who can an optometrist discuss a patient's care with without written authorization?

Except upon written authorization of the patient ... the condition of the patient may not be discussed with any person other than the patient or his or her legal representative or other health care providers licensed under Ch 463, 458, or 459, who are involved in the diagnosis and treatment of that patient

Who is responsible for maintaining the confidentiality of your medical records?

You are!

It is the responsibility of a licensed practitioner to insure that his or her employees, as well as any personnel who are not his or her employees but who are performing assigned ministerial duties, tasks, and functions, do not violate the confidentiality of patient records.

Are you responsible for computerize data?

In addition to federal HIPPA rules FL Statute 817.5681 governs the security breach of unencrypted "personal information" in optometrists computerized data systems.

What is "personal information"

"personal information" means an individual's name or initials, in combination with any one or more of the following data elements when the data elements are not encrypted:

(a) Social security #.

(b) Driver's license # or FI Id Card #.

(c) Account #, credit or debit card #, in combination with any required security code, access code, or password that would permit access to an individual's financial account.

What is a security breach?

"breach" means unlawful and unauthorized acquisition of computerized data that materially compromises the security, confidentiality, or integrity of personal information...

What do you do if you believe data has been acquired by an unauthorized person?

You must notify your patients in writing or electronically within 45 days.

Failure can lead to fines of \$1000/day.

Or \$500,000 fine if not reported in 180 days.

If more than 1000 records are breached notice must also be given to all consumer reporting agencies.

Pensacola News Journal June,2013

Optometry EHR Breached in Florida, 9,000 Notified

An unauthorized individual or company accessed and copied all or parts of the electronic health records system at Sight and Sun Eyeworks in Gulf Breeze, Fla.

According to a notice from parent company Gulf Breeze Family Eyecare Inc. "Patients should closely monitor their credit card, bank and other financial statements for signs of fraud and identity theft."

The Pensacola News Journal reports about 9,000 patients were affected. Clinical and demographic information, along with Social Security numbers, were among the compromised data.

Delivering Eyeglasses When the Optometrist is Out of the Office

Can non-licensed support personnel deliver prescription eyeglasses to a patient when the optometrist is out of the office?

And the answer is?

It Depends...

...on whether the non-licensed support personnel is simply transferring physical possession of the eyeglasses to the patient or whether the non-licensed support personnel performs data gathering, such as obtaining PD or seg height, as part of the delivery.

What is General Supervision?

"General supervision" as defined in subsection 463.002 (7), Florida Statutes, does not require the optometrist to be on the premises when the ministerial duty, task, or function is performed but does require the optometrist to be readily available.

What are ministerial duties?

Non-licensed supportive personnel, who need not be employees of the optometrist, may perform ministerial duties, tasks, and functions under the optometrist's general supervision. The Board of Optometry has described the types of ministerial duties, tasks, and functions which can be performed under general supervision as including the delivery of eyeglasses, selection of frames, adjustment of frames, and instruction for the insertion, removal, and care of contact lenses.

What is Direct Supervision?

463.002 (6), Fl. Statutes, defines direct supervision as requiring the optometrist to be on the premises while all delegated procedures are performed and to give final approval once the procedure has been performed.

Need to be on the premises for..

Section 463.009 allows non-licensed supportive personnel to perform data gathering, preliminary testing, prescribed visual therapy, and related duties under the optometrist's direct supervision.

General Supervision Summary

Non-licensed supportive personnel may transfer physical possession of the glasses to the patient when the optometrist is not on the premises

The non-licensed supportive personnel may also adjust frames in the optometrist's absence.

Direct Supervision Summary

Obtaining PD measurements or obtaining seg ht. measurements for bifocal or trifocal lenses are data gathering duties which are required by law to be performed only under the direct supervision of the optometrist.

Footnote:

M.D.'s may use General Supervision for most of their activities.

Licensed Opticians personnel must be under Direct Supervision at all times.

64B13-3.009 Advertising

Who is responsible to make sure Optometric Advertising is not false or fraudulent ?

Advertising

The licensed practitioner has the duty to review and proof all advertisements prior to publication, and is fully responsible for the content therein.

3.009 Affirmative Disclosure

Are you allowed to practice under a trade name?

YES

) A licensed practitioner may practice under .., trade names,.., so long as any dissemination of information, including signs,... contains the name under which the practitioner is licensed... in which the

practitioner practices and so long as the information identifies the practitioner... as being engaged in the practice of optometry

Examples (all ok)

Irving Borish O.D.

Dr. Irving Borish

Optometrist

Irving Borish O.D.P.A.

Dr. Irving Borish

Board Certified Optometric Physician

Example (not ok)

Dr. Irving Borish O.D.

This is not illegal it is just bad grammar!

(One of my personal pet peeves!)

Trade names

Is it OK to name your practice

“Best” Optometry?

No

...may not adopt and publish or cause to be published any practice identification name, trade name, which is, contains, or is intended to serve as an affirmation of the quality or competitive value of the optometric services...

Trade names cont:

What is the requirement to practice under a trade name?

You must register trade names

Any licensed practitioner who is practicing under a practice identification name, trade name must register with the Board of Optometry identifying the specific name as registered...

Is it legal to have your patients sign this form?

Patient Dilation Waiver

Dilating your patients with eye drops is a routine procedure, and a standard part of a comprehensive eye exam for new patients.

Pupil dilation allows your doctor to see the internal parts of your eyes and examine them for eye diseases or abnormalities.

Refusal to undergo dilation may prevent detection of diseases that could potentially lead to permanent vision loss.

By signing this form you are indicating that you do not want your pupils dilated today. Be advised, you may return at your convenience to have this procedure performed on a different day, at no extra charge.

And the answer is:

To be in compliance with 64B13-3.007(2)(f), certified optometrists shall perform a dilated fundus examination during the patient's initial presentation, and thereafter, whenever medically indicated. If, in the certified optometrist's sound professional judgment, dilation is not performed because of the patient's age, physical limitations, or conditions, the reason(s) shall be noted in the patient's medical record

Dilation Rule Summary:

Shall means you have to do something

Do not ask the patient if they want to be dilated.

Tell them you are going to dilate them,

Then if they refuse ,Document the reason.

What is your responsibility to your patients outside your regular office hours?

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

Can you have your answering machine send patients to the emergency room?

Since the licensed practitioner's continuing responsibility to the patient is of a personal professional nature, no licensed practitioner shall primarily rely upon a hospital emergency room as a means of discharging this responsibility.

What is your responsibility with your records when treating patients with other doctors?

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

How long do you need to keep your patient records?

A licensed practitioner shall keep patient records for a period of at least five years after the last entry

Statute of Limitations

Some optometrists choose to retain patient records in excess of the required five (5) years period. Their motivation includes not wanting to discard any patient record prior to the expiration of the potential seven (7) year statutes of limitation for malpractice actions contained in section 95.11, Florida Statutes.

What do you need to do with your records if you leave or discontinue your practice?

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, 458, or 459, 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.

What is the number one rules violation that optometrists are charged with?

Answer:

Minimum Exam rule violation

64B13-3.007 Minimum Procedures for Comprehensive Eye Examination.

(2) A comprehensive eye examination 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);

(b) Visual acuity (unaided and with present correction at initial presentation; thereafter, unaided or with present correction);

(c) External examination;

(d) Pupillary examination;

Minimum Exam Cont:

(e) Visual field testing (confrontation or other);

(f) Internal examination (recording, optic nerve health, blood vessel status, macula health, and any abnormalities);

(g) Biomicroscopy (binocular or monocular);

- (h) Tonometry; (with time of measurement);
- (i) Refraction (with recorded visual acuity);
- (j) Extra ocular muscle balance assessment;
- (k) Other tests and procedures that may be indicated by case history or objective signs and symptoms discovered during the comprehensive eye examination;
- (l) Diagnosis and treatment plan.

What do you need to do if you can't perform all the required minimum examination tests?

Just document the reason on the record!

(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

How often are you required to perform a minimum exam?

Minimum Exam cont:

4), the minimum procedures 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 optometrist's sound professional judgment: provided,

Comprehensive Eye Exam

however, that each optometric patient shall receive a comprehensive eye examination prior to the provision of further optometric care if the last comprehensive eye examination was performed more than two years before.

What are the exceptions?

Minimum Exam exceptions:

- (a) Emergencies;
- (b) Trauma;
- (c) Infectious disease;
- (d) Allergies;
- (e) Toxicities; or

(f) Inflammations

Minimum Exam exceptions:

above shall not be required in the following circumstances:

(a) providing specific optometric services on a secondary or tertiary basis in patient co-management with one or more health care practitioners skilled in the dx and tx of diseases of the human eye

Minimum Exam exceptions:

providing consultative optometric services on a limited basis at the request of health care practitioners licensed to Ch 458, 459, or 463

Minimum Exam exceptions:

(c) When an optometrist performs public service visual screenings or visual screenings for governmental agencies.

When you are performing a visual screening what do you need to inform the patient of in writing?

Minimum Exam exceptions:

1. The limitations of the screening;
2. That the screening is not representative of or a substitute for a comprehensive eye examination; and
3. That the screening will not result in a prescription for visual correction.

Daily Wear Contact Lenses

How long is a daily wear contact lens prescription good for?

Answer:

2 years

This applies to FDA approved daily wear contact lenses only.

1 800-Contacts is filing complaints against

OD's who are writing year on their daily wear cl prescriptions.

How Long is a spectacle Prescription good for?

?

Spectacle Prescriptions!

A spectacle prescription shall be considered valid for a period of five (5) years,

What is the number one reason complaints about optometrists are filed with the board?

Economic Disputes

Most complaints are filed by unhappy patients mad that the doctor did not refund money for a variety of alleged grievances.

Patients didn't like Rx, glasses, cl's

Crazy

Solution

Always refund patients

It is much cheaper and less stressful than having a complaint filed.

What don't you do if a complaint is filed?

Don'ts

Don't call a board member.

Don't talk to the complainant.

DO NOT alter your records!

You do not have to respond to the complaint without counsel.

Do's

Seriously consider hiring an attorney familiar with Florida administrative law.

If you decide to defend yourself:

Carefully review your record and prepare a typed narrative response explaining your examination, diagnosis and treatment plan.

Consumer Services Unit

The Consumer Services Unit (CSU)

is the central intake for all complaints

CSU includes investigators and government analysts assigned to specific professions. Staff reviews each complaint for possible violations of laws and rules.

CSU cont:

All complaints are assigned a complaint number

An acknowledgement of receipt of a complaint is sent to the complainant

Staff reviews each complaint for possible violations of laws and rules.

CSU cont:

Section 456.073(1), F.S., specifically provides that "...A complaint is legally sufficient if it contains ultimate facts that show that a violation ...has occurred."

After review of a complaint, if the allegations and supporting documentation show that a violation may have occurred the complaint is legally sufficient for investigation

Examples of complaints that may be investigated

Practicing below minimum standards or negligence

Impairment/medical condition

Advertising violation

Sexual misconduct with a patient

Misfilled/mislabeled prescription

Failure to release patient records

Complaints that may not be investigated

Fee disputes (broken or missed appointments)

Billing disputes

Personality conflicts

Anonymous Complaints

CSU may investigate an anonymous complaint provided it is legally sufficient

Complaints cont:

It is important to respond in a timely manner.

If an investigator calls or comes in to talk to you remember even though he may be friendly he is a detective trying to discover evidence against you.

Investigative Services Unit

Obtaining medical records, documentation and evidence related to the complaint

Locating and interviewing the complainant, the patient, the subject and any witnesses

Drafting and serving subpoenas for necessary information

ISU cont:

After the information is collected and interviews are conducted, the investigator will write an investigative report.

The report is forwarded to the department's attorneys for legal review.

Prosecution Services Unit

Attorneys review the investigative report to recommend a course of action which may include:

Emergency Order

Expert Review

Closing Order

Administrative Complaint

Cont:

If it is clear no violation has occurred the case is dismissed.

If not...

Complaint process:

If the case has merit it is next sent to Board of Optometry Probable Cause Panel consisting of 2 or 3 board members and the prosecuting attorney and board attorney.

Probable cause:

The case is reviewed for legal merit and if there is clear and convincing evidence the case is voted to be sent to the board

Probable cause is “confidential”

Board Options

If sent for prosecution the optometrist has Four options.

Option One

Hearings Involving Disputed Issues of Material Fact –

The subject disputes the facts in the Complaint and elects to have a hearing before the Division of Administrative Hearings (DOAH). If this occurs, all parties may be asked to testify.

Option Two

Consent/Stipulation Agreement –

The subject enters into an agreement to be presented before the board or . Terms of this agreement may impose penalties negotiated

Option Three

Hearings Not Involving Disputed Issues of Material Fact –

The subject does not dispute the facts in the Complaint. The subject elects to be heard before the board . At that time, the subject will be permitted to give oral and/or written evidence in mitigation or in opposition to the action

Option Four

Voluntary Relinquishment of License – The subject of the Administrative Complaint elects to surrender the license and to cease practice.

Final Action

- Cases (as well as cases where the subject has failed to respond) are presented before the board for final action. The subject may be required to appear before the board. The complainant is notified of the date and location where the case will be heard and may attend.

Punishment

If found guilty the board determines the punishment based on the type and extent of the violation.

This may range from a letter of guidance to fines, increased CE courses, probation, suspension or revocation of license.

Questions?

End