

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** CS/CS/HB 239 Practice of Optometry

**SPONSOR(S):** Health & Human Services Committee; Health Quality Subcommittee, Caldwell and others

**TIED BILLS:** **IDEN./SIM. BILLS:** CS/SB 278

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	10 Y, 3 N, As CS	Holt	O'Callaghan
2) Health & Human Services Committee	14 Y, 2 N, As CS	Holt	Calamas

### SUMMARY ANALYSIS

The bill amends ch. 463, F.S., the Optometry Practice Act, authorizing certified optometrists to administer and prescribe ocular pharmaceutical agents, including certain Schedule III, IV, and V controlled substances that may be ingested orally for the relief of pain due to ocular conditions of the eye and its appendages. Currently, a certified optometrist is only permitted to administer and prescribe topical ocular pharmaceutical agents. The bill revises the definitions of "certified optometrist" and "optometry" to reflect the broader authority. The bill provides a definition of "ocular pharmaceutical agent." The bill provides a definition of surgery, which certified optometrists are prohibited from performing.

To be authorized to prescribe or administer oral ocular pharmaceutical agents, a certified optometrist or an optometry faculty certificateholder must send proof to the Department of Health (DOH) that he or she has successfully completed additional coursework and passed an exam. The exam must be jointly developed by the Florida Medical Association and the Florida Optometric Association. The first examination must be presented by July 1, 2013.

The bill states that the formulary of ocular pharmaceutical agents must consist of agents that are appropriate to treat and diagnose ocular diseases and disorders. The bill amends the composition of the advisory committee by requiring two optometrists to be certified optometrists and clarifies the advisory opinions and recommendations of the committee must be based on specific findings of fact. The bill provides a standard that the Board of Optometry (board) must meet to rebut the committee's recommendations or advisory opinions. The bill also amends the board's rule-making authority.

The bill authorizes a certified optometrist to perform any eye examination, including a dilated examination, if required or authorized under laws related to pugilistic exhibitions.

The bill provides for the comanagement of postoperative care of a patient, requiring the use of a transfer of care letter governing the relationship between the physician who performed the operation and the optometrist and written patient consent to the comanagement relationship.

The bill defines "practitioner" under s. 893.02, F.S., to include certified optometrists who have obtained a federal controlled substance registry number to prescribe, administer, dispense, mix, or otherwise prepare a controlled substance.

The bill requires a licensed clinical laboratory to accept a human specimen submitted for examination by a licensed optometrist. Finally, the bill makes conforming changes to cross-references.

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

The bill provides an effective date of July 1, 2013.

## FULL ANALYSIS

### I. SUBSTANTIVE ANALYSIS

#### A. EFFECT OF PROPOSED CHANGES:

##### **Present Situation**

##### Optometrists and Ophthalmologists

Optometrists are the primary health care professionals for the eye. Optometrists examine, diagnose, treat, and manage diseases and injuries of the visual system as well as identify systemic conditions which affect visual health. Optometrists may prescribe certain medications, vision therapy, and corrective lenses, but may not perform surgical procedures in Florida.<sup>1</sup>

Optometrist training involves an undergraduate degree and completion of a 4-year program at a college of optometry. Some optometrist's complete residencies to gain more specialized knowledge, but residency training is not required for licensure or practice.<sup>2</sup>

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. Ophthalmologist training involves an undergraduate degree, 4 years of medical school, and completion of at least 4 years of residency training in ophthalmology.<sup>3</sup>

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.<sup>4</sup> Additionally, 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.<sup>5</sup> 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.<sup>6</sup>

##### 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.<sup>7</sup> In Florida, licensed optometrists, if they are appropriately certified by the Board of Optometry (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, [or hospital emergency room] for treatment. If an optometrist administers or prescribes a topical pharmaceutical<sup>8</sup>, it must be related to the diagnosis and treatment of ocular conditions and must not require surgery or

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<sup>1</sup> Section 463.014(4), F.S.

<sup>2</sup> American Optometric Association, *What is a Doctor of Optometry?*, available at: <http://www.aoa.org/x4891.xml> (last visited March 10, 2013).

<sup>3</sup> American Academy of Ophthalmology, *About Ophthalmology and Eye M.D.s.*, available at: <http://www.aao.org/about/eyemds.cfm> (last visited March 10, 2013).

<sup>4</sup> 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.

<sup>5</sup> Section 463.0135(4), F.S.

<sup>6</sup> Section 463.0135(8), F.S.

<sup>7</sup> 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.

<sup>8</sup> 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.

other invasive techniques for administration. Medications approved for prescription by certified optometrists are listed in a formulary<sup>9</sup> maintained by the board.<sup>10</sup>

To be certified for prescribing privileges, an optometrist must:<sup>11</sup>

- 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;<sup>12</sup> and
- Pay a \$250 fee.<sup>13</sup>

For over 25 years, certification for prescribing privileges is a required component of the general licensure process for optometrists.<sup>14</sup> Optometrists who are not certified are only authorized to use topical anesthetics for glaucoma examinations.<sup>15</sup>

### 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

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<sup>9</sup> 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.

<sup>10</sup> Section 463.0055, F.S.

<sup>11</sup> Rule 64B13-10.001, F.A.C.

<sup>12</sup> 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](http://www.optometry.org/part_2_pam.cfm) (last visited March 10, 2013).

<sup>13</sup> Rule 64B13-6.001(7), F.A.C.

<sup>14</sup> See s. 463.006(1), F.S.; and Department of Health, *Bill Analysis for HB 239 (2013)*, dated February 1, 2013, on file with committee staff.

<sup>15</sup> Section 463.0055(1), F.S.

with less than 200 milligrams of codeine.<sup>16</sup> 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, which may be suspended or revoked upon any disciplinary action taken against the licensee. 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.<sup>17</sup>

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.<sup>18</sup>

### Physicians and Pugilistic Exhibitions

In Florida, the law 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 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.<sup>19</sup>

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.<sup>20</sup>

### 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.<sup>21</sup> 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.<sup>22</sup>

A clinical laboratory may examine human specimens at the request of the following licensed practitioners:<sup>23</sup>

- Physicians
- Chiropractors
- Podiatrists
- Naturopaths

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<sup>16</sup> DEA, Office of Diversion Control, *Controlled Substance Schedules*, available at: <http://www.deadiversion.usdoj.gov/21cfr/cfr/2108cfr.htm> (last visited March 10, 2013).

<sup>17</sup> DEA, *Questions and Answers*, available at: <http://www.deadiversion.usdoj.gov/drugreg/faq.htm> (last visited March 10, 2013).

<sup>18</sup> Sections 893.02 and 893.05, F.S.

<sup>19</sup> Section 548.046, F.S.

<sup>20</sup> *Id.*

<sup>21</sup> Section 483.041, F.S.

<sup>22</sup> Section 483.051, F.S.

<sup>23</sup> Section 483.181, F.S.

- Dentists
- Advanced registered 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.

### **Effect of Proposed Changes**

Currently, a certified optometrist is issued a prescriber number to prescribe and administer 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 prescribing and administering authority for certified optometrists by authorizing the use of oral pharmaceutical agents. 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 mean pharmaceutical agents that are 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.

The bill defines “surgery” to mean a procedure using an instrument including a laser, scalpel, or needle to cut, burn, vaporize, remove, or otherwise alter human tissue by incision, injection, ultrasound, radiation, infusion, cyrotherapy, or scraping. Current law prohibits an optometrist from performing surgery of any kind, including the use of lasers. However, current law allows an optometrist to remove a superficial foreign body as long as the embedded foreign matter has not penetrated the globe of the eye (eyeball). The bill expressly authorizes a certified optometrist to:

- Scrape the surface of the cornea for the purpose of taking a culture,
- Probe an uninflamed tear duct, or
- Remove an eyelash by epilation.

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 unless they are analgesics for the relief of pain due to an ocular condition of the eye and its appendages. The bill also expressly prohibits the use of an ocular pharmaceutical agent for the treatment of chronic nonmalignant pain.<sup>24</sup> 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.<sup>25</sup> Anyone who is authorized to prescribe controlled substances for the treatment of chronic nonmalignant pain is required to register with the 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.

In addition, the bill requires certified optometrists and optometric faculty certificateholders to successfully complete certain coursework and an examination, and provide proof of such to the DOH, before being authorized to administer or prescribe oral ocular pharmaceutical agents. The course and subsequent examination must cover general and ocular pharmaceutical agents and the side effects of those agents. The bill permits certified optometrists or optometric faculty certificateholders who do not complete the course and subsequent examination to administer topical pharmaceutical agents, conforming to current authority provided for in law.

The bill specifies that for certified optometrists licensed before January 1, 1990, the course must consist of 50 contact hours and 25 of those hours are to be web-based. Whereas, for certified optometrists licensed on or after January 1, 1990, the course must consist of 20 contact hours and 10 of those hours are to be web-based. The first course and examination must be available by July 1, 2013, and must be administered at least annually thereafter. The Florida Medical Association and the

<sup>24</sup> Chronic nonmalignant pain is defined in s. 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.

<sup>25</sup> Section 456.44(2), F.S.

Florida Optometric Association are required to jointly develop and administer the course and examination and must jointly determine the site or sites for the course and examination.

The bill amends the composition of the formulary advisory committee to require the two appointed optometrists to be certified optometrists. The bill requires that the advisory opinions and recommendations of the formulary committee must state specific findings of fact and grounds for its recommendations. The bill specifies that the board is bound by the committee's advisory opinions and recommendations unless competent substantial evidence is presented to the board to rebut the committee's advisory opinion or recommendation. The bill provides that the committee's advisory opinion or recommendation is not subject to rule review hearings or challenge proceedings pursuant to ss. 120.569 and 120.57, F.S.

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 must state 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 the patient to provide written consent to the comanagement relationship for his or her care. Additionally, the bill requires that the patient be informed in writing of the following prior the commencement of comanagement:

- The patient has the right to be seen by the physician who performed the surgery during the entire postoperative period;
- The fees, if any; and
- 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.

In addition, the bill:

- Authorizes a certified optometrist to perform any eye examination, including a dilated examination, if required or authorized under ch. 548, F.S., relating to pugilistic exhibitions, or rules adopted thereunder;
- Requires a licensed clinical laboratory to accept a human specimen submitted for examination by a licensed optometrist;
- Includes certified optometrists in 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; and
- The bill amends ss. 463.009 and 641.31, F.S., to update cross-references.

The bill allows the board to adopt rules relating to the administration and prescription of ocular pharmaceutical agents.

#### B. SECTION DIRECTORY:

**Section 1.** Amends s. 463.002, F.S., relating to definitions.

**Section 2.** Amends s. 463.005, F.S., relating to authority of the Board of Optometry.

**Section 3.** Amends s. 463.0055, F.S., relating to administration and prescription of topical ocular pharmaceutical agents; committee.

**Section 4.** Amends s. 463.0057, F.S., relating to optometric faculty certificate.

**Section 5.** Amends s. 463.006, F.S., relating to licensure and certification by examination.

**Section 6.** Amends s. 463.0135, F.S., relating to standards of practice.

**Section 7.** Amends s. 463.014, F.S., relating to certain acts prohibited.

**Section 8.** Amends s. 483.035, F.S., relating to clinical laboratories operated by practitioners for exclusive use; licensure and regulation.

**Section 9.** Amends s. 483.041, F.S., relating to definitions.

**Section 10.** Amends s. 483.181, F.S., relating to acceptance, collection, identification, and examination of specimens.

**Section 11.** Amends s. 893.02, F.S., relating to definitions.

**Section 12.** Amends s. 463.009, F.S., relating to supportive personnel.

**Section 13.** Amends s. 641.31, F.S., relating to health maintenance contracts.

**Section 14.** Provides an effective date of July 1, 2013.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

### A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The 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.<sup>26</sup>

### B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

### C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Certified optometrists and an optometric faculty certificateholder, wanting to prescribe and administer oral ocular pharmaceutical agents, may incur costs associated with the coursework and examination required by the bill.<sup>27</sup>

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.<sup>28</sup>

### D. FISCAL COMMENTS:

None.

## III. COMMENTS

### A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

### B. RULE-MAKING AUTHORITY:

The bill provides for additional rule-making authority, which is necessary to implement the provisions of this bill.

### C. DRAFTING ISSUES OR OTHER COMMENTS:

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<sup>26</sup> Department of Health, *Bill Analysis for HB 239 (2013)*, dated February 1, 2013, on file with committee staff.

<sup>27</sup> *Id.*

<sup>28</sup> *Supra* Note 7.

The bill provides that the committee's advisory opinion or recommendation is not subject to rule review hearings or challenge proceedings pursuant to ss. 120.569 and 120.57, F.S. It is unclear whether this prohibition is necessary, because the committee's role is advisory and the committee does not take any final agency action to trigger any process under ch. 120, F.S.

On line 142, the bill used the term "analgesic" which is a term that is not defined in Florida Law.

#### **IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES**

On February 7, 2013, the Health Quality Subcommittee adopted a strike-all amendment and reported the bill favorably as a committee substitute. The amendment:

- Defines "ocular pharmaceutical agents" to clarify the term means only those pharmaceutical agents that may be administered orally or applied topically.
- Uses the term "ocular pharmaceutical agents" consistently throughout the bill.
- Provides that if a certified optometrist does not complete a course and subsequent examination, they are only authorized to administer ocular pharmaceutical agents by topical application.
- Requires a person who is an optometric faculty certificateholder to complete a course and subsequent examination in order to administer or prescribe oral ocular pharmaceutical agents.
- Comports with the style of the definition and clarifies the application of the term "licensed practitioner" under s. 483.041, F.S., by adding "a certified optometrist licensed under."

On March 7, 2013, the Health & Human Services Committee adopted a strike-all amendment and reported the bill favorably as a committee substitute. The amendment:

- Adds to the definition of "ocular pharmaceutical agents" the phrase "without the use of surgery or other invasive techniques."
- Adds a definition of "surgery" to clarify which acts are prohibited to be performed by optometrists.
- Requires a certified optometrist who wishes to administer or prescribe oral ocular pharmaceutical agents to send proof to the Department of Health of successful completion of a course and subsequent examination.
- Prohibits a certified optometrist from administering or prescribing pharmaceutical agents:
  - Listed in Schedule II.
  - Listed in Schedule III, IV, or V unless for oral analgesics for the relief of pain due to ocular conditions of the eye and its appendages.
  - For the treatment of chronic nonmalignant pain.
- Requires that advisory opinions and recommendations of the committee must state specific findings of fact and grounds for any recommendations made to the board for what changes should be made to the formulary.
- Specifies that the formulary which a certified optometrist may use in the practice of optometry consist of ocular pharmaceutical agents approved to treat and diagnose ocular diseases and disorders.
- Specifies that the board is bound by the committee's advisory opinions and recommendations unless competent substantial evidence is presented to the board to rebut the committee's advisory opinion or recommendation.
- Provides that a committee's advisory opinion or recommendation is not subject to rule review hearings or challenge proceedings provided under ss. 120.569 and 120.57, F.S.
- Requires an optometric faculty certificateholder to complete the course and subsequent examination requirements in order to administer or prescribe oral ocular pharmaceutical agents.
- Requires that co-management of postoperative care be conducted with written patient consent and pursuant to a transfer of care letter.
- Requires the transfer of care letter to inform the patient of the right to engage in an alternative postoperative care arrangement and provide transparency in the cost of each alternative care scenario.

This analysis is drafted to the committee substitute.