**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 Staff of the Committee on Appropriations

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| BILL: | CS/CS/SB 278 |
| INTRODUCER: | Committee on Appropriations (Recommended by Appropriations Subcommittee on Health and Human Services); Health Policy Committee; and Senator Richter |
| SUBJECT: | Optometry |
| DATE: | March 21, 2013 REVISED: |

| | ANALYST | STAFF DIRECTOR | REFERENCE | ACTION |
|---|---|---|---|---|
| 1. | Stovall | Stovall | HP | **Fav/CS** |
| 2. | Brown | Pigott | AHS | **Fav/CS** |
| 3. | Brown | Hansen | AP | **Fav/CS** |
| 4. | | | | |
| 5. | | | | |
| 6. | | | | |

## Please see Section VIII. for Additional Information:

| | | |
|---|---|---|
| A. COMMITTEE SUBSTITUTE..... | X | Statement of Substantial Changes |
| B. AMENDMENTS..... | | Technical amendments were recommended |
| | | Amendments were recommended |
| | | Significant amendments were recommended |

## I. Summary:

CS/CS/SB 278 authorizes licensed certified optometrists to administer or prescribe oral ocular pharmaceutical agents, including statutorily specified analgesics which are controlled substances, for the relief of pain due to ocular conditions of the eye and its appendages. The 14 oral ocular pharmaceutical agents that may be administered or prescribed by a certified optometrist are identified in a statutory formulary. The bill repeals the formulary committee and authorizes the Board of Optometry (board) to establish and update the formulary for topical ocular pharmaceutical agents.

The bill is expected to result in a small savings for the Medicaid program; create a need for three full-time equivalent positions (FTEs) in the Agency for Health Care Administration (AHCA); generate a small amount of new trust fund revenue due to an increase in laboratory licensing fees; and create workload demands within the Department of Health (DOH) that can be absorbed within existing resources.

Before administering or prescribing oral ocular pharmaceutical agents, the certified optometrist must provide proof to the Department of Health (DOH) of successful completion of a course and

examination on general and ocular pharmaceutical agents and the side effects of those agents. The first course and examination must be presented by October 1, 2013. The 20-hour course and examination may satisfy 20 hours of continuing education for the optometrist.

The bill provides a definition of surgery and specifies that certain procedures under the practice of optometry are excluded from this definition. Any adverse incident identified in this law that is attributable to the prescription of an oral ocular pharmaceutical agent by a certified optometrist must be reported to the DOH.

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 also 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, 463.009, 463.0135, 463.014, 483.035, 483.041, 483.181, 641.31, 893.02, 893.05, and 893.055.

The bill creates section 463.0141, Florida Statutes.

## 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 bodes (foreign matter that is embedded in the conjunctiva or cornea but which has not penetrated the globe).[4]

[1] *See* s. 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] *See* s. 463.014(4), F.S.
[4] *Ibid.*

To be licensed as a certified optometrist[5] in Florida, the applicant must:[6]

- 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 physicians[7] 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]

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[5] All practitioners initially licensed after July 1, 1993. must be certified optometrists. *See* s. 463.002(3)(c), F.S.
[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 rule[11] 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; 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]

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[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, anti-viral medications, 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] *See* s. 463.0055, F.S.
[18] *Supra* 14.
[19] *See* 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 certain 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 bill, 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 definition for surgery is added to mean a procedure using an instrument, including a laser, scalpel, or needle, in which human tissue is cut, burned, scraped except as provided in s. 463.014(4), F.S., [which authorizes superficial scraping for the purpose of removing damaged epithelial tissue or superficial foreign bodies or taking a culture of the surface of the cornea or conjunctiva] , or vaporized, by incision, injection, ultrasound, laser, infusion, cryotherapy, or radiation. The term includes a procedure using an instrument which requires the closure of human tissue by suture, clamp, or other such device.

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 ocular pharmaceutical agents." A similar 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 ocular 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 ocular pharmaceutical agents.

The bill requires a certified optometrist to provide proof to the DOH of successful completion of a course and subsequent examination on general and ocular pharmaceutical agents and the side effects of those agents prior to administering or prescribing the oral ocular pharmaceutical agents authorized in law. The course must consist of 20 contact hours, all of which may be web-based. These 20 hours may be used to satisfy 20 hours of the continuing education requirements in the licensure cycle in which the course and examination are completed.

A statewide professional association of physicians accredited to provide a certain level of educational activities and a statewide professional association of licensed practitioners which provides board-approved continuing education are required to jointly develop and administer the course and examination. The first course and examination must be presented by October 1, 2013. The board must review and approve the content of the initial course and examination to determine that they adequately and reliably satisfy the criteria set forth in this section. The criteria are that the course and examination must cover general and ocular pharmaceutical agents and the side effects of those agents. Annually thereafter, the board must review and approve the course and examination for ongoing adherence to these criteria.

The bill specifies that if a certified optometrist does not complete the coursework and examination required for prescribing and administering oral ocular pharmaceutical agents, then he or she is authorized only to administer and prescribe topical ocular pharmaceutical agents.

The bill repeals the formulary committee and authorizes the board to establish and update, by rule, a formulary of topical ocular pharmaceutical agents that a certified optometrist may

administer and prescribe. The topical ocular pharmaceutical agents included on the formulary must be limited to those that are appropriate to treat or diagnose ocular diseases and disorders, in addition to those that the certified optometrist is qualified to use in the practice of optometry.

The bill creates a statutory formulary of 14 oral ocular pharmaceutical agents composed of:

- Analgesics or their generic or therapeutic equivalents, which may be administered or prescribed only for period of up to 72 hours without consultation with an allopathic physician or osteopathic physician who is skilled in diseases of the eye (ophthalmologist):
  - Tramadol hydrochloride
  - Acetaminophen 300 mg with No. 3 codeine phosphate 30 mg.
- Antibiotics or their generic or therapeutic equivalents:
  - Amoxicillin with or without clavulanic acid
  - Arithromycin
  - Erythromycin
  - Dicloxacillin
  - Doxycycline/Tetracycline
  - Keflex
  - Minocycline
- Antivirals or their generic or therapeutic equivalents:
  - Acyclovir
  - Famciclovir
  - Valacyclovir
- Anti-glaucoma agents or their generic or therapeutic equivalents, which may be administered or prescribed only for a period of up to 72 hours:
  - Acetazolamide
  - Methazolamide.

If the U.S. Food and Drug Administration removes approval of any drug identified above, i.e., the drug is determined to be unsafe for administration or prescription, then the oral ocular pharmaceutical agent is deleted by law from the formulary. The board, the DOH, and the state surgeon general are expressly prohibited from otherwise deleting pharmaceuticals from this formulary.

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 ocular pharmaceutical agents. A certified optometrist is prohibited from prescribing a Schedule III, Schedule IV, or Schedule V controlled substance except for an oral analgesic placed on the statutory formulary for the relief of pain due to ocular conditions of the eye and its appendages. A certified optometrist is also prohibited from prescribing a controlled substance for the treatment of chronic nonmalignant pain.[26]

**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

[26] Chronic nonmalignant pain is defined in s. 456.44(1)(e), F.S., to mean pain unrelated to cancer which persists beyond the usual course of disease or injury that is the cause of the pain or more than 90 days after surgery.

administering and prescribing topical ocular pharmaceutical agents, prior to administering or prescribing oral ocular 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 ocular pharmaceutical agents. This is a change from current law that requires the examination to emphasize the topical application and side effects of ocular pharmaceutical agents.

**Section 6** amends s. 463.0135, F.S., relating to the standards of practice of an optometrist. The bill authorizes a certified optometrist to perform any eye examination, including a dilated examination required or authorized for pugilistic exhibitions (boxing, kickboxing, or mixed martial arts matches).

The bill provides for a process for the co-management of a surgical patient's postoperative care. A patient-specific transfer of care letter must govern the relationship between the physician who performed the surgery and the optometrist. This letter must confirm that it is not medically necessary for the physician to provide the postoperative care to the patient and that it is clinically appropriate for the optometrist to provide the postoperative care.

Before the postoperative care begins, the patient must be informed in writing that he or she has the right to be seen during the entire postoperative period by the physician who performed the surgery and the patient must consent in writing to the co-management relationship for his or her care. The patient must also be informed of any fees to be charged by the optometrist or the physicians and provided with an accurate and comprehensive itemized statement of the specific postoperative care services that each practitioner rendered and the corresponding charge for each service.

**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. A certified optometrist is, however, authorized to use commonly accepted means or methods to immediately address incidents of anaphylaxis, such as the use of epinephrine or an epi-pen.

The bill provides that notwithstanding the definition of surgery, a certified optometrist may provide any optometric care within the practice of optometry, and specifically lists certain procedures. These procedures include:

- Removing an eyelash by epilation,
- Probing an uninflamed tear duct in a patient at least 18 years of age,
- Blocking the puncta by plug, or
- Superficial scraping for the purpose of removing damaged epithelial tissue or superficial foreign bodies or taking a culture of the surface of the cornea or conjunctiva.

**Section 8** creates s. 463.0141, F.S., which is effective January 1, 2014, to require the reporting of an adverse incident occurring in the practice of optometry in relation to the prescription of an oral ocular pharmaceutical agent.

An adverse incident is defined to mean any of the following events when it is reasonable to believe that the event is attributable to the prescription of an oral ocular pharmaceutical agent by the licensed practitioner:

- A condition that requires the transfer of a patient to a hospital.
- A condition that requires the patient to obtain care from a physician other than a referral or a consultation required under the practice of optometry.
- Permanent physical injury to the patient.
- Partial or complete permanent loss of sight by the patient.
- Death of the patient.

The report must be submitted in writing to the DOH by certified mail. It must be postmarked within 15 days after the adverse incident if the incident occurs when the patient is at the optometrist's office. If the patient is not at the optometrist's office when the incident occurs, the notification must be postmarked within 15 days after the optometrist discovers, or reasonably should have discovered, the occurrence of the adverse incident.

The DOH is required to review each incident to determine whether it potentially involved conduct by the optometrist who may be subject to disciplinary action. If it does, the board must proceed with disciplinary procedures as set forth in the general provisions pertaining to the regulation of health care practitioners in s. 456.073, F.S.

**Sections 9, 10, and 11** amend ss. 483.035, 483.041, and 483.181, F.S., respectively, to authorize an optometrist to operate a clinical laboratory to treat his or her own patients, subject the optometrist to applicable regulations for the operation of a clinical laboratory, and require other clinical laboratories to accept specimens submitted for examination by an optometrist.

**Section 12** 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 13** amends s. 893.05, F.S., to prohibit a certified optometrist from administering or prescribing a Schedule I or Schedule II controlled substance.

**Section 14** amends s. 893.055, F.S., to include optometrists in the definition of a health care practitioner for purposes of complying with the requirements of the prescription drug monitoring program.

**Sections 15 and 16** amend ss. 463.009 and 641.31, F.S., to make conforming changes to statutory references.

**Section 17** 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. However, this fee will likely be offset by the applicability of the 20 hours to the currently mandated continuing education requirement.

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 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, potential complaints related to enactment of the bill's provisions, and managing adverse incident reports. However, the DOH indicates that current resources are adequate to absorb the workload and costs.

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

The bill 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 bill. 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 9 of the bill 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 bill 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)** |

## VI. Technical Deficiencies:

Section 8 of the bill requires the reporting of adverse incidents in the practice of optometry; however, it does not specify who is required to report.

## 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.)

**CS/CS by Appropriations on March 21, 2013:**

- Includes a definition of surgery;
- Education hours are changed to 20 for everyone, all of which may be web-based;
- Changes who develops the education / examination;
- Board approves content of initial course and examination, then reviews and approves annually thereafter;
- Postpones the initial date for presentation of the course and examination to October 1, 2013;
- Passage of training/ examination offsets 20 hours of continuing education for that cycle;
- Repeals formulary committee; the Board establishes topical formulary;
- Statutory formulary established for 14 oral ocular pharmaceuticals which may only be modified statutorily (unless FDA removes approval status of a drug);
- Oral analgesics and anti-glaucoma agents may not be administered or prescribed for more than 72-hours;
- Prohibits the administration or prescribing for chronic nonmalignant pain;
- Requires a co-management process including a patient-specific transfer of care letter, written consent of patient and certain disclosures to the patient;

- Further defines optometric care that may be provided and which is not considered surgery;
- Requires reporting of adverse incidents to the DOH; within 15 days if it occurs in-office or within 15 days upon discovery of incident or should have discovered incident otherwise; and
- Adds certified optometrist to the definition of a practitioner under s. 893.02 (general definitions for chapter) and s. 893.055 relating to the Prescription Drug Monitoring Program.

**CS by Health Policy on February 21, 2013:**
The committee substitute 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.