

Laura Schneider

Legislative Service Commission

Sub. H.B. 149

127th General Assembly (As Passed by the General Assembly)

Reps. Daniels and Strahorn, J. Stewart, Driehaus, Aslanides, Bolon, J. McGregor, Wolpert, Luckie, Gibbs, R. Hagan, Combs, Flowers, Healy, Setzer, J. Hagan, Lundy, S. Williams, Heard, Sykes, Widener, Hughes, Adams, Garrison, Uecker, Huffman, DeBose, Fessler, Distel, Blessing, Patton, Domenick, Fende, Bubp, Beatty, Collier, Peterson, Okey, D. Stewart, Foley, Boyd, Carmichael, Reinhard, Hite, Brown, Gerberry, Koziura, Miller, Sayre, Seitz, Ujvagi, Wachtmann, Webster, Zehringer

Sens. Coughlin, Gardner, D. Miller, Morano, Mumper, Seitz, Austria, Cates, Fedor, Grendell, Harris, Niehaus, Padgett, Roberts, Sawyer, Schaffer, Schuler, Schuring, Spada, Stivers, Wilson, Faber, Carey

Effective date: March 24, 2008

ACT SUMMARY

- Modifies the scope of practice of an optometrist holding a therapeutic pharmaceutical agents certificate by doing all of the following: (1) eliminating the statutory specifications of the particular drugs and dosages that may be administered or prescribed, (2) specifying the classifications of oral drugs that may be used in the practice of optometry, with limitations on the use of analgesics and anti-inflammatories, (3) eliminating the provision that limits the use of drug treatment to conditions involving the anterior segment of the eye, (4) authorizing the use of any topical drug that pertains to the practice of optometry, (5) permitting the administration of epinephrine by injection in emergency situations, (6) allowing the use of glucose-monitoring devices, and (7) authorizing the prescription and dispensing of vision-correcting devices that also deliver drugs.
- Requires the State Board of Optometry to adopt rules governing the use of Schedule III controlled substances in the practice of optometry.

- Permits an optometrist who holds a topical ocular pharmaceutical agents certificate to use any topical drug or dangerous drug for evaluative purposes.
- Prescribes the manner in which the Board may share information with other investigating boards and agencies.
- Increases the requirement for annual continuing optometric education in pharmacology to ten hours (from five) and applies it to all optometrists.
- Modifies the licensing exemption that applies to optometry students by permitting students from optometry schools in other states to participate in an optometry training program in Ohio.
- Provides that prescriptions for contact lenses must contain all information required by federal law, including an expiration date.
- Expressly requires the Ohio Optical Dispensers Board to regulate the dispensing of contact lenses, regardless of whether they address visual function, and expressly requires that all contact lenses, including cosmetic contact lenses, be dispensed pursuant to a valid prescription.

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CONTENT AND OPERATION

AUTHORITY OF OPTOMETRISTS TO ADMINISTER AND PRESCRIBE DRUGS

Background

Optometrists in Ohio are licensed in one of three ways: (1) to practice only general optometry, signified by holding a certificate of licensure, (2) to practice general optometry and to use topical ocular pharmaceutical agents, signified by holding a certificate of licensure and a topical ocular pharmaceutical agents certificate, or (3) to practice general optometry and to administer and prescribe therapeutic pharmaceutical agents, signified by holding a certificate of licensure and a therapeutic pharmaceutical agents certificate.¹

Therapeutic pharmaceutical agents certificate

(R.C. 4725.01(A)(3) and (C))

Prior law permitted an optometrist holding a therapeutic pharmaceutical agents (TPA) certificate to employ, apply, administer, and prescribe instruments, devices, procedures (other than invasive procedures),² and therapeutic pharmaceutical agents for the following purposes:

- (1) Examination, investigation, diagnosis, or prevention of any disease, injury, or other abnormal condition of the visual system;
- (2) Treatment or cure of any disease, injury, or other abnormal condition of the anterior segment of the human eye.

¹ According to the 2006 Annual Report of the State Board of Optometry, 1,978 optometrists hold a therapeutic pharmaceutical agent certificate, 58 hold a topical ocular pharmaceutical agent certificate, and 63 hold no certificate to prescribe (2006 Annual Report, *available at*: http://optometry.ohio.gov, last visited December 10, 2007).

² "Invasive procedure" means any procedure that involves cutting or otherwise infiltrating human tissue by mechanical means including surgery, laser surgery, ionizing radiation, therapeutic ultrasound, administering medication by injection, or the removal of intraocular foreign bodies (R.C. 4725.01).

"Therapeutic pharmaceutical agent" was defined as a drug used for the above-specified purposes that is an antimicrobial agent, anti-allergy agent, antiglaucoma agent, topical anti-inflammatory agent, cycloplegic agent, or analgesic. "Therapeutic pharmaceutical agent" included any of the topical ocular pharmaceutical agents that could be used for evaluative purposes by an optometrist practicing under a topical ocular pharmaceutical agents certificate.

With regard to oral dosages of therapeutic pharmaceutical agents, the law listed the specific drugs that could be used, and in some cases, the specific dosage. Examples included diphenhydramine, methazolamide, ampicillin, cephalexin, penicillin VK, and tetracycline.

Classifications of oral therapeutic drugs

(R.C. 4725.01(C)(1) and (3))

The act eliminates the provisions of law specifying particular drugs and dosage amounts that may be used in the practice of optometry under a TPA certificate, but retains, with modifications, the classifications of oral drugs that may be used. Specifically, it provides that a therapeutic pharmaceutical agent is an oral drug or dangerous drug in one of the following classifications:

Anti-infectives, including antibiotics, antivirals, antimicrobials, and antifungals.

Antiglaucoma agents.

Analgesics, including only the following:

- Analgesics available without a prescription.
- Analgesics that require a prescription but are not controlled substances.
- Analgesics that are Schedule III controlled substances authorized by rule of the State Board of Optometry.

Anti-inflammatories. excluding oral steroids other than **methylpredisolone**, which may be prescribed only as follows:

- -- For use in allergy cases.
- -- For use by an individual who is 18 or older.
- -- On the basis of an individual's particular episode of illness.

-- In an amount not exceeding the amount packaged for a single course of therapy.

Any other oral drug or dangerous drug, if the drug is approved, exempt from approval, certified, or exempt from certification by the federal Food and Drug Administration for ophthalmic purposes and the drug is specified in rules adopted by the State Board of Optometry in consultation with the State Board of Pharmacy (R.C. 4725.09(B)).

Rules for use of Schedule III controlled substances

(R.C. 4725.091)

The act requires the State Board of Optometry to adopt rules governing the authority of optometrists holding TPA certificates to employ, apply, administer, and prescribe Schedule III controlled substances.³ The rules must be adopted in accordance with the Administrative Procedure Act (R.C. Chapter 119.) and in consultation with the State Board of Pharmacy. In adopting the rules, the State Board of Optometry must comply with the following:

- (1) The rules may not permit an optometrist to employ, apply, administer, or prescribe a Schedule III controlled substance other than a drug included within the Schedule III "narcotics-narcotic preparations" category;⁴
- (2) The rules must limit the Schedule III controlled substances that an optometrist may use to those the Board determines are appropriate for use in the practice of optometry under a TPA certificate;
- (3) The Board must establish standards for the prescription of Schedule III controlled substances to be followed by optometrists who hold TPA certificates,

³ Schedule III controlled substances are drugs with a potential for abuse and dependence that is lower than the potential that applies to a Schedule II controlled substance, but higher than the potential that applies to drugs in Schedules IV and V. (Schedule I controlled substances have no accepted medicinal purpose and cannot be prescribed.) Schedule III controlled substances include preparations containing limited quantities of narcotics, as well as drugs that are not narcotics. Not all drugs that require a prescription are classified as controlled substances. (R.C. Chapter 3719. and U.S. Department of Justice Drug Enforcement Administration, Controlled Substances Security Manual, available at: http://www.deadiversion.usdoj.gov/pubs/manuals/sec/security.pdf, last visited, December 10, 2007.)

⁴ This category of Schedule III controlled substances includes drugs such as morphine, codeine, and opium in specific amounts mixed with other active, nonnarcotic ingredients in specific amounts (R.C. 3719.41, Schedule III, Division (D)).

taking into account the prescribing standards that exist within the health care marketplace;

(4) The Board must establish standards and procedures for use of Schedule III controlled substances under a TPA certificate by taking into consideration and examining issues that include appropriate length of drug therapy, appropriate standards for drug treatment, necessary monitoring systems, and any other factors the Board considers relevant.

Epinephrine injections for anaphylaxis

(R.C. 4725.01(C)(2))

Under the act, epinephrine administered by injection is included as a therapeutic pharmaceutical agent that may be used in the practice of optometry under a TPA certificate. The drug may be administered to individuals in emergency situations to counteract anaphylaxis or anaphylactic shock.⁵ The act specifies that the administration of epinephrine by injection does not constitute performance of an invasive procedure, notwithstanding any conflicting provision in the statutes describing the practice of optometry.

Treatment beyond the anterior segment of the eye

(R.C. 4725.01(A)(3))

The act eliminates provisions of law that limited use of a therapeutic pharmaceutical agent by an optometrist practicing under a TPA certificate to treatment of the anterior segment of the eye. It also removes references to the use of a therapeutic pharmaceutical agent for purposes of curing a disease, injury, or other abnormal condition.

Use of topical drugs

(R.C. 4725.01(A)(3)(b) and (B)(2))

The act eliminates provisions of law that authorized an optometrist practicing under a TPA certificate to use only (1) topical ophthalmic preparations

⁵ "Anaphylaxis" is a "hypersensitivity to a foreign substance, especially in animals, induced by a small preliminary or sensitizing injection of the substance." Conditions such as anaphylactic shock can lead to a drop in blood pressure, breathing difficulties, and possible death. (*The American Heritage Dictionary*, 2d ed., at 107; *see also* "Anaphylaxis," available at: http://dictionary.reference.com/browse/anaphylaxis, last visited December 10, 2007.)

of drugs in certain categories⁶ and (2) topical drugs that could be used for evaluative purposes by an optometrist holding a topical ocular pharmaceutical agents certificate. Instead, the act provides that an optometrist practicing under a TPA certificate may use any drug or dangerous drug that is a topical drug and is used for purposes of examination, investigation, diagnosis, treatment, or prevention of any disease, injury, or other abnormal condition of the visual system.

Use of glucose-monitoring devices

(R.C. 4725.01(A)(3))

The act provides that the practice of optometry under a TPA certificate includes assisting an individual in determining the individual's blood glucose level by using a commercially available glucose-monitoring device. It specifies that nothing in the statutes describing the practice of optometry precludes the optometrist from using any particular type of commercially available glucose-monitoring device.

Vision correction devices that deliver drugs

(R.C. 4725.011)

The act provides that in prescribing and dispensing vision correction devices under a TPA certificate, an optometrist is permitted to prescribe and dispense any device that has vision correction as its primary purpose but also combines with that purpose the delivery of a drug or dangerous drug. The drug delivered by the device must be a drug or dangerous drug that otherwise could be used by the optometrist as a topical ocular or therapeutic pharmaceutical agent. The devices authorized by this provision include, but are not limited to, vision-correcting contact lenses that deliver drugs or dangerous drugs.

Topical ocular pharmaceutical agents certificates

(R.C. 4725.01(A)(2) and (B))

Under prior law, an optometrist with a topical ocular pharmaceutical agents (TOPA) certificate could administer only specified topical drugs in the examination of human eyes. Examples included benoximate hydrochloride (an anesthetic) and tropicamide (used in pupil dilation). The State Board of

⁶ The topical ophthalmic preparations that may be used under prior law were limited to drugs in the following categories: antimicrobial agents, anti-allergy agents, antiglaucoma agents, anti-inflammatory agents, cycloplegic agents, and analgesics.

Optometry was authorized to approve by rule additional drugs that could be administered under a TOPA certificate, but the primary indications for the drugs' use had to be consistent with the practice of general optometry.

The act eliminates from statute the listing of specific types of drugs that may be administered by optometrists holding TOPA certificates, including the provisions for approval of additional drugs by Board rule. Instead, it defines "topical ocular pharmaceutical agent" as a drug or dangerous drug that is topical and used by an optometrist under a TOPA certificate for evaluative purposes in the practice of general optometry.

ADMINISTRATIVE AND LICENSING PROVISIONS

Board investigations

(R.C. 4725.23(C))

The act authorizes the State Board of Optometry to share any information it receives pursuant to an investigation, including patient records and patient record information, with other licensing boards and governmental agencies that are investigating alleged professional misconduct and with law enforcement agencies and other governmental agencies that are investigating or prosecuting alleged criminal offenses. A board or agency with which the Board shares information must comply with the same confidentiality requirements as the Board, notwithstanding any conflicting provision of law or procedure that applies to the particular board or agency. The shared information may be admitted into evidence in a criminal trial in accordance with the Rules of Evidence, but the court must require that appropriate measures are taken to ensure that confidentiality is maintained with respect to any information that contains names or other identifying information. The court may seal records or delete information from its records to ensure confidentiality.

Continuing education

(R.C. 4725.16(B))

All licensed optometrists must annually complete continuing education in subjects relating to the practice of optometry. Under prior law, the length of study was determined by the Board, but could be not less than six nor more than 25 clock hours each year. Board rules required optometrists to complete 15 hours of continuing education.⁷ In addition, optometrists who held TPA or TOPA certificates were required to complete five hours of instruction in pharmacology.

⁷ Ohio Administrative Code 4725-9-01.



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The act requires that all optometrists complete 25 hours of continuing education each year. The pharmacology instruction requirement is increased to ten hours each year, but is included within the 25-hour requirement. The act applies the pharmacology instruction requirement to all optometrists, including those holding certificates of licensure to practice only general optometry.

Notifications for license renewal

(R.C. 4725.16(C) and (F))

An optometrist's license expires annually at the end of December. Under prior law, the Board was required to send each licensed optometrist a renewal notice and application not later than November 1. If an optometrist failed to file the license renewal application, the Board was required to send another notice of renewal not later than December 1. An additional notice of renewal had to be sent before the Board could classify the optometrist's license as delinquent.

The act modifies the provisions for annual renewal notification as follows:

- (1) The Board is required to mail a license renewal notice only if the optometrist is eligible for renewal. If the Board knows that the optometrist has completed the required continuing education, the Board may include a renewal application.
- (2) If an optometrist fails to respond to the initial notice, the Board must mail another notice not later than December 15, rather than December 1.
- (3) The statutory references to the notices that are sent subsequent to the initial notice are changed to reflect the order in which they are sent (i.e., the second notice and third notice).

Optometry students

(R.C. 4725.26)

A student at a school of optometry located in Ohio is not required to have a license to practice optometry while enrolled in an optometry training program. The act provides further that a student enrolled in a school of optometry is exempt from licensure in Ohio while the student is participating in Ohio in an optometry training program provided or sponsored by the school. The school in which the student is enrolled may be located in Ohio or another state.

CONTACT LENSES

Contact lens prescription information

(R.C. 4725.28 and 4731.44)

An optometrist or physician who prescribes any vision correction item, device, or procedure must provide one copy of the prescription to the patient. The prescription must include the date of its issuance and sufficient information to enable the patient to obtain the vision correction item, device, or procedure from a supplier of the patient's choice. In the case of a contact lens prescription, the act provides that in addition to this information, the prescription must include all information required under federal law, which specifies the following:

- (1) Name of the patient;
- (2) Date of the patient's examination;
- (3) Issue date and expiration date of the prescription;
- (4) Prescriber's name, address, telephone number, and fax number;
- (5) Power and material or manufacturer of the contact lens;
- (6) Base curve or appropriate designation;
- (7) Diameter, where appropriate;
- (8) In the case of a private label contact lens, name of manufacturer, trade name of private label brand, and, if applicable, trade name of equivalent brand name.

Regulation of contact lenses by the Ohio Optical Dispensers Board

(R.C. 4725.40)

The Ohio Optical Dispensers Board licenses opticians and regulates the practice of optical dispensing, which entails specified activities involving optical aids. An "optical aid" is defined as an instrument or device prescribed by a physician or optometrist licensed by any state to correct human vision, including spectacles, eyeglasses, contact lenses, and accessories. Contact lenses must be dispensed only in accordance with a written prescription for contact lenses.

⁸ "Fairness to Contact Lens Consumers Act," 117 Stat. 2024 (2003), 15 United States Code 7610.



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The act modifies the definition of "optical aid" as it is used in the statutes governing the practice of optical dispensing. Under the act, an "optical aid" means both of the following:

- (1) Spectacles or other instruments or devices that are not contact lenses, if the spectacles or other instruments or devices may aid or correct human vision and have been prescribed by a physician or optometrist licensed by any state;
- (2) Contact lenses, regardless of whether they address visual function, if they are designed to fit over the cornea of the eye or are otherwise designed for use in or on the eye or orbit.

The act provides that (a) a contact lens prescription must be valid and (b) the prescription requirement applies to all contact lenses, including the following:

- -- Zero-powered plano contact lenses;
- -- Cosmetic contact lenses;
- -- Performance-enhancing contact lenses;
- -- Any other contact devices determined by the Board to be contact lenses.

HISTORY

ACTION	DATE
Introduced	04-12-07
Reported, H. Health	06-14-07
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Passed Senate (32-0)	12-11-07
House concurred in Senate amendments (91-1)	12-12-07

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