HOUSE OF REPRESENTATIVES
FINAL BILL ANALYSIS

BILL #:	CS/CS/HB 239	**FINAL HOUSE FLOOR ACTION:**	
SPONSOR(S):	Health & Human Services Committee; Health Quality Subcommittee; Caldwell; Williams, A. and others	116 **Y's**	0 **N's**
COMPANION BILLS:	(CS/CS/SB 278)	**GOVERNOR'S ACTION:**	Approved

SUMMARY ANALYSIS

CS/CS/HB 239 passed the House on March 22, 2013, and subsequently passed the Senate on April 4, 2013. The bill amends ch. 463, F.S., the Optometry Practice Act, to expand the scope of practice for optometrists.

The bill authorizes a certified optometrist who successfully completes a training course and examination developed by two professional associations to administer and prescribe oral ocular pharmaceutical agents listed in a statutory formulary. The statutory formulary consists of 7 types of antibiotics, 3 types of antiviral agents, 2 types of anti-glaucoma agents, 2 types of analgesic agents, and the generic or therapeutic equivalents of any of these drugs. Anti-glaucoma and analgesic agents may only be administered or prescribed for 72 hours without a consultation with an ophthalmologist. Beginning January, 1, 2014, a certified optometrist is required to report to the Department of Health any adverse incident that may be attributable to the prescription of an oral ocular pharmaceutical agent. Additionally, certified optometrists are subjected to the reporting requirements under the prescription drug monitoring program, and to the requirements under the Florida Comprehensive Drug Abuse Prevention and Control Act if they hold a valid federal controlled substance registry number.

The bill authorizes a certified optometrist to perform additional optometric practices, including:

- Performing an eye examination, including a dilated examination, if required or authorized under laws related to pugilistic exhibitions;
- Removing an eyelash by epilation;
- Probing an uninflamed tear duct in a patient 18 years of age or older;
- Blocking the puncta by plug; or
- Performing a superficial scraping to remove damaged epithelial tissue or superficial foreign bodies or take a culture of the surface of the cornea or conjunctiva.

The bill defines "ocular pharmaceutical agent" and "surgery." A certified optometrist is prohibited under current law to perform "surgery," but the term is not defined. The bill provides for the co-management of a patient's postoperative care by an optometrist and the physician who performed the operation by requiring the use of a transfer of care letter governing the relationship between the physician and the optometrist and written patient consent to the co-management relationship.

The bill requires a licensed clinical laboratory to accept a human specimen submitted for examination by a licensed optometrist.

The bill has an insignificant, negative fiscal impact to the state and no fiscal impact to local governments.

The bill was approved by the Governor on April 19, 2013, ch. 2013-26, L.O.F., and will become effective on July 1, 2013.

I. SUBSTANTIVE INFORMATION

A. EFFECT OF CHANGES:

PRESENT SITUATION

Medical Quality Assurance

The Department of Health (DOH), Division of Medical Quality Assurance (MQA), regulates health care practitioners to ensure the health, safety and welfare of the public. Currently, MQA works in conjunction with 22 boards and 6 councils to regulate activities of 200-plus license types in 41 health care professions and 8 types of facilities. MQA's three core business processes are the licensure of and enforcement of laws and rules governing Florida's 1,059,958 health care practitioners and facilities, as well as providing information and data to the public.[1]

Boards

A board is a statutorily created entity that is authorized to exercise regulatory or rulemaking functions within the MQA.[2] Boards are responsible for approving or denying applications for licensure and making disciplinary decisions on whether a practitioner practices within the authority of their practice act. Practice acts refer to the legal authority in state statute that grants a profession the authority to provide services to the public. The range of disciplinary actions taken by a board includes citations, suspensions, reprimands, probations, and revocations.

Optometrists and Ophthalmologists

Optometrists examine, diagnose, treat, and manage diseases and injuries of the visual system as well as identify systemic conditions which affect visual health. Optometrists are regulated under ch. 463, F.S., by the Board of Optometry (board) within DOH. Optometrists may prescribe certain medications, vision therapy, and corrective lenses, but may not perform surgical procedures in Florida.[3]

Optometrist training involves an undergraduate degree and completion of a 4-year program at a college of optometry. Some optometrists complete residencies to gain more specialized knowledge, but residency training is not required for licensure or practice.[4]

Ophthalmologists are medical doctors 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. Ophthalmologists also care for patients with more advanced and complicated diseases than do optometrists. Ophthalmologists are regulated under ch. 458 and 459, F.S., by the Board of Medicine and the Board of Osteopathic Medicine within DOH. Ophthalmologist training involves an undergraduate degree, 4 years of medical school, and completion of at least 4 years of residency training in ophthalmology.[5]

Florida law requires optometrists diagnosing a patient with certain diseases to refer such patients to "physician skilled in the diseases of the eye" (ophthalmologists) or for further treatment.[6] Additionally,

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[1] Florida Department of Health, Division of Medical Quality Assurance, *About Medical Quality Assurance*, *available at*: http://doh.state.fl.us/mqa/wearemqa.htm (last viewed May 10, 2013).
[2] Section 456.001, F.S.
[3] Section 463.014(4), F.S.
[4] American Optometric Association, *What is a Doctor of Optometry?*, *available at*: http://www.aoa.org/x4891.xml (last visited May 10, 2013).
[5] American Academy of Ophthalmology, *About Ophthalmology and Eye M.D.s*., *available at:* http://www.aao.org/about/eyemds.cfm (last visited May 10, 2013).
[6] Diagnoses which mandate a referral to an ophthalmologist include angle closure glaucoma, congenital or infantile glaucoma, and infectious corneal diseases that are unresponsive to standard treatment. Section 463.0135, F.S.

an optometrist is required to promptly advise a patient to seek an evaluation by an ophthalmologist for diagnosis and possible treatment whenever the optometrist is informed by the patient of the sudden onset of spots or "floaters" with loss of all or part of the visual field.[7] 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.[8]

Administration of Medications by Optometrists in Florida

Florida is one of three states that do not authorize optometrists to prescribe oral medications for their patients. Of the 47 states that grant optometrists the authority to prescribe oral medications, 43 allow optometrists to prescribe controlled substances.[9] In Florida, licensed optometrists, if they are appropriately certified by the board, may administer and prescribe topical ocular pharmaceutical agents. If an optometrist diagnoses a condition that would be best addressed with an oral medication, the patient must see another practitioner, such as an ophthalmologist for treatment. If an optometrist administers or prescribes a topical pharmaceutical[10], it must be related to the diagnosis and treatment of ocular conditions and must not require surgery or other invasive techniques for administration. Medications approved for prescription by certified optometrists are listed in a formulary[11] maintained by the board.[12]

To be certified for prescribing privileges, an optometrist must:[13]

- Complete at least 110 hours of board-approved coursework and clinical training in general and ocular pharmacology at an accredited institution which has facilities for both didactic and clinical instruction in pharmacology. Training already completed by the applicant under an optometry training program provided by a board-approved school of optometry may be accepted by the board toward the required coursework and training;
- Complete at least 1 year of supervised experience in differential diagnosis of eye diseases or disorders, which may occur during training or clinical practice;
- Pass part II of the National Board of Examiners in Optometry examination;[14] and
- Pay a $250 fee.[15]

For over 25 years, certification for prescribing privileges has been a required component of the general licensure process for optometrists.[16] Optometrists who are not certified are only authorized to use topical anesthetics for glaucoma examinations.[17]

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[7] Section 463.0135(4), F.S.
[8] Section 463.0135(8), F.S.
[9] The Florida Legislature, Office of Program Policy Analysis and Government Accountability, *Expanding Scope of Practice for Advanced Registered Nurse Practitioners, Physician Assistants, Optometrists, and Dental Hygienists*, December 30, 2010, on file with committee staff.
[10] A topical medication is a medication that is applied to body surfaces such as the skin or mucous membranes to treat ailments via a large range of classes including but not limited to creams, foams, gels, lotions and ointments.
[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] Section 463.0055, F.S.
[13] Rule 64B13-10.001, F.A.C.
[14] 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 May 10, 2013).
[15] Rule 64B13-6.001(7), F.A.C.
[16] *See* section 463.006(1), F.S.; and Department of Health, *Bill Analysis for HB 239 (2013)*, dated February 1, 2013, on file with committee staff.
[17] Section 463.0055(1), F.S.

Prescribing Controlled Substances

The Drug Enforcement Administration (DEA) within the United States 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 DEA 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 cannabis.

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 dihydrocodeine 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), zolpidem (Ambien) 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 with less than 200 milligrams of codeine.[18] Schedule V substances are generally used for antidiarrheal, antitussive, and analgesic purposes.

Any health care professional wishing to prescribe controlled substances must apply for a federal Controlled Substance Registry Number (DEA number). A DEA number is linked to a state license, and may be suspended or revoked upon any disciplinary action taken against the licensee.[19] The DEA will grant DEA 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. DEA numbers must be renewed every 3 years.[20]

In Florida, only licensed physicians, dentists, veterinarians, naturopaths, and podiatrists are currently permitted to prescribe controlled substances and receive a DEA number. However, they may only prescribe medications that are within the scope of their practice.[21]

Physicians and Pugilistic Exhibitions

In Florida, the law[22] requires at least one physician to be assigned to each boxing match to observe the physical condition of the participants and advise the commissioner or commission representative in charge of the Florida State Boxing Commission (commission) and the referee of the participants' conditions before, during, and after the match. The commission establishes a schedule of fees for the physician's services. The physician's fee is paid by the promoter of the match attended by the

[18] DEA, Office of Diversion Control, *Controlled Substance Schedules*, *available at*: http://www.deadiversion.usdoj.gov/21cfr/cfr/2108cfrt.htm (last visited May 10, 2013).
[19] DEA, Office of Diversion Control, Questions and Answers: Registration, *available at*: http://www.deadiversion.usdoj.gov/drugreg/faq.htm#1 (last viewed May 14, 2013).
[20] DEA, *Questions and Answers*, *available at*: http://www.deadiversion.usdoj.gov/drugreg/faq.htm (last visited May 10, 2013).
[21] Sections 893.02 and 893.05, F.S.
[22] Section 548.046, F.S.

physician. The physician is considered an agent of the commission in determining the state insurance coverage and sovereign immunity protection applicability of ss. 284.31 and 768.28, F.S.[23]

In addition to any other required examination under law, each participant must be examined by the attending physician at the time of weigh-in. If the physician determines that a participant is physically or mentally unfit to proceed, the physician must notify any commissioner or the commission representative who must immediately cancel the match. The examination must conform to rules adopted by the commission. The result of the examination must be reported in writing signed by the physician and filed with the commission prior to completion of the weigh-in.[24]

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.[25] Practitioners authorized to operate their own clinical laboratories exclusively to diagnose and treat their own patients are physicians, chiropractors, podiatrists, naturopaths, and dentists. Clinical laboratories must be biennially licensed and inspected by the Agency for Health Care Administration to ensure quality standards in examination of specimens, equipment, sanitation, staffing, and other measures.[26]

A clinical laboratory may examine human specimens at the request of the following licensed practitioners:[27]

- Physicians;
- Chiropractors;
- Podiatrists;
- Naturopaths;
- Dentists; and
- Advanced registered nurse practitioners.

Clinical laboratories are not authorized to accept specimens from optometrists. 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.

EFFECT OF CHANGES

Prescribing Authority of Certified Optometrists

A certified optometrist is currently issued a prescriber number to prescribe and administer only topical pharmaceutical agents as long as the agent relates to the diagnosis and treatment of ocular conditions and is listed in a formulary adopted by the board. The bill expands the scope of practice for certified optometrists by authorizing them to prescribe and administer certain oral ocular pharmaceutical agents after proof of successful completion of certain training and examination requirements is provided to DOH.

The 20 contact hour web-based course and subsequent examination required in the bill must cover general and ocular pharmaceutical agents and the side effects of those agents. The bill permits certified optometrists who do not complete the course and subsequent examination to administer and prescribe topical pharmaceutical agents, conforming to current authority provided for in law. An

[23] Section 548.046, F.S.
[24] *Id*.
[25] Section 483.041, F.S.
[26] Section 483.051, F.S.
[27] Section 483.181, F.S.

optometric faculty certificateholder is required to complete the same training and examination to prescribe or administer oral ocular pharmaceutical agents.

The first course and examination must be available by October 1, 2013, and must be administered at least annually thereafter. The course and examination are to be jointly developed by two statewide professional associations. One association must consist of Florida physicians accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award Category I credit. The second association must consist of optometrists and provide board-approved continuing education. The board is required to review and approve the content of the initial course and examination to determine if the materials adequately and reliably satisfy the required criteria. A certified optometrist may apply the 20 contact hours earned for completing the course and subsequent examination toward his or her continuing education requirement for the biennial period in which they are earned.

The bill creates a statutory formulary of oral ocular pharmaceutical agents, to include their generic or therapeutic equivalents, which may be administered or prescribed by a certified optometrist who has successfully completed the course and examination. The agents include:

- The following seven antibiotics:
    1. Amoxicillin with or without clavulanic acid;
    2. Azithromycin;
    3. Erythromycin;
    4. Dicloxacillin;
    5. Doxycycline/Tetracycline;
    6. Keflex; and
    7. Minocycline.

- The following three antivirals:
    1. Acyclovir;
    2. Famciclovir; and
    3. Valacyclovir.

Agents included in the formulary that may not be administered or prescribed for more than 72 hours are:

- The following two analgesics:
    1. Tramadol hydrochloride; and
    2. Acetaminophen 300 mg with No. 3 codeine phosphate 30 mg.

- The following two anti-glaucoma agents:
    1. Acetazolamide; and
    2. Methazolamide.

Any oral ocular pharmaceutical agent listed in the statutory formulary which is subsequently determined by the U.S. Food and Drug Administration to be unsafe for the administration or prescription is considered deleted from the statutory formulary.

The bill expressly prohibits a certified optometrist licensed in Florida from administering or prescribing Schedule II controlled substances, and prohibits Schedule III, IV, or V controlled substances except for an oral analgesic listed in the statutory formulary.

The bill also expressly prohibits the use of an ocular pharmaceutical agent for the treatment of chronic nonmalignant pain.[28] Currently, only physicians, podiatrists, and dentists are authorized to prescribe controlled substances listed in Schedule II, III, or IV for the treatment of chronic nonmalignant pain.[29] Anyone who is authorized to prescribe controlled substances for the treatment of chronic nonmalignant pain is required to register with DOH to designate him or herself as a controlled substance prescribing practitioner, which will be reflected on the physician's practitioner profile. Since the bill specifically prohibits a certified optometrist from prescribing controlled substances for the treatment of nonmalignant chronic pain, registration is not necessary.

Additionally, the bill subjects certified optometrists to the reporting requirements under the prescription drug monitoring program, and to the requirements under the Florida Comprehensive Drug Abuse Prevention and Control Act if they hold valid federal controlled substance registry numbers.

The bill requires a certified optometrist to report to DOH in writing of any adverse incident occurring on or after January 1, 2014, in the practice of optometry that is reasonable to believe is attributable to the prescription of an oral pharmaceutical agent. The events that must be reported are:

- Any condition that requires the transfer of a patient to a licensed hospital;
- Any condition that requires the patient to obtain care from a medical doctor other than a referral or a consultation to receive an analgesic or an anti-glaucoma agent for longer than 72 hours;
- A permanent physical injury to the patient;
- The partial or complete permanent loss of sight by the patient; and
- The death of the patient.

The bill directs DOH to review each incident and determine whether the event involves conduct by the certified optometrist that necessitates disciplinary action be taken by the board. The board is authorized to adopt rules relating to the administration and prescription of ocular pharmaceutical agents.

Scope of Optometric Practice

The bill clarifies which procedures a certified optometrist may perform. Current law and the bill prohibit an optometrist from performing surgery of any kind. The bill creates a definition of "surgery" to mean a procedure using an instrument including a laser, scalpel, or needle in which human tissue is cut, burned, scraped or vaporized, by incision, injection, ultrasound, laser, infusion, cryotherapy, or radiation. Additionally, the term surgery includes a procedure using an instrument which requires the closure of human tissue by suture, clamp, or other such device.

The bill authorizes a certified optometrist to perform additional optometric practices, including:

- Performing an eye examination, including a dilated examination, if required or authorized under laws related to pugilistic exhibitions;
- Removing an eyelash by epilation;
- Probing an uninflamed tear duct in a patient 18 years of age or older;
- Blocking the puncta by plug;
- Performing a superficial scraping to remove damaged epithelial tissue or superficial foreign bodies or take a culture of the surface of the cornea or conjunctiva; and
- Using commonly accepted means or methods to immediately address incidents of anaphylaxis.

The bill requires a licensed clinical laboratory to accept a human specimen submitted for examination by a licensed optometrist.

[28] Chronic nonmalignant pain is defined in section 456.44, F.S., as pain unrelated to cancer which persists beyond the usual course of disease or the injury that is the cause of the pain or more than 90 day after surgery.
[29] Section 456.44(2), F.S.

The bill conforms the definitions of the terms "certified optometrist" and "optometry" to authorize the administration and prescription of ocular pharmaceutical agents. The bill defines "ocular pharmaceutical agents" to a mean pharmaceutical agent that is administered topically or orally for the diagnosis and treatment of ocular conditions of the human eye and its appendages without the use of surgery or other invasive techniques. A certified optometrists is added into the definition of the term "practitioner" in s. 893.02, F.S., to regulate the prescription, administration, and dispensing of controlled substances by certified optometrists who hold a valid DEA number.

Co-management of Postoperative Care

Current law is silent on the issue of co-management of postoperative care. The bill requires the creation of a patient-specific transfer of care letter to govern the relationship between the physician who performed surgery and the optometrist who provides postoperative care to a patient. The transfer of care letter confirm that it is not medically necessary for the physician who performed the surgery to provide postoperative care and that it is clinically appropriate for the optometrist to provide the postoperative care. The bill requires that the patient be fully informed and consent in writing to the co-management relationship for his or her care before the co-management of postoperative care begins. In addition, the patient must be:

- Informed that they have the right to be seen by the physician who performed the surgery during the entire postoperative period;
- Informed of the fees, if any; and
- Provided an accurate comprehensive customized statement of services rendered that may be charged to the patient by the optometrist or the physician who performed the surgery.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

DOH reports that it will incur additional costs and workload to implement the provisions of the bill, but anticipates that current resources are adequate to absorb the costs and workload.[30]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

[30] Department of Health, *Bill Analysis for HB 239 (2013)*, dated February 1, 2013, on file with committee staff.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Certified optometrists and optometric faculty certificateholders wanting to prescribe and administer oral ocular pharmaceutical agents may incur costs associated with the coursework and examination required by the bill.[31]

Patients may experience some cost-savings if they can be treated immediately by an optometrist, without having to be referred to an ophthalmologist for treatment.[32]

D. FISCAL COMMENTS:

None.

[31] *Id*.
[32] *Supra* Note 7.