The Florida Senate BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

	Prepared By: The	Professional Sta	ff of the Health Re	gulation Committee			
BILL:	CS/SB 330						
INTRODUCER:	Health Regulation Committee and Senators Bennett, Rich and Dockery						
SUBJECT:	The Practice of Optometry						
DATE:	February 3, 2010	REVISED:					
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I. Summary:

The bill authorizes certified optometrists to administer and prescribe certain *oral* ocular pharmaceutical agents and such agents may be personally prescribed only by a certified optometrist. The bill revises requirements for the existing formulary of *topical* ocular pharmaceutical agents that certified optometrists may administer and prescribe to include those *topical* pharmaceutical agents appropriate to treat and diagnose ocular disease or disorders within the scope of optometric practice.

The bill specifies certain *oral* analgesics, antibiotics, antivirals, and anti-glaucoma agents which must be included in the formulary. The specified analgesics and anti-glaucoma agents may not be administered or prescribed by a certified optometrist to treat a specific patient for more than 72 hours without consultation with a Florida-licensed medical physician or osteopathic physician who is skilled in diseases of the eye. The Board of Optometry may not add to, delete from, or modify the formulary with respect to the *oral* ocular pharmaceutical agents listed in the bill. The formulary committee may not review a request or provide an advisory opinion or recommendation regarding any *oral* ocular pharmaceutical agent.

The bill amends the Florida Comprehensive Drug Abuse Prevention and Control Act (chapter 893, F.S.) to expand the definition of "practitioner" to include an optometrist certified

pursuant to ch. 463, F.S., to administer and prescribe *topical and oral* ocular pharmaceutical agents. This would allow certified optometrists to administer or prescribe controlled substances, however, certified optometrists are prohibited from administering or prescribing a controlled substance listed in Schedule I or Schedule II of ch. 893, F.S.

The bill prohibits the holder of an optometric faculty certificate from administering or prescribing an *oral* ocular pharmaceutical agent unless the certificateholder has satisfied specified requirements for optometrists to administer or prescribe *oral* ocular pharmaceutical agents.

This bill amends sections 463.002, 463.005, 463.0055, 463.0057, 463.006, 893.02, and 893.05, Florida Statutes.

II. Present Situation:

Practice of Optometry

Chapter 463, F.S., regulates the practice of optometry in Florida through the Board of Optometry. Doctors of optometry examine, diagnose, treat, and manage disorders that affect the eye or vision. Optometrists receive four years of graduate education to earn their doctoral degree. Their education concentrates on the eye and visual system and disease. It includes coursework in the sciences, such as human anatomy, biochemistry, and physiology.

Florida-licensed optometrists who are certified may administer and prescribe topical ocular pharmaceutical agents for the diagnosis and treatment of ocular conditions of the human eye and its appendages without the use of surgery or other invasive techniques. Certified optometrists may administer and prescribe only those topical ocular pharmaceutical agents identified by rule of the Board of Optometry. A committee reviews requests for additions to, deletions from, or modifications of the formulary of topical ocular pharmaceutical agents for administration and prescription by certified optometrists. The committee is composed of two Florida-licensed optometrists who are appointed by the Board of Optometry, two board-certified ophthalmologists appointed by the Board of Medicine, and one additional person with a doctorate degree in pharmacology who is not a Florida-licensed medical or osteopathic physician. The committee must also provide advisory opinions and recommendations on the formulary to the Board of Optometry. The Board of Optometry has adopted a formulary of topical ocular pharmaceutical agents in Rule 64B13-18.002, Florida Administrative Code.

The State Surgeon General has standing to challenge any rule of the Board of Optometry and an administrative law judge may declare all or part of a rule or proposed rule invalid under specified circumstances. Section 463.0055, F.S., states that there shall not be created a presumption of the existence of any of the conditions in the event that the rule or proposed rule is challenged.

To become certified, a Florida-licensed optometrist must successfully complete at least 110 hours of Board of Optometry-approved coursework and clinical training in general and ocular pharmacology at an accredited institution; completion of at least one year of supervised experience in differential diagnosis of eye diseases or disorders, that must be received during

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¹ See s. 463.0055, F.S.

optometric training or in a clinical setting; and successful completion of a board-approved examination testing knowledge of general and ocular pharmacology with particular emphasis on the topical application and side effects of pharmaceutical agents. The Board of Optometry will accept coursework and clinical training received by the applicant during his or her basic optometric curriculum or at post-graduate courses if the coursework and training was provided by a board-approved school of optometry or equivalent educational entity.

A Florida-licensed optometrist must keep a record of the prescriptions that he or she writes for a minimum of two years.³

Section 463.0135, F.S., requires a certified optometrist to consult with a physician skilled in diseases of the eye when an infectious corneal disease condition has not responded to standard methods of treatment within the scope of optometric practice. The section requires a licensed optometrist to promptly advise a patient to seek evaluation by a medical physician or osteopathic physician skilled in diseases of the eye for diagnosis and possible treatment whenever an optometrist is informed by the patient of a sudden onset of spots or floaters with loss of all or part of the visual field. The optometrist must routinely advise a patient to immediately contact the optometrist if the patient experiences an adverse drug reaction and, when appropriate, the optometrist must refer patients to medical specialists or facilities. The optometrist must maintain the names of at least three physicians, physician clinics, or hospitals to whom the optometrist will refer patients who experience an adverse drug reaction.

Optometrists are authorized to prescribe oral medications to treat eye disease in 47 states.⁴ Optometrists are designated by the federal Drug Enforcement Administration as "mid-level practitioners" for the prescribing of controlled substances. Forty-three states authorize optometrists to prescribe controlled substances.⁵

Controlled Substances

Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act. The chapter classifies controlled substances into five schedules in order to regulate the manufacture, distribution, preparation, and dispensing of the substances. Substances in Schedule I have a high potential for abuse and have no currently accepted medical use in the United States. Schedule II drugs have a high potential for abuse and a severely restricted medical use. Cocaine and morphine are examples of Schedule II drugs. Schedule III controlled substances have less potential for abuse than Schedule I or Schedule II substances and have some accepted medical use. Substances listed in Schedule III include anabolic steroids, codeine, and derivatives of barbituric acid. Schedule IV and Schedule V substances have a low potential for abuse, compared to substances in Schedules I, II, and III, and currently have accepted medical use. Substances in Schedule IV include phenobarbital, librium, and valium. Substances in Schedule V include certain stimulants and narcotic compounds.

⁵ Source: American Optometric Association.

² See Rule 64B13-10.001, F.A.C.

³ See s. 463.012, F.S.

⁴ According to the Florida Department of Health, Florida, Massachusetts, and New York are the only states where optometrists cannot prescribe oral drugs for treatment of eye disease.

Section 893.02, F.S., defines practitioner to mean a licensed medical physician, dentist, veterinarian, osteopathic physician, naturopathic physician, or podiatrist, if such practitioner holds a valid federal controlled substance registry number. The prescribing of controlled substances is a privilege that is separate from the regulation of the practice of the prescribing practitioner.

Section 893.05, F.S., allows a practitioner, in good faith and in the course of his or her professional practice only, to prescribe, administer, dispense, mix, or otherwise prepare a controlled substance, or the practitioner may direct the administration of a controlled substance by a licensed nurse or an intern practitioner under his or her direction and supervision.

Section 893.04, F.S., authorizes a pharmacist, in good faith and in the course of professional practice only, to dispense controlled substances upon a written or oral prescription under specified conditions. An oral prescription for controlled substances must be promptly reduced to writing by the pharmacist. The written prescription must be dated and signed by the prescribing practitioner on the day when issued. There must appear on the face of the prescription or written record for the controlled substance: the full name and address of the person for whom, or the owner of the animal for which, the controlled substance is dispensed; the full name and address of the prescribing practitioner and the prescriber's federal controlled substance registry number must be printed thereon; if the prescription is for an animal, the species of animal for which the controlled substance is prescribed; the name of the controlled substance prescribed and the strength, quantity, and directions for the use thereof; the number of the prescription, as recorded in the prescription files of the pharmacy in which it is filled; and the initials of the pharmacist filling the prescription and the date filled. Section 893.04(1)(d), F.S., requires the proprietor of the pharmacy in which a prescription for controlled substances is filled to retain the prescription on file for a period of two years. The chapter requires the original container in which a controlled substance is dispensed to bear a label with specified information.

III. Effect of Proposed Changes:

Section 1. Amends s. 463.002, F.S, relating to definitions for the "Optometry Practice Act," to revise the definitions of "licensed practitioner," "certified optometrist," and "optometry" to conform to provisions that authorize the prescription and administration of oral ocular pharmaceutical agents by certified optometrists.

Section 2. Amends s. 463.005, F.S., relating to the rulemaking authority of the Board of Optometry, to expand the Board of Optometry's rulemaking authority for rules relating to the administration and prescription of topical ocular pharmaceutical agents to include oral ocular pharmaceutical agents.

Section 3. Amends s. 463.0055, F.S., relating to the administration and prescription of topical ocular pharmaceutical agents, to authorize certified optometrists to administer and prescribe certain oral ocular pharmaceutical agents. These oral ocular pharmaceutical agents may only be personally prescribed by a certified optometrist. Qualifications of optometry members of the formulary committee are revised to require the members to be Florida-certified optometrists. The formulary committee may not review a request or provide an advisory opinion or recommendation regarding any oral ocular pharmaceutical agent.

The formulary for topical ocular pharmaceutical agents must include those pharmaceutical agents appropriate to treat and diagnose ocular diseases or disorders within the scope of optometric practice. The formulary must also include specified oral analgesics, antibiotics, antivirals, and anti-glaucoma agents that may be personally prescribed only by a certified optometrist. The specified oral ocular pharmaceutical agents include: acetaminophen with propoxyphene napsylate; tramadol hydrochloride; acetaminophen 300 mg with No. 3 codeine phosphate 30 mg; amoxicillin; azithromycin; ciprofloxacin; dicloxacillin; doxycycline; acyclovir; famciclovir; valacyclovir; acetazolamide; and methazolamide. The analgesics and anti-glaucoma agents may not be administered or prescribed by a certified optometrist to treat a specific patient for more than 72 hours without consultation with a Florida-licensed medical physician or osteopathic physician who is skilled in diseases of the eye.

The Board of Optometry may not add to, delete from, or modify the formulary with respect to the oral ocular pharmaceutical agents listed in the bill. The section is also amended to make minor technical changes.

Section 4. Amends s. 463.0057, F.S., relating to optometric faculty certificates, to prohibit the holder of an optometric faculty certificate from administering or prescribing an oral ocular pharmaceutical agent unless the certificateholder has completed at least 110 hours of transcript-quality coursework and clinical training in general and ocular pharmacology at certain institutions and has completed at least one year of supervised experience in differential diagnosis of eye disease or disorders.⁶

Section 5. Amends s. 463.006, F.S., relating to optometric licensure and certification by examination, to revise the certification requirements for optometrists to conform to provisions in the bill authorizing the oral administration of ocular pharmaceutical agents.

Section 6. Amends s. 893.02, F.S., relating to definitions under the Florida Comprehensive Drug Abuse Prevention and Control Act, to expand the definition of "practitioner" to include an optometrist certified pursuant to ch. 463, F.S., to administer and prescribe topical and oral ocular pharmaceutical agents.

Section 7. Amends s. 893.05, F.S., relating to practitioners and persons administering controlled substances in their absence, to prohibit a certified optometrist from administering and prescribing topical and ocular pharmaceutical agents in Schedule I or Schedule II of the Florida Comprehensive Drug Abuse Prevention and Control Act.

Section 8. Provides an effective date of July 1, 2010.

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⁶ See s. 463.006(1)(b)4. and 5., F.S.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

Officials at the Department of Health indicate that, to implement the bill, the department will need to: amend the current licensure examination for optometrists to include an emphasis on the oral administration and side effects of ocular pharmaceutical agents; reimburse travel expenses for contracted examination consultants; and mail the formulary modified by the bill to each certified optometrist and each pharmacy. The Department of Health estimates that it will require nonrecurring resources equal to \$8,082 to accommodate the additional workload and travel under the bill.

VI.	Technical	Deficien	cies:
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None.

VII. Related Issues:

None.

VIII. Additional Information:

A. Committee Substitute – Statement of Substantial Changes: (Summarizing differences between the Committee Substitute and the prior version of the bill.00)

CS by Health Regulation on February 3, 2010:

The committee substitute prohibits a certified optometrist from delegating to another person his or her authority to prescribe oral ocular pharmaceutical agents by requiring such agents to be personally prescribed only by a certified optometrist. Additionally, the committee substitute clarifies that the 72-hour limit on the administration or prescription of analgesics and anti-glaucoma agents by a certified optometrist relates to the treatment of a specific patient.

B. Amendments:

None.

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