

The bill defines the term “ocular pharmaceutical agent” to mean 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. The formulary committee is required to submit specific findings of fact and grounds for recommendations for additions and modifications to, or deletions from the formulary of ocular pharmaceutical agents that certain optometrists may use in their practice. The board is bound by the formulary committee’s recommendations on oral ocular pharmaceutical agents that certified optometrists may administer and prescribe unless competent substantial evidence is presented to the board sufficient to rebut the committee’s recommendation.

The bill prohibits an optometrist from prescribing, ordering, dispensing, administering, supplying, selling, or giving any drug for the purpose of treating a systemic disease.

A certified optometrist is authorized to perform eye examinations, including a dilated examination, related to pugilistic exhibitions (boxing, kickboxing, or mixed martial arts matches). The bill authorizes an optometrist to operate a clinical laboratory to treat his or her own patients and requires other clinical laboratories to accept specimens submitted for examination by an optometrist.

The bill is effective July 1, 2013.

This bill substantially amends the following sections of the Florida Statutes: 463.002, 463.005, 463.0055, 463.0057, 463.006, 463.0135, 463.014, 483.035, 483.041, 483.181, 893.02, and 893.05.

II. Present Situation:

Optometry is the diagnosis of conditions of the human eye and its appendages (eyelids, eyebrows, the conjunctiva, and the lacrimal apparatus).¹ An optometrist is a primary health care provider licensed to engage in the practice of optometry.²

In Florida, certified optometrists may administer topical ocular pharmaceutical agents to assist in determining refractive powers of the human eyes, or any visual, muscular, neurological, or anatomic anomalies of the human eyes and their appendages. Certified optometrists may prescribe vision therapy, corrective lenses, and topical pharmaceutical agents for the eyes and appendages, but may not perform surgical procedures in Florida.³ A certified optometrist may remove superficial foreign bodies (foreign matter that is embedded in the conjunctiva or cornea but which has not penetrated the globe).⁴

To be licensed as a certified optometrist⁵ in Florida, the applicant must:⁶

¹ Section 463.002(5), F.S.

² As of January 30, 2013, there were 3,137 active licenses in Florida. 3,019 were certified optometrists and 118 were optometrists according to the Department of Health, *2013 Bill Analysis, Economic Statement, and Fiscal Note for SB 278*, dated February 1, 2013. A copy is on file with the Senate Health Policy Committee

³ Section 463.014(4), F.S.

⁴ *Ibid.*

⁵ All practitioners initially licensed after July 1, 1993, must be certified optometrists. *See s. 463.002(3)(c), F.S.*

- Be at least 18 years of age.
- Submit satisfactory proof that the applicant is of good moral character.
- Have graduated from a 4-year program at an accredited school or college of optometry.
- Have completed at least 110 hours of transcript-quality coursework and clinical training in general and ocular pharmacology at an institution that:
 - has facilities for both didactic and clinical instructions in pharmacology; and
 - is accredited by a regional or professional accrediting organization that is recognized and approved by the Commission of Postsecondary Accreditation of the U.S. Department of Education.
- Have completed at least one year of supervised experience in differential diagnosis of eye disease or disorders as part of the optometric training or in a clinical setting as part of the optometric experience.
- Pass the Florida Examination, which consists of
 - Part I – a written examination on applicable Florida laws and rules governing the practice of optometry;
 - Part II – a practical examination containing a clinical portion and a pharmacology/ocular disease portion;
 - Part III – the Applied Basic Science portion of the examination developed by the National Board of Examiners in Optometry (NBEO); and
 - Part IV – the Clinical Science portion of the examination developed by the NBEO.
- Complete a two-hour course relating to prevention of medical errors.

Ophthalmologists are medical physicians⁷ who specialize in diseases of the eye. Ophthalmologists provide a full spectrum of eye care, from prescribing corrective lenses and medications to performing eye surgery. In addition, ophthalmologists care for patients with more advanced and complicated diseases than do optometrists. The training for ophthalmologists involves an undergraduate degree, four years of medical school, completion of one year of an internship, and at least three years of residency training in ophthalmology.⁸

Florida law requires optometrists who diagnose patients with certain diseases to refer such patients to ophthalmologists for further treatment.⁹ Optometrists are also required to maintain the names of at least three physicians, clinics, or hospitals to which they may refer patients who experience adverse drug reactions.¹⁰

⁶ See Rule 64B13-4.004, F.A.C.

⁷ Ophthalmologists are licensed under ch. 458, F.S., relating to Medical Practice or ch. 459, F.S., relating to Osteopathic Medicine.

⁸ American Academy of Ophthalmology, *About Ophthalmology and Eye M.D.s.*, available at: <http://www.aao.org/about/eyemds.cfm> (last visited Feb. 17, 2013).

⁹ Diagnoses which mandate a referral to an ophthalmologist include acute angle glaucoma, congenital or infantile glaucoma, infectious corneal diseases refractory to standard treatment, and retinal detachment. See s. 463.0135(2), F.S.

¹⁰ See s. 463.0135, F.S.

Administration of Medications by Optometrists

Licensed certified optometrists may administer and prescribe topical ocular pharmaceutical agents that are included in a formulary adopted by rule¹¹ by the board. Such pharmaceuticals must be related to the diagnosis and treatment of ocular conditions and must not require surgery or other invasive techniques for administration.

To be certified for prescribing privileges, an optometrist must:¹²

- Complete at least 110 hours of board-approved coursework and clinical training in general and ocular pharmacology at an accredited institution. Such training may have been part of an optometry training program;
- Complete at least one year of supervised experience in differential diagnosis of eye disorders, which may occur during training or clinical practice;
- Pass part II of the National Board of Examiners in Optometry examination;¹³ and
- Pay a \$500 fee.¹⁴

Certification for prescribing privileges is a required component of the general licensure process for optometrists and has been so for over 25 years.¹⁵ Optometrists who are not certified may use topical anesthetics solely for glaucoma examinations.¹⁶

Formulary Committee and Formulary

A committee of five members reviews requests for additions to, deletions from, or modifications to a formulary of topical ocular pharmaceutical agents (TOPA) for administration and prescription by certified optometrists. The formulary committee provides to the board advisory opinions and recommendations on such requests. The formulary committee is comprised of two optometrists, appointed by the Board of Optometry; two ophthalmologists, appointed by the Board of Medicine; and one person with a doctorate degree in pharmacology, appointed by the State Surgeon General.¹⁷ Currently, the two optometrists on the formulary committee are certified optometrists.¹⁸

The board adopts the TOPA by rule. The State Surgeon General may challenge any rule or proposed rule for the TOPA formulary on the grounds that it:¹⁹

¹¹ The formulary is listed in Rule 64B13-18.002, F.A.C., and includes agents to dilate and constrict pupils, local anesthetics, antibiotics, anti-inflammatory agents, antihistamines, antivirals, and anti-glaucoma medications. All medications are for topical ocular use only.

¹² Rule 64B13-10.001, F.A.C.

¹³ This examination consists of 60 simulated patient cases to assess the examinee's performance in clinical practice situations available at: http://www.optometry.org/part_2_pam.cfm (last visited Feb. 17, 2013).

¹⁴ Rule 64B13-6.001(9), F.A.C.

¹⁵ See s. 463.006, F.S.; and Department of Health, *2013 Bill Analysis, Economic Statement, and Fiscal Note for SB 278*, dated February 1, 2013. A copy is on file with the Senate Health Policy Committee.

¹⁶ See s. 463.0055(1), F.S.

¹⁷ s. 463.0055, F.S.

¹⁸ *Supra* 14.

¹⁹ s. 463.0055(4)(c), F.S.

- Is an invalid exercise of delegated legislative authority.
- Does not protect the public from any significant and discernible harm or damage.
- Unreasonably restricts competition or the availability of professional services in the state or in a significant part of the state.
- Unnecessarily increases the cost of professional services without a corresponding or equivalent public benefit.

Prescribing Controlled Substances

The Drug Enforcement Administration (DEA) within the U.S. Department of Justice is tasked with monitoring controlled substances and preventing their abuse. Controlled substances fall into five categories, or schedules, depending on their addictive potential. Drug schedules are specified by the United States Department of Justice Drug Enforcement Administration in 21 C.F.R. §§ 1308.11-15 and in s. 893.03, F.S.

- Schedule I controlled substances currently have no accepted medical use in treatment in the United States and therefore may not be prescribed, administered, or dispensed for medical use. These substances have a high potential for abuse and include heroin, lysergic acid diethylamide (LSD), and marijuana.
- Schedule II controlled substances have a high potential for abuse which may lead to severe psychological or physical dependence, including morphine and its derivatives, amphetamines, cocaine, and pentobarbital.
- Schedule III controlled substances have lower abuse potential than Schedule II substances but may still cause psychological or physical dependence. Schedule III substances include products containing less than 15 milligrams (mg) of hydrocodone (such as Vicodin) or less than 90 mg of codeine per dose (such as Tylenol #3), ketamine, and anabolic steroids.
- Schedule IV substances have a low potential for abuse and include propoxyphene (Darvocet), alprazolam (Xanax), and lorazepam (Ativan).
- Schedule V controlled substances have an extremely low potential for abuse and primarily consist of preparations containing limited quantities of certain narcotics, such as cough syrup.²⁰

Any health care professional wishing to prescribe controlled substances must apply for a prescribing number from the DEA. Prescribing numbers are linked to state licenses and may be suspended or revoked upon any disciplinary action taken against a licensee. The DEA will grant prescribing numbers to a wide range of health care professionals, including physicians, nurse practitioners, physician assistants, optometrists, dentists, and veterinarians, but such professionals may only prescribe controlled substances that have been authorized to them under state law. The DEA prescribing numbers must be renewed every three years.²¹

²⁰ DEA, Office of Diversion Control, *Controlled Substance Schedules*, available at: <http://www.deadiversion.usdoj.gov/schedules/index.html> (last visited Feb. 17, 2013).

²¹ DEA, *Questions and Answers* available at: <http://www.deadiversion.usdoj.gov/drugreg/faq.htm#3> (last visited Feb. 17, 2013).

In Florida, only licensed physicians, dentists, veterinarians, naturopaths, and podiatrists are currently permitted to prescribe controlled substances, and they may only prescribe medications within the scope of their own practices.²²

Clinical Laboratories

A clinical laboratory is a location in which body fluids or tissues are analyzed for purposes of the diagnosis, assessment, or prevention of a medical condition. Clinical laboratories may be free-standing facilities, may be part of a hospital, or may be part of a private practitioner's office.²³ Practitioners authorized to operate their own clinical laboratories exclusively to diagnose and treat their own patients are physicians, chiropractors, podiatrists, naturopaths, and dentists. Laboratories must be biennially licensed and inspected by the AHCA to ensure quality standards in examination of specimens, equipment, sanitation, staffing, and other measures.²⁴

A clinical laboratory may examine human specimens at the request of the following licensed practitioners:²⁵

- Physicians
- Physician assistants
- Medical assistants
- Chiropractors
- Chiropractic assistants
- Chiropractic physician's assistants
- Podiatrists
- Naturopaths
- Dentists
- Nurse practitioners

Results of laboratory tests must be reported directly to the requesting practitioner. The same price must be charged regardless of what type of practitioner requests the testing.

III. Effect of Proposed Changes:

The bill authorizes licensed certified optometrists to administer or prescribe oral ocular pharmaceutical agents in addition to the topical ocular pharmaceutical agents that optometrists are currently authorized to administer or prescribe.

Section 1 amends s. 463.002, F.S., to remove the limiting reference to *topical* ocular pharmaceutical agents in the definition of optometry and defines the term "ocular pharmaceutical agent." Under the CS, this term 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.

²² See ss. 893.02(21) and 893.05, F.S.

²³ See s. 483.041, F.S.

²⁴ See s. 483.051, F.S.

²⁵ See s. 483.181, F.S.

A licensed practitioner who is not a certified optometrist is required to display at his or her practice a sign that states, "I am a licensed practitioner, not a certified optometrist, and I am not able to prescribe pharmaceutical agents." This disclosure is currently required, however, it refers to not being able to prescribe topical ocular pharmaceutical agents.

Section 2 amends s. 463.005, F.S., to remove the limiting reference to *topical* with respect to authority for the board to adopt rules relating to the administration and prescription of ocular pharmaceutical agents.

Section 3 amends s. 463.0055, F.S., to authorize certified optometrists to administer and prescribe oral pharmaceutical agents in addition to topical ocular pharmaceutical agents. A licensed practitioner who is not a certified optometrist is authorized under existing law to use topically applied anesthetics solely for glaucoma examination and prohibited from administering or prescribing topical ocular pharmaceutical agents. The CS continues to authorize the use of topically applied anesthetics for glaucoma examinations but prohibits the licensed optometrist who is not also certified from administering or prescribing pharmaceutical agents.

The bill requires a certified optometrist to complete a course and subsequent examination on general and ocular pharmaceutical agents and the side effects of those agents prior to administering or prescribing these agents. The Florida Medical Association and the Florida Optometric Association are required to jointly develop and administer the course and examination at a site or sites selected by these associations. The first course and examination must be presented by July 1, 2013, and subsequent courses and examinations must occur at least annually thereafter.

The required number of hours for the training depends upon when the certified optometrist was licensed. For certified optometrists licensed before January 1, 1990, the course must consist of 50 contact hours with 25 of these hours Internet-based. For certified optometrists licensed on or after January 1, 1990, the course must consist of 20 contact hours, with 10 of these hours Internet-based.

The composition of the formulary committee is modified to require that the two optometrist members must be certified optometrists. The bill adds that the formulary must consist of pharmaceutical agents that are appropriate to treat and diagnose ocular diseases and disorders, in addition to the existing requirement that it include those agents that a certified optometrist is qualified to use in the practice of optometry.

The formulary committee is required to submit to the board as a part of its opinions and recommendations concerning additions to, deletions from, of modifications for the formulary, specific findings of fact and grounds for its recommendations. The CS provides that these findings, opinions, and recommendations are not considered decisions which affect substantial interests subject to administrative review under ss. 120.569 and 120.57, F.S. The board is bound by the committee's recommendations on oral ocular pharmaceutical agents unless competent substantial evidence is presented to the board sufficient to rebut the committee's recommendation.

The bill conforms the requirement for a certified optometrist to have a prescriber number and include that number on a prescription to include all authorized pharmaceutical agents.

Section 4 amends s. 463.0057, F.S., to require the holder of a faculty certificate to satisfy the additional coursework and examination requirements in addition to the existing requirements for administering and prescribing topical ocular pharmaceutical agents prior to administering or prescribing *any* pharmaceutical agents.

Section 5 amends s. 463.006, F.S., to require the examination for licensure and certification as a certified optometrist in Florida to include the use and side effects of [all] pharmaceutical agents. This is a change from current law that requires the examination to emphasize the side effects of ocular pharmaceutical agents.

Section 6 amends s. 463.0135, F.S., to add that a certified optometrist is authorized to perform any eye examination, including a dilated examination required or authorized for pugilistic exhibitions (boxing, kickboxing, or mixed martial arts matches).

Section 7 amends s. 463.014, F.S., to prohibit a licensed practitioner from prescribing, ordering, dispensing, administering, supplying, selling, or giving any drug to treat a systemic disease. Current law prohibits a licensed practitioner from performing any of these activities with a systemic drug.

Sections 8 and 10 amend ss. 483.035 and 483.181, F.S., respectively, to authorize an optometrist to operate a clinical laboratory to treat his or her own patients and require other clinical laboratories to accept specimens submitted for examination by an optometrist.

Section 9 amends s. 483.041, F.S., to modify the definition of “licensed practitioner” with respect to clinical laboratories. It refers to a person licensed under ch. 463, F.S., related to the practice of optometry as a physician. However, ch. 463, F.S., does not refer to licensed practitioners and certified optometrists as physicians.

Section 11 amends s. 893.02, F.S., to add certified optometrists to the list of practitioners who may prescribe or administer controlled substances if licensed by the federal DEA.

Section 12 amends s. 893.05, F.S., to prohibit a certified optometrist from administering or prescribing a Schedule I or Schedule II controlled substance. The CS authorizes a certified optometrist who has complied with the additional coursework and examination requirements in this bill to administer oral analgesics listed in Schedule III, Schedule IV, or Schedule V for the relief of pain due to ocular conditions of the eye and its appendages.

Section 13 provides that the act is effective July 1, 2013.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Certified optometrists who complete the additional coursework and successfully pass the examination will be able to provide a broader range of services for their patients by administering and prescribing oral pharmaceutical agents. Although a fee for the coursework and examination is not specified in the bill, it is reasonable to assume that optometrists would incur a fee.

If licensed optometrists seek to establish clinical laboratories as allowed under the bill, they will incur licensure fees for an accredited laboratory of \$100 for a two-year licensure period; or, for a laboratory performing less than 2,000 non-waived tests per year, a fee of \$400 for a two-year licensure period.

C. Government Sector Impact:

The Agency for Health Care Administration (AHCA) estimates the following fiscal impacts in terms of potential savings, revenues, and expenditures:

The CS allows Medicaid recipients to receive prescriptions for ocular medications from an optometrist, thereby saving the recipient from the need to see a physician to get a prescription for a condition diagnosed by the optometrist. The additional billing by the physician to Florida Medicaid would not then be necessary. The total number of recipients during FY 2011-12 seeing a physician within two months of an optometrist visit was 150,033, with an expenditure total of \$20,577,279. Assuming that one-half of one percent of those recipients were seeing a physician for an ocular pharmaceutical agent prescription, then a total of 750 recipient visits and total expenditures of \$102,889 in the Medicaid program could have been avoided under the CS. The savings for the state share of Medicaid costs are estimated to be \$42,524 for FY 2013-14 and \$42,257 for FY 2014-15.

If Section 8 of the CS is implemented, some percentage of the 3,089 currently licensed optometrists seeking to establish clinical laboratories

would begin submitting initial clinical laboratory licensure applications beginning July 1, 2013. Should as many as 13.1 percent (the percentage of all physicians currently opting to offer clinical laboratory services) of these licensed optometrists seek to establish a clinical laboratory, AHCA would need to process an additional 405 initial applicants in FY 2013-14. Several elements of the clinical laboratory licensure application are technical in nature and necessitate review and processing by professional staff. AHCA estimates that, in order to review and process this increase in application volume, one additional professional full-time equivalent (FTE) would be required.

An on-site inspection would be required both prior to initial licensure and biennially thereafter. AHCA field office staff currently perform on-site inspections on 1,267 (51 percent) of the 2,484 licensed laboratories. If inspections are required by this same percentage of the 405 optometry-based laboratory applicants, the CS would require AHCA staff to perform an additional 207 on-site inspections during SFY 2012-13 and biennially thereafter. AHCA estimates that, in order to perform this number of inspections, an additional two FTEs for survey staff would be required. One of these additional FTEs would be needed in the Miami field office.

The fiscal impact for the three FTE positions is \$168,329 for year one and each recurring year; this includes a request for 10 percent above minimum salary for the two FTE survey staff due to recruitment challenges. There is an additional recurring expense of \$22,020 for travel for the two FTE survey staff. Two tablet computers are also required at a nonrecurring expense of \$2,830 in year one for the survey staff to use in the field while on inspections.

The total estimated fiscal impact to AHCA’s Health Care Trust Fund for three FTE positions and the two tablets for year one is \$222,339. The estimated total recurring fiscal impact for the three FTE positions is \$209,078.

Licensure fees in the amount of \$102,600, to be deposited into the Health Care Trust Fund, are expected during FY 2013-14 with initial applicants and recurring biennially thereafter upon renewal. This number is based on 198 applicants seeking licensure as an accredited laboratory and 207 applicants seeking licensure to perform less than 2,000 non-waived tests per year. The licensure fee for an accredited laboratory is \$100 per two-year licensure period, and the fee for a laboratory performing less than 2,000 non-waived tests per year is \$400 per two-year licensure fee.

	FY 2013-14 General Revenue	FY 2013-14 Health Care Trust Fund	FY 2014-15 General Revenue	FY 2014-15 Health Care Trust Fund
Recurring Medicaid savings, state share	\$42,524		\$42,257	
Nonrecurring expenditures		(\$13,261)		
Recurring expenditures		(\$209,078)		(\$209,078)

Recurring revenue		\$102,600		\$102,600
Total Savings/Revenue (Costs)	\$42,524	(\$119,739)	\$42,257	(\$106,478)

The Department of Health (DOH) indicates additional workload and costs will be incurred for rulemaking, modifications to the licensure system, tracking of certified optometrists who have completed the coursework and examination, and potential complaints related to enactment of the bill’s provisions. However, the DOH indicates that current resources are adequate to absorb the workload and costs.

VI. Technical Deficiencies:

The CS amends the definition of a licensed practitioner for purposes of clinical laboratories. As amended, a “licensed practitioner” means a physician licensed under ... chapter 463. However, ch. 463, F.S., does not refer to an optometrist, whether licensed or certified and licensed, as a physician. This could be corrected by deleting lines 238 and 239 and inserting:

under chapter 458, chapter 459, chapter 460, or chapter 461; a certified optometrist licensed under chapter 463; a dentist licensed under chapter 466, a person

Line 291 refers to Schedule III, IV, or V. It should state, Schedule III, Schedule IV, or Schedule V.

VII. Related Issues:

Section 456.44, F.S., provides standards of practice and registration requirements for practitioners who prescribe certain controlled substances for the treatment of chronic nonmalignant pain. This section of law lists the specific practice acts under which the practitioners to whom this requirement applies are regulated. Chapter 463, F.S., relating to the practice of optometry, is not included in this list and these provisions are not included in this bill. As a result, certified optometrists would not be required to register and follow these standards of practice if treating chronic nonmalignant pain with controlled substances.

VIII. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
 (Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Policy on February 21, 2013:

Defines ocular pharmaceutical agent; requires the first course and examination to be available on or before July 1, 2013; requires the formulary committee to submit specific findings of fact and grounds for recommendations which the board must follow when the board adopts the formulary by rule unless it has competent substantial evidence to rebut the recommendation; expands the subject matter of the examination for licensure as a certified optometrist to emphasize the use and side effects of [all] pharmaceutical agents, not just ocular pharmaceutical agents; and authorizes certified optometrists who have completed the coursework and examination to administer (Schedule III, IV, or V) oral analgesics for relief of pain due to ocular conditions.

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.
