

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** CS/HB 1037 Optometry  
**SPONSOR(S):** Health Quality Subcommittee, Diaz, Jr.  
**TIED BILLS:** **IDEN./SIM. BILLS:** SB 1168

| REFERENCE                            | ACTION          | ANALYST | STAFF DIRECTOR or<br>BUDGET/POLICY CHIEF |
|--------------------------------------|-----------------|---------|--|
| 1) Health Quality Subcommittee       | 8 Y, 7 N, As CS | Royal   | McElroy                                  |
| 2) Health & Human Services Committee |                 | Royal   | Calamas                                  |

### SUMMARY ANALYSIS

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 within the Department of Health (DOH). Optometrists may prescribe certain ocular medications listed in law or established in a formulary by the Board of Optometry, but may not perform certain surgical procedures using an instrument, including a laser, scalpel, or needle.

Ch. 463 creates a category of licensed optometrists, "certified optometrists," that authorizes licensed optometrists who have completed board approved coursework and training to administer and prescribe certain topical medications as established by the Board of Optometry or certain oral medications listed in statute. Certified optometrists may also perform certain procedures as listed in statute that are not considered surgical procedures under ch. 463.

CS/HB 1037 amends ch. 463, the Optometry Practice Act, to create two categories of certification for licensed optometrists: "certified optometrists in pharmaceutical agents" and "certified optometrists in ophthalmic surgery." To be certified optometrist, the bill requires the licensed optometrist provide proof to DOH that he or she has successfully completed a board-approved course and examination.

The bill authorizes certified optometrists in pharmaceutical agents to administer and prescribe topical or oral ocular pharmaceutical agents as established by the Board of Optometry. The bill repeals the permitted oral medications listed in statute and authorizes the Board of Optometry to establish a list of permitted oral and topical medications. The bill authorizes certified optometrists in ophthalmic surgery to perform laser and non-laser ophthalmic surgeries in which human tissue is injected, cut, burned, frozen, sutured, vaporized, coagulated, or photodisrupted by the use of surgical instrumentation, including but not limited to, a scalpel, cryoprobe, laser, electric cautery, or ionizing radiation. The bill prohibits certain surgeries. Optometrists who not meet certain requirements may not administer or prescribe topical or oral medications or perform surgery.

The bill states that the Board of Optometry has the sole authority to determine the scope of practice of optometry.

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

The bill provides an effective date of July 1, 2017.

## FULL ANALYSIS

### I. SUBSTANTIVE ANALYSIS

#### A. EFFECT OF PROPOSED CHANGES:

##### Background

##### 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.

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.<sup>1</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. 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.<sup>2</sup>

The American Council for Graduate Medical Education (ACGME)<sup>3</sup> requires each ophthalmologist resident to perform a minimum number of certain surgeries before he or she may graduate from the program. Residents must perform the following minimum number of surgeries:<sup>4</sup>

|   |    |
|---|----|
| Cataract  | 86 |
| Laser Surgery- YAG Capsulotomy                    | 5  |
| Laser Surgery - Laser Trabeculoplasty             | 5  |
| Laser Surgery – Laser Iridotomy                   | 4  |
| Laser Surgery – Panretinal Laser Photocoagulation | 10 |
| Keratoplasty                                      | 5  |
| Pterygium/Conjunctival and other cornea           | 3  |
| Keratorefractive Surgery                          | 6  |
| Strabismus  | 10 |
| Glaucoma – Filtering/Shunting Procedures          | 5  |
| Retinal Vitreous                                  | 10 |
| Intravitreal Injection                            | 10 |
| Oculoplastic and orbit– Total                     | 28 |
| Oculoplastic and orbit – Eyelid Laceration        | 3  |
| Oculoplastic and orbit – Chalazia Excision        | 3  |
| Oculoplastic and orbit – Ptosis/Blepharoplasty    | 3  |
| Globe Trauma – Total                              | 4  |

<sup>1</sup> American Optometric Association, *What is a Doctor of Optometry?*, Available at: <http://www.aoa.org/about-the-aoa/what-is-a-doctor-of-optometry?sso=y> (last visited March 10, 2017).

<sup>2</sup> American Academy of Ophthalmology, *What is an Ophthalmologist?*. Available at: <https://www.aao.org/eye-health/tips-prevention/what-is-ophthalmologist> (last visited March 10, 2017).

<sup>3</sup> ACGME sets standards for and accredits US graduate medical education (residency and fellowship) programs. Available at: <http://www.acgme.org/What-We-Do/Overview> (last visited March 15, 2017).

<sup>4</sup> ACGME Review Committee for Ophthalmology. *Frequently Asked Questions*. Available at: [https://www.acgme.org/Portals/0/PDFs/FAQ/240\\_ophthalmology\\_FAQs.pdf](https://www.acgme.org/Portals/0/PDFs/FAQ/240_ophthalmology_FAQs.pdf) (last visited March 15, 2017).

ACGME resident case logs between 2015 and 2016 showed that the average resident performed 183 cataract surgeries, 13.4 glaucoma surgeries, and 107.6 laser surgeries.

Florida law requires optometrists diagnosing a patient with certain diseases to refer such patients to “physician skilled in the diseases of the eye” (ophthalmologists) for further treatment.<sup>5</sup> Additionally, an optometrist must 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>6</sup> Optometrists must maintain the names of at least three physicians, clinics, or hospitals to which they may refer patients who experience adverse drug reactions.<sup>7</sup>

Three states, Oklahoma, Kentucky, and Louisiana, allow optometrists to perform surgical procedures.<sup>8</sup> Oklahoma has allowed optometrists to perform surgical procedures since 1988.<sup>9</sup> Oklahoma requires passage of the Laser Therapy for the Anterior Segment Course offered by Northeastern State University to become a licensed optometrist.<sup>10</sup> The course consists of 9 hours of lectures and 4 hours of laboratory sessions with hands-on training.<sup>11</sup>

Between 1988 and 1998, 5,000 laser surgeries were performed by optometrists in Oklahoma.<sup>12</sup> A review by the Oklahoma Board of Examiners in Optometry of the outcomes of those surgeries found that negative outcome rates ranged between 0.5%-1.5% and were the same as those of surgeries performed by ophthalmologists in Oklahoma.<sup>13</sup> Since 1998, 25,000 anterior laser surgeries have been performed by optometrists in Oklahoma and the Oklahoma Board of Examiners in Optometry has not received any complaints regarding those surgeries.<sup>14</sup>

A 2016 peer-reviewed study that analyzed the outcomes for laser glaucoma surgeries between 2008 and 2013 in Oklahoma found that patients were nearly twice as likely to need additional treatment when the procedure was performed by an optometrist as compared to an ophthalmologist.<sup>15</sup> The study also found there was a 189% increased risk of needing additional treatment in the eye that had been treated when the procedure was performed by an optometrist as compared to an ophthalmologist.<sup>16</sup>

Laser Glaucoma Surgery Outcomes in Oklahoma<sup>17</sup>

| Provider        | Number of eyes that received laser surgery | Number of eyes that received 1 or more additional surgeries | Probability of 1 or more additional surgeries performed during 10 days after initial surgery | Probability of 1 or more additional surgeries performed 11-30 days after initial surgery |
|-----------------|--|---|--|--|
| Ophthalmologist | 1150                                       | 174 (15%)   | 0  | 1.1%   |
| Optometrist     | 234  | 84 (35.9%)  | 0.4%   | 10.3%  |

<sup>5</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>6</sup> Section 463.0135(4), F.S.

<sup>7</sup> Section 463.0135(8), F.S.

<sup>8</sup> American Optometric Association, In Scope. Available at: <http://www.aoa.org/news/aoa-focus/novemberdecember-2014/in-scope?ss=y> (last visited on March 13, 2017).

<sup>9</sup> Testimony of Dr. April Jasper, President of the Florida Optometric Association, on file with the Health Quality Subcommittee.

<sup>10</sup> Oklahoma Board of Examiners. *Licensing*. Available at: <https://optometry.ok.gov/licensing.htm> (last visited March 15, 2017).

<sup>11</sup> Stein, J.D., et. al. *Comparison of Outcomes of Laser Trabeculoplasty Performed by Optometrists vs. Ophthalmologists in Oklahoma*. JAMA Ophthalmol. 2016;134(10):1095-1101.

<sup>12</sup> *Supra*, note 9.

<sup>13</sup> *Id.*

<sup>14</sup> *Id.*

<sup>15</sup> *Supra*, note 11.

<sup>16</sup> *Id.*

<sup>17</sup> *Id.*

## Optometrist Prescribing Authority in Florida

Currently, Florida law allows licensed optometrists to administer and prescribe drugs under limited circumstances. Licensed optometrists may only use topical anesthetics for glaucoma examinations, unless the licensed optometrist is also a certified optometrist.<sup>18</sup> Certified optometrists may administer and prescribe topical or oral 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.<sup>19</sup>

To be certified by the board to administer and prescribe topical ocular pharmaceuticals, a licensed optometrist must be complete at least 110 hours of board approved coursework and training and one year of supervised experience in differential diagnosis of eye diseases or disorders.<sup>20</sup> Certified optometrists that also wish to administer and prescribe oral ocular pharmaceutical agents must also complete a board-approved 20-hour course and examination on general and ocular pharmaceutical agents and their side effects.<sup>21</sup> If a certified optometrist does not complete the course and examination, he or she may only administer or prescribe topical ocular pharmaceutical agents as established by board rule.<sup>22</sup>

The oral ocular pharmaceutical agents a certified optometrist may administer or prescribe are specified in a statutory formulary.<sup>23</sup> The agents include seven antibiotics and three antivirals:

- Amoxicillin with or without clavulanic acid;
- Azithromycin;
- Erythromycin;
- Dicloxacillin;
- Doxycycline/Tetracycline;
- Keflex; and
- Minocycline.
- Acyclovir;
- Famciclovir; and
- Valacyclovir.

Current law prohibits a certified optometrist from administering or prescribing certain drugs for more than 72 hours, including two analgesics and two anti-glaucoma agents:

- Tramadol hydrochloride; and
- Acetaminophen 300 mg with No. 3 codeine phosphate 30 mg.
- Acetazolamide; and
- 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 to have been deleted from the statutory formulary.<sup>24</sup>

The statutory formulary prohibits the administration or prescription of a controlled substance listed in Schedule III<sup>25</sup>, Schedule IV<sup>26</sup>, or Schedule V<sup>27</sup> of s. 893.03, F.S., except for the oral analgesics

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<sup>18</sup> Section 453.0055(1)(a), F.S.; Chapter No. 2013-26, L.O.F.

<sup>19</sup> Ss. 463.0055(1)(a) and 463.002(4), F.S.

<sup>20</sup> Rule 64B13-10.001, F.A.C.

<sup>21</sup> Section 463.0055, F.S.

<sup>22</sup> Rule 64B13-18.002, F.A.C.

<sup>23</sup> Section 463.0055(3), F.S.

<sup>24</sup> Id.

specified in the statutory formulary for the relief of pain due to ocular conditions of the eye and its appendages, or a controlled substance for the treatment of chronic nonmalignant pain.<sup>28</sup>

### Optometrist Scope of Practice in Florida

Optometrists may prescribe certain medications, vision therapy, and corrective lenses, but may not perform surgical procedures in Florida.<sup>29</sup> Florida law defines surgery as 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 and also includes a procedure using an instrument which requires the closure of human tissue by suture, clamp, or a similar device.<sup>30</sup> However, certified optometrists that are authorized to administer or prescribe certain medication, may perform the following optometric practices<sup>31</sup>:

- Performing an eye examination, including a dilated examination, if required or authorized under laws related to pugilistic exhibitions<sup>32</sup>;
- 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.

### **Effect of Proposed Changes**

CS/HB 1037 amends s. 463.005, F.S. to create two separate categories of certification for licensed optometrists: “certified optometrist in pharmaceutical agents” and “certified optometrist in ophthalmic surgery.”

### Optometrist Prescribing Authority

The bill allows certified optometrists in pharmaceutical agents to administer and prescribe pharmaceutical agents. The bill retains the training and examination requirements for a certified optometrist to be able to administer or prescribe oral ocular pharmaceutical agents. The bill retains the prohibition on a licensed optometrist administering or prescribing any ocular pharmaceutical agents, except for topically applied anesthetics solely for glaucoma examinations, if he or she does not complete the required board-approved course and examination.

The bill expands the range of medications a certified optometrist can administer or prescribe to include any prescription or non-prescription drug, including approved narcotics, delivered by any route of administration that is used to treat, prevent, or mitigate abnormal conditions or diseases of the eye, its

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<sup>25</sup> Section 893.03(3), F.S. defines a Schedule II substance as a substance that has a potential for abuse less than the substances contained in Schedules I and II and has a currently accepted medical use in treatment in the United States, and abuse of the substance may lead to moderate or low physical dependence or high psychological dependence or, in the case of anabolic steroids, may lead to physical damage.

<sup>26</sup> Section 893.03(4) defines a Schedule IV substance as a substance that has a low potential for abuse relative to the substances in Schedule III and has a currently accepted medical use in treatment in the United States, and abuse of the substance may lead to limited physical or psychological dependence relative to the substances in Schedule III.

<sup>27</sup> Section 893.03(5), F.S. defines a Schedule V substance, compound, mixture or preparation that has a low potential for abuse relative to the substances in Schedule IV and has a currently accepted medical use in treatment in the United States, and abuse of such compound, mixture, or preparation may lead to limited physical or psychological dependence relative to the substances in Schedule IV.

<sup>28</sup> 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.

<sup>29</sup> Section 463.014(4), F.S.

<sup>30</sup> Section 463.002(6), F.S.

<sup>31</sup> Section 463.014(4), F.S.

<sup>32</sup> Ch. 548, F.S.

appendages and visual system. The bill repeals the statutory formulary of permitted ocular pharmaceutical agents, including both oral and topical. Instead, the bill requires the board to establish by rule a formulary of permitted topical and oral ocular pharmaceutical agents.

The bill prohibits the administration and prescription of Schedule I controlled substances by optometrists. It repeals the current law's prohibition on the administration or prescription of Schedule III, IV, and V controlled substances and controlled substances for the treatment of chronic non-malignant pain, which allows certified optometrists to administer and prescribe these drugs.

### Optometrist Scope of Practice

The bill creates a new certification category for licensed optometrists, "certified optometrists in ophthalmic surgery." To become a certified optometrist in ophthalmic surgery, the bill requires a licensed optometrist successfully complete a board-approved course and examination. The bill allows certified optometrists in ophthalmic surgery to perform laser and non-laser ophthalmic surgery. The bill defines ophthalmic surgery as any procedure performed on the human eye and its appendages and visual system in which human tissue is injected, cut, burned, frozen, sutured, vaporized, coagulated, or photodisrupted by the use of surgical instrumentation, including but not limited to, a scalpel, cryoprobe, laser, electric cautery, or ionizing radiation.

The bill also specifies certain surgical procedures that certified optometrists in ophthalmic surgery are prohibited from performing, including:

- Penetrating keratoplasty, corneal transplant, or lamellar keratoplasty.
- The administration of general anesthesia.
- Surgery done with general anesthesia.
- Laser or non-laser injection into the vitreous chamber of the eye to treat amacular or retinal disease.
- Surgery related to the removal of the eye from a living human being.
- Surgery requiring full-thickness incision or excision of the cornea or sclera, other than paracentesis in an emergency situation requiring immediate reduction of the pressure inside the eye.
- Surgery requiring incision of the iris and ciliary body, including iris diathermy or incision with cryotherapy.
- Surgery requiring incision of the vitreous.
- Surgery requiring incision of the retina.
- Surgical extraction of the crystalline lens.
- Surgical intraocular prosthetic implants.
- Incisional or excisional surgery of extraocular muscles.
- Surgery of the eyelid for suspect eyelid malignancies or for repair of, including plastic surgery for, blepharochalasis or mechanical ptosis.
- Tarsorrhaphy.
- Surgery of the boney orbit, including orbital implants.
- Incisional or excisional surgery of the lacrimal system other than lacrimal probing or related procedures.
- Surgery requiring full-thickness conjunctivoplasty with graft or flap.
- Pterygium surgery.

The bill makes the necessary conforming changes throughout Florida Statutes relating to the creation of the two new certification categories.

The bill also grants sole authority to the Board of Optometry to determine the scope of the practice of optometry which appears to prohibit any other board or entity of the state other than the Board of

Optometry from determining what constitutes the practice of optometry. It is unclear what kind of impact, if any, this language will have on the authority of the board.<sup>33</sup>

### Board Authority

The bill also grants the board the authority to issue advisory opinions and declaratory rulings related to Ch. 463 and the rules adopted thereunder. Currently, the Administrative Procedures Act, Ch. 120, F.S., governs the issuance of declaratory statements by agencies and boards. Section 120.565, F.S., allows any substantially affected person to seek a declaratory statement of an agency or board's opinion as to the applicability of a statutory provision or rule or order of the agency or board as it applies to the person's particular set of circumstances. The bill's express authority on this issue appears unnecessary.

Although the bill grants the board sole authority to determine the scope of practice of optometry, the bill authorizes the State Health Officer<sup>34</sup> to permit a licensed optometrist to prescribe, order, dispense, administer, supply, sell, or give any drug for the treatment of a systemic disease during a public health emergency pursuant to s. 381.00315, F.S.<sup>35</sup>

The bill provides an effective date of July 1, 2017.

#### B. SECTION DIRECTORY:

**Section 1:** Amends s. 463.002 relating to definitions.

**Section 2:** Amends s. 463.005 relating to the authority of the board.

**Section 3:** Amends s. 463.0055 relating to the administration and prescription of ocular pharmaceutical agents.

**Section 4:** Creates s. 463.0056 relating to the administration and performance of laser and non-laser surgical procedures.

**Section 5:** Amends s. 463.014 relating to prohibited acts.

**Section 6:** Amends s. 463.007 relating to renewal of licenses and continuing education.

**Section 7:** Amends s. 463.009 relating to supportive personnel.

**Section 8:** Amends s. 463.013 relating to optometric services for certain public agencies.

**Section 9:** Amends s. 463.0135 relating to standards of practice.

**Section 10:** Amends s. 641.31 relating to health maintenance contracts.

**Section 11:** Provides an effective date of July 1, 2017.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

#### A. FISCAL IMPACT ON STATE GOVERNMENT:

##### 1. Revenues:

None.

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<sup>33</sup> In 1998, Oklahoma's statute regulating the profession of optometry was amended to allow optometrists to perform some laser surgeries. The statute also includes language granting sole authority to the Board to determine the scope of practice of optometry. In 2004, the Oklahoma Attorney General issued an advisory opinion that regardless of this grant of authority the board did not have the authority to authorize optometrists to perform nonlaser surgical procedures. Oklahoma subsequently amended its statute to allow performance of nonlaser surgeries by optometrists. See *OKLA. ATTY. GEN. OP. 04-009 (Apr. 6, 2004)* and *OKLA. STAT. ANN. Tit. 59, § 581*.

<sup>34</sup> The State Health Officer is the State Surgeon General and is responsible for declaring public health emergencies. Section 20.43, F.S.; Section 381.00315, F.S.

<sup>35</sup> A public health emergency is any natural or manmade occurrence, or the threat of such occurrence, that results or may result in substantial injury or harm to the public health from infectious disease, chemical agents, nuclear agents, biological toxins, or situations involving mass casualties or natural disasters. During a public health emergency, the State Health Officer may take actions necessary to protect the public health, such as directing drug manufacturers to priority ship drugs to pharmacies and health care providers, temporarily reactivating inactive licenses of certain health care practitioners and ordering individuals to be examined, tested, vaccinated, treated, isolated or quarantined for communicable diseases that present a severe danger to public health.

2. Expenditures:

DOH anticipates that it will incur additional costs and workload to implement the provisions of the bill.<sup>36</sup> DOH anticipates the need for an additional Full Time Employee (FTE) position to handle the increased workload associated with regulation, complaints, investigation and communication of the new certification category created the bill for certified optometrist in ophthalmic surgery.

DOH reports that it will likely incur costs to modify its licensure system, but the fiscal impact is indeterminate at this time.

DOH will incur additional costs and workload associated with developing an application for the new certification category created by the bill for certified optometrists in ophthalmic surgery, for updating its licensure, enforcement, and continuing education databases, and for rulemaking, but current resources are adequate to absorb the costs and workload.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Licensed optometrists wanting to prescribe and administer ocular pharmaceutical agents or perform ophthalmic surgery may incur costs associated with the coursework and examination required by the bill. Such optometrists will experience increased revenues for performing such services.

Patients may experience cost-savings if they can be treated immediately by an optometrist without having to be referred to an ophthalmologist for treatment.<sup>37</sup>

D. FISCAL COMMENTS:

None.

### III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

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<sup>36</sup> Department of Health, *Bill Analysis for HB 1037(2017)*, dated February 24, 2017, on file with committee staff.

<sup>37</sup> *Supra*, note 5.



C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill grants the board the authority to issue advisory opinions or declaratory rulings related to Ch. 463 and rules adopted thereunder. It is unclear whether the issuance of such advisory opinions or declaratory rulings is subject to Ch. 120, the Administrative Procedures Act. If Ch. 120 applies, this language may be unnecessary as Ch. 120 already provides procedures for such activity by the board.

**IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES**

On March 15, 2017 the Health Quality Subcommittee adopted an amendment that added a cross-reference to s. 381.00315, F.S. which governs the declaration of public health emergencies by the State Health Officer. The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute.