



Alan Van Dyne

*Bill Analysis*  
*Legislative Service Commission*

## **Sub. H.B. 149**

127th General Assembly

(As Reported by S. Health, Human Services & Aging)

**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, Bulp, 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**

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### **BILL SUMMARY**

- Modifies the scope of practice of an optometrist holding a therapeutic pharmaceutical agents certificate by (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

In 1992, Sub. S.B. 110 of the 119th General Assembly expanded the scope of practice of optometry by permitting optometrists to be licensed to prescribe and administer specific types and amounts of therapeutic pharmaceutical agents. Prior to S.B. 110, optometrists were licensed to practice general optometry and had the option of obtaining an additional license to administer topical ocular pharmaceutical agents. Since the enactment of S.B. 110, persons who apply for optometry licenses are required to be licensed in the use of therapeutic pharmaceutical agents, which includes the use of topical ocular pharmaceutical agents. Optometrists who were already practicing on S.B. 110's effective date may choose to upgrade their licenses to allow for the administration and prescription of therapeutic pharmaceutical agents. Optometrists who do not upgrade their licenses continue to practice according to the licenses they received prior to S.B. 110.

Thus, 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.<sup>1</sup>

#### Therapeutic pharmaceutical agents certificate

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

Under current law, an optometrist who holds a therapeutic pharmaceutical agents (TPA) certificate may employ, apply, administer, and prescribe

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<sup>1</sup> 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).

instruments, devices, procedures (other than invasive procedures),<sup>2</sup> 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.<sup>3</sup>

Current law defines "therapeutic pharmaceutical agent" as a drug that is used for the above-specified purposes and is an antimicrobial agent, anti-allergy agent, antiglaucoma agent, topical anti-inflammatory agent, cycloplegic agent, or analgesic. The drug must be either an oral dosage or a topical ophthalmic preparation. In the case of topical drugs, current law also provides that a therapeutic pharmaceutical agent includes any of the topical ocular pharmaceutical agents that may 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, current law lists the specific drugs that may be used, and in some cases, the specific amount of the dosage that may be used. Examples include diphenhydramine, methazolamide, ampicillin, cephalexin, penicillin VK, and tetracycline. The State Board of Optometry is permitted to adopt rules specifying other oral dosages of drugs that may be used. The rules must be adopted in consultation with the State Board of Pharmacy.

### **Classifications of oral therapeutic drugs**

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

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

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<sup>2</sup> "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).

<sup>3</sup> Current law does not specify what segment of the human eye constitutes the "anterior segment."

**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 bill 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.<sup>4</sup> The rules must be adopted in

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<sup>4</sup> 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

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;<sup>5</sup>

(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, 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 bill, 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.<sup>6</sup> The bill

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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.dea/diversion.usdoj.gov/pubs/manuals/sec/security.pdf>, last visited, December 10, 2007.)

<sup>5</sup> 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)).

<sup>6</sup> "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*

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 bill eliminates the provisions of existing law that limit an optometrist practicing under a TPA certificate from using a therapeutic pharmaceutical agent to treat a part of the visual system other than the anterior segment of the eye. The bill 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 bill eliminates the provisions of existing law that authorize an optometrist practicing under a TPA certificate to use (1) topical ophthalmic preparations of drugs in certain categories<sup>7</sup> and (2) any of the topical drugs that may be used for evaluative purposes by an optometrist who holds a topical ocular pharmaceutical agents certificate. Instead, the bill provides that an optometrist practicing under a TPA certificate may use any drug or dangerous drug that is a topical drug and 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 bill 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. The bill specifies that nothing in the statutes describing the practice of optometry precludes the

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"Anaphylaxis," available at: <http://dictionary.reference.com/browse/anaphylaxis>, last visited December 10, 2007.)

<sup>7</sup> The topical ophthalmic preparations that may be used under existing law are limited to drugs in the following categories: antimicrobial agents, anti-allergy agents, antiglaucoma agents, anti-inflammatory agents, cycloplegic agents, and analgesics.

optometrist from using any particular type of commercially available glucose-monitoring device.

**Vision correction devices that deliver drugs**

(R.C. 4725.011)

The bill 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 bill specifies that 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 current law, an optometrist with a topical ocular pharmaceutical agents (TOPA) certificate may administer specified topical drugs in the examination of human eyes. Examples include benoximate hydrochloride (an anesthetic) and tropicamide (used in pupil dilation). The State Board of Optometry is authorized to approve by rule additional drugs that may be administered under a TOPA certificate. The primary indications for the drugs' use must be consistent with the practice of general optometry.<sup>8</sup>

The bill eliminates from statute the 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, the bill defines a 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.

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<sup>8</sup> With regard to the Board's authority to add topical drugs that may be administered by optometrists holding TOPA certificates, existing law includes a reference to drugs approved by the federal government after January 1, 1983. According to representatives of the State Board of Pharmacy, the date was included to accommodate the approval of new drugs relative to the effective date of the legislation that authorized optometrists to practice under TOPA certificates.



## ADMINISTRATIVE AND LICENSING PROVISIONS

### **Board investigations**

(R.C. 4725.23(C))

Under current law, the State Board of Optometry must conduct all of its investigations and proceedings in a manner that protects the confidentiality of patients and persons who file complaints with the Board. The Board may not make public the names or other identifying information about patients or persons who file complaints unless proper consent is given.

The bill provides that the Board may 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))

Under current law, all licensed optometrists must annually complete continuing education in subjects relating to the practice of optometry. The length of study is determined by the Board, but must be not less than six nor more than 25 clock hours each year. Current Board rules require optometrists to complete 15 hours of continuing education.<sup>9</sup> In addition, current law requires optometrists who hold TPA or TOPA certificates to complete five hours of instruction in pharmacology.

The bill 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 bill

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<sup>9</sup> Ohio Administrative Code 4725-9-01.

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))

Under current law, an optometrist's license expires annually at the end of December. The Board must send each licensed optometrist a renewal notice and application not later than November 1. If an optometrist fails to file the license renewal application, the Board is required to send another notice of renewal not later than December 1. An additional notice of renewal must be sent before the Board can classify the optometrist's license as delinquent.

The bill 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)

Under current law, 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 bill provides 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)

Current law requires an optometrist or physician who prescribes any vision correction item, device, or procedure to 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 bill provides that in addition to the information required above, the prescription must include all information required under federal law,<sup>10</sup> 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)

Current law requires the Ohio Optical Dispensers Board to license opticians and regulate the practice of optical dispensing, which entails specified activities

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<sup>10</sup> "Fairness to Contact Lens Consumers Act," 117 Stat. 2024 (2003), 15 United States Code 7610.

involving optical aids.<sup>11</sup> 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. Current law further provides that contact lenses must be dispensed only in accordance with a written prescription for contact lenses (*see* **COMMENT**).

The bill modifies the definition of "optical aid" as it is used in the statutes governing the practice of optical dispensing. Under the bill, 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.

Within the provision of existing law specifying that contact lenses must be dispensed only in accordance with a written prescription, the bill provides that (a) the 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.

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## **COMMENT**

On July 6, 2007, the Court of Appeals of Ohio, Sixth Appellate District, Lucas County, affirmed the Lucas County Court of Common Pleas decisions of July 17, and November 6, 2006, in which it was held that the Ohio Optical Dispensers Board has authority to regulate the dispensing of zero-powered or plano (cosmetic) contact lenses and that a prescription is required for the lenses to be dispensed (*Ohio Optical Dispensers Bd. v. Star Beauty Supply, Inc.*, 2007-Ohio-3464, at ¶¶ 1, 13, and 16).

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<sup>11</sup> Optometrists, physicians, and persons employed and supervised by optometrists or physicians are not subject to licensure by the Ohio Optical Dispensers Board (R.C. 4725.59, not in the bill).

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## HISTORY

ACTION	DATE
Introduced	04-12-07
Reported, H. Health	06-14-07
Passed House (92-5)	06-26-07
Reported, S. Health, Human Services & Aging	12-06-07

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