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By the Committee on Health Regulation; and Senator Thrasher

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A bill to be entitled An act relating to health care; amending s. 463.002, F.S.; conforming provisions to changes made by the act; amending s. 463.005, F.S.; authorizing the Board of Optometry to adopt rules for the administration and prescription of ocular pharmaceutical agents; amending s. 463.0055, F.S.; authorizing certified optometrists to administer and prescribe pharmaceutical agents under certain circumstances; requiring that a certified optometrist complete a course and subsequent examination on general and ocular pharmacology; providing requirements for the course; requiring that the Florida Medical Association and the Florida Optometric Association jointly develop and administer the course and examination; revising qualifications of certain members of the formulary committee; providing for a formulary of topical ocular pharmaceutical agents which the committee may modify; specifying the agents that make up the statutory formulary of oral pharmaceutical agents; authorizing the deletion of an oral pharmaceutical agent listed in the statutory formulary under certain circumstances; prohibiting the board, the Department of Health, or the State Surgeon General from deleting an oral pharmaceutical agent listed in the statutory formulary; amending ss. 463.0057 and 463.006, F.S.; conforming provisions to changes made by the act; amending s. 463.0135, F.S.; requiring that a certified optometrist administer and prescribe oral ocular pharmaceutical agents in a

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certain manner; requiring that a licensed practitioner who diagnoses a patient who has a neovascular form of glaucoma or progressive glaucoma immediately refer the patient to a physician who is skilled in the diseases of the eye; requiring that comanagement of postoperative care be conducted pursuant to an established protocol; requiring that the patient be informed that a physician will be available for emergency care throughout the postoperative period; requiring that the patient consent in writing to the comanagement relationship; amending s. 463.014, F.S.; revising certain prohibited acts regarding an optometrist conducting surgery and dispensing, administering, ordering, supplying, or selling certain drugs; creating s. 463.0141, F.S.; requiring that adverse incidents in the practice of optometry be reported to the Department of Health; providing requirements for notifying the department of an adverse incident; providing a definition; requiring that the department review each incident and determine whether it involved conduct that is subject to disciplinary action; requiring that the Board of Optometry take disciplinary action if necessary; amending s. 483.035, F.S., relating to licensure and regulation of clinical laboratories operated by practitioners for exclusive use; providing applicability to clinical laboratories operated by practitioners licensed to practice optometry; amending s. 483.041, F.S.; revising the definition of the term

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"licensed practitioner" to include a practitioner licensed under ch. 463, F.S.; amending s. 483.181, F.S.; requiring clinical laboratories to accept human specimens submitted by practitioners licensed to practice under ch. 463, F.S.; amending s. 766.102, F.S.; providing that the claimant has the burden of proving by clear and convincing evidence that the actions of a health care provider represented a breach of the prevailing professional standard of care in an action for damages based on death or personal injury which alleges that the death or injury resulted from the failure of a health care provider to order, perform, or administer supplemental diagnostic tests; amending s. 766.106, F.S.; authorizing a prospective defendant to obtain informal discovery by conducting ex parte interviews of treating health care providers; requiring advance notice to the claimant of an ex parte interview; creating s. 766.1091, F.S.; authorizing a health care provider or health care clinic and a patient or prospective patient to agree to submit a current or future claim of medical negligence to arbitration; requiring that the arbitration agreement be governed by ch. 682, F.S.; authorizing the arbitration agreement to contain a provision that limits an award of damages; amending s. 893.02, F.S.; revising the definition of the term "practitioner" to include certified optometrists for purposes of the Florida Comprehensive Drug Abuse Prevention and Control Act; amending s. 893.05, F.S.;

prohibiting certified optometrists from administering and prescribing certain controlled substances; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsections (3), (4), and (5) of section 463.002, Florida Statutes, are amended to read:

463.002 Definitions.—As used in this chapter, the term:

- (3) (a) "Licensed practitioner" means a person who is a primary health care provider licensed to engage in the practice of optometry under the authority of this chapter.
- (b) A licensed practitioner who is not a certified optometrist shall be required to display at her or his place of practice a sign which states, "I am a Licensed Practitioner, not a Certified Optometrist, and I am not able to prescribe topical ocular pharmaceutical agents."
- (c) All practitioners initially licensed after July 1, 1993, must be certified optometrists.
- (4) "Certified optometrist" means a licensed practitioner authorized by the board to administer and prescribe topical ocular pharmaceutical agents.
- (5) "Optometry" means the diagnosis of conditions of the human eye and its appendages; the employment of any objective or subjective means or methods, including the administration of topical ocular pharmaceutical agents, for the purpose of determining the refractive powers of the human eyes, or any visual, muscular, neurological, or anatomic anomalies of the human eyes and their appendages; and the prescribing and

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employment of lenses, prisms, frames, mountings, contact lenses, orthoptic exercises, light frequencies, and any other means or methods, including topical ocular pharmaceutical agents, for the correction, remedy, or relief of any insufficiencies or abnormal conditions of the human eyes and their appendages.

Section 2. Paragraph (g) of subsection (1) of section 463.005, Florida Statutes, is amended to read:

463.005 Authority of the board.-

- (1) The Board of Optometry has authority to adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this chapter conferring duties upon it. Such rules shall include, but not be limited to, rules relating to:
- (g) Administration and prescription of $\frac{1}{2}$ ocular pharmaceutical agents.

Section 3. Section 463.0055, Florida Statutes, is amended to read:

- 463.0055 Administration and prescription of topical ocular pharmaceutical agents; committee.—
- (1) (a) Certified optometrists may administer and prescribe topical ocular pharmaceutical agents as provided in this section for the diagnosis and treatment of ocular conditions of the human eye and its appendages without the use of surgery or other invasive techniques. However, a licensed practitioner who is not certified may use topically applied anesthetics solely for the purpose of glaucoma examinations, but is otherwise prohibited from administering or prescribing topical ocular pharmaceutical agents.
- (b) Before a certified optometrist may administer or prescribe oral ocular pharmaceutical agents, the certified

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optometrist must complete a course and subsequent examination on general and ocular pharmacology which have a particular emphasis on the ingestion of oral pharmaceutical agents and the side effects of those agents. For certified optometrists licensed before January 1, 1990, the course shall consist of 50 contact hours and 25 of those hours shall be Internet-based. For certified optometrists licensed on or after January 1, 1990, the course shall consist of 20 contact hours and 10 of those hours shall be Internet-based. The first course and examination shall be presented by January 1, 2013, and shall thereafter be administered at least annually. The Florida Medical Association and the Florida Optometric Association shall jointly develop and administer a course and examination for such purpose and jointly determine the site or sites for the course and examination.

(2) (a) There is hereby created a committee composed of two certified optometrists licensed pursuant to this chapter, appointed by the Board of Optometry, two board-certified ophthalmologists licensed pursuant to chapter 458 or chapter 459, appointed by the Board of Medicine, and one additional person with a doctorate degree in pharmacology who is not licensed pursuant to chapter 458, chapter 459, or this chapter, appointed by the State Surgeon General. The committee shall review requests for additions to, deletions from, or modifications of a formulary of topical ocular pharmaceutical agents for administration and prescription by certified optometrists and shall provide to the board advisory opinions and recommendations on such requests. The formulary of topical ocular pharmaceutical agents shall consist of those topical ocular pharmaceutical agents that are appropriate to treat and

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diagnose ocular diseases and disorders and that which the certified optometrist is qualified to use in the practice of optometry. The board shall establish, add to, delete from, or modify the formulary by rule. Notwithstanding any provision of chapter 120 to the contrary, the formulary rule shall become effective 60 days from the date it is filed with the Secretary of State.

- (b) The <u>topical</u> formulary may be added to, deleted from, or modified according to the procedure described in paragraph (a). Any person who requests an addition, deletion, or modification of an authorized topical ocular pharmaceutical agent shall have the burden of proof to show cause why such addition, deletion, or modification should be made.
- (c) The State Surgeon General shall have standing to challenge any rule or proposed rule of the board pursuant to s. 120.56. In addition to challenges for any invalid exercise of delegated legislative authority, the administrative law judge, upon such a challenge by the State Surgeon General, may declare all or part of a rule or proposed rule invalid if it:
- 1. Does not protect the public from any significant and discernible harm or damages;
- 2. Unreasonably restricts competition or the availability of professional services in the state or in a significant part of the state; or
- 3. Unnecessarily increases the cost of professional services without a corresponding or equivalent public benefit.

However, there shall not be created a presumption of the existence of any of the conditions cited in this subsection in

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the event that the rule or proposed rule is challenged.

- (d) Upon adoption of the <u>topical</u> formulary required by this section, and upon each addition, deletion, or modification to the <u>topical</u> formulary, the board shall mail a copy of the amended <u>topical</u> formulary to each certified optometrist and to each pharmacy licensed by the state.
- (3) In addition to the formulary of topical ocular pharmaceutical agents in subsection (2), there is created a statutory formulary of oral pharmaceutical agents, which include the following agents:
- (a) The following analgesics, or their generic or therapeutic equivalents, which may not be administered or prescribed for more than 72 hours without consultation with a physician licensed under chapter 458 or chapter 459 who is skilled in diseases of the eye:
 - 1. Tramadol hydrochloride.
 - 2. Acetaminophen 300 mg with No. 3 codeine phosphate 30 mg.
- (b) The following antibiotics, or their generic or therapeutic equivalents:
 - 1. Amoxicillin.
 - 2. Azithromycin.
 - 3. Ciproflaxacin.
- 4. Dicloxacillin.
- 5. Doxycycline.
- 228 6. Keflex.
- 7. Minocycline.
- (c) The following antivirals, or their generic or
- 231 therapeutic equivalents:
- 232 1. Acyclovir.

- 2. Famciclovir.
 - 3. Valacyclovir.
 - (d) The following oral anti-glaucoma agents, or their generic or therapeutic equivalents, which may not be administered or prescribed for more than 72 hours without consultation with a physician licensed under chapter 458 or chapter 459 who is skilled in diseases of the eye:
 - 1. Acetazolamide.
 - 2. Methazolamide.

Any oral pharmaceutical agent that is listed in the statutory formulary set forth in this subsection and that is subsequently determined by the United States Food and Drug Administration to be unsafe for administration or prescription shall be considered to have been deleted from the formulary of oral pharmaceutical agents. The oral pharmaceutical agents on the statutory formulary set forth in this subsection may not otherwise be deleted by the board, the department, or the State Surgeon General.

(4)(3) A certified optometrist shall be issued a prescriber number by the board. Any prescription written by a certified optometrist for a topical ocular pharmaceutical agent pursuant to this section shall have the prescriber number printed thereon.

Section 4. Subsection (3) of section 463.0057, Florida Statutes, is amended to read:

463.0057 Optometric faculty certificate.

(3) The holder of a faculty certificate may engage in the practice of optometry as permitted by this section, but may not

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administer or prescribe topical ocular pharmaceutical agents unless the certificateholder has satisfied the requirements of ss. 463.0055(1) (b) and s. 463.006(1) (b) 4. and 5.

Section 5. Subsections (2) and (3) of section 463.006, Florida Statutes, are amended to read:

463.006 Licensure and certification by examination.-

- (2) The examination shall consist of the appropriate subjects, including applicable state laws and rules and general and ocular pharmacology with emphasis on the <u>use topical</u> application and side effects of ocular pharmaceutical agents. The board may by rule substitute a national examination as part or all of the examination and may by rule offer a practical examination in addition to the written examination.
- (3) Each applicant who successfully passes the examination and otherwise meets the requirements of this chapter is entitled to be licensed as a practitioner and to be certified to administer and prescribe topical ocular pharmaceutical agents in the diagnosis and treatment of ocular conditions.

Section 6. Subsections (1) and (2) of section 463.0135, Florida Statutes, are amended, and subsection (10) is added to that section, to read:

463.0135 Standards of practice.-

(1) A licensed practitioner shall provide that degree of care which conforms to that level of care provided by medical practitioners in the same or similar communities. A certified optometrist shall administer and prescribe oral ocular pharmaceutical agents in a manner consistent with applicable preferred practice patterns of the American Academy of Ophthalmology. A licensed practitioner shall advise or assist

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her or his patient in obtaining further care when the service of another health care practitioner is required.

- (2) A licensed practitioner diagnosing angle closure, neovascular, infantile, or congenital forms of glaucoma shall promptly and without unreasonable delay refer the patient to a physician skilled in diseases of the eye and licensed under chapter 458 or chapter 459. In addition, a licensed practitioner shall timely refer any patient who experiences progressive glaucoma due to failed pharmaceutical intervention to a physician who is skilled in diseases of the eye and licensed under chapter 458 or chapter 459.
- (10) Comanagement of postoperative care shall be conducted pursuant to an established protocol that governs the relationship between the operating surgeon and the optometrist. The patient shall be informed that either physician will be available for emergency care throughout the postoperative period, and the patient shall consent in writing to the comanagement relationship.

Section 7. Subsections (3) and (4) of section 463.014, Florida Statutes, are amended to read:

463.014 Certain acts prohibited.-

- (3) Prescribing, ordering, dispensing, administering, supplying, selling, or giving any systemic drugs for the purpose of treating a systemic disease by a licensed practitioner is prohibited. However, a certified optometrist is permitted to use commonly accepted means or methods to immediately address incidents of anaphylaxis.
- (4) Surgery of any kind, including the use of lasers, is expressly prohibited. For purposes of this subsection, the term

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"surgery" means a procedure using an instrument, including lasers, scalpels, or needles, in which human tissue is cut, burned, or vaporized by incision, injection, ultrasound, laser, or radiation. The term includes procedures using instruments that require closing by suturing, clamping, or another such device. Certified optometrists may remove superficial foreign bodies. For the purposes of this subsection, the term "superficial foreign bodies" means any foreign matter that is embedded in the conjunctiva or cornea but which has not penetrated the globe.

Section 8. Section 463.0141, Florida Statutes, is created to read:

- $\underline{\text{463.0141}}$ Reports of adverse incidents in the practice of optometry.—
- (1) Any adverse incident that occurs on or after January 1, 2013, in the practice of optometry must be reported to the department in accordance with this section.
- (2) The required notification to the department must be submitted in writing by certified mail and postmarked within 15 days after the occurrence of the adverse incident.
- (3) For purposes of notification to the department, the term "adverse incident," as used in this section, means an event that is associated in whole or in part with the prescribing of an oral ocular pharmaceutical agent and that results in one of the following:
- (a) Any condition that requires the transfer of a patient to a hospital licensed under chapter 395;
- (b) Any condition that requires the patient to obtain care from a physician licensed under chapter 458 or chapter 459,

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other than a referral or a consultation required under this chapter;

- (c) Permanent physical injury to the patient;
- (d) Partial or complete permanent loss of sight by the patient; or
 - (e) Death of the patient.
- (4) The department shall review each incident and determine whether it potentially involved conduct by the licensed practitioner which may be subject to disciplinary action, in which case s. 456.073 applies. Disciplinary action, if any, shall be taken by the board.
- Section 9. Subsection (1) of section 483.035, Florida Statutes, is amended to read:
- 483.035 Clinical laboratories operated by practitioners for exclusive use; licensure and regulation.—
- (1) A clinical laboratory operated by one or more practitioners licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, or chapter 466, exclusively in connection with the diagnosis and treatment of their own patients, must be licensed under this part and must comply with the provisions of this part, except that the agency shall adopt rules for staffing, for personnel, including education and training of personnel, for proficiency testing, and for construction standards relating to the licensure and operation of the laboratory based upon and not exceeding the same standards contained in the federal Clinical Laboratory Improvement Amendments of 1988 and the federal regulations adopted thereunder.
 - Section 10. Subsection (7) of section 483.041, Florida

Statutes, is amended to read:

483.041 Definitions.—As used in this part, the term:

(7) "Licensed practitioner" means a physician licensed under chapter 458, chapter 459, chapter 460, or chapter 461, or chapter 463; a dentist licensed under chapter 466; a person licensed under chapter 462; or an advanced registered nurse practitioner licensed under part I of chapter 464; or a duly licensed practitioner from another state licensed under similar statutes who orders examinations on materials or specimens for nonresidents of the State of Florida, but who reside in the same state as the requesting licensed practitioner.

Section 11. Subsection (5) of section 483.181, Florida Statutes, is amended to read:

483.181 Acceptance, collection, identification, and examination of specimens.—

(5) A clinical laboratory licensed under this part must accept a human specimen submitted for examination by a practitioner licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, s. 464.012, or chapter 466, if the specimen and test are the type performed by the clinical laboratory. A clinical laboratory may only refuse a specimen based upon a history of nonpayment for services by the practitioner. A clinical laboratory shall not charge different prices for tests based upon the chapter under which a practitioner submitting a specimen for testing is licensed.

Section 12. Subsection (4) of section 766.102, Florida Statutes, is amended to read:

766.102 Medical negligence; standards of recovery; expert witness.—

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(4) (a) The Legislature is cognizant of the changing trends and techniques for the delivery of health care in this state and the discretion that is inherent in the diagnosis, care, and treatment of patients by different health care providers. The failure of a health care provider to order, perform, or administer supplemental diagnostic tests <u>is shall</u> not be actionable if the health care provider acted in good faith and with due regard for the prevailing professional standard of care.

(b) The claimant has the burden of proving by clear and convincing evidence that the alleged actions of the health care provider represent a breach of the prevailing professional standard of care in an action for damages based on death or personal injury which alleges that the death or injury resulted from the failure of a health care provider to order, perform, or administer supplemental diagnostic tests.

Section 13. Paragraph (b) of subsection (6) of section 766.106, Florida Statutes, is amended to read:

766.106 Notice before filing action for medical negligence; presuit screening period; offers for admission of liability and for arbitration; informal discovery; review.—

- (6) INFORMAL DISCOVERY.-
- (b) Informal discovery may be used by a party to obtain unsworn statements, the production of documents or things, and physical and mental examinations, and ex parte interviews, as follows:
- 1. Unsworn statements.—Any party may require other parties to appear for the taking of an unsworn statement. Such statements may be used only for the purpose of presuit screening

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and are not discoverable or admissible in any civil action for any purpose by any party. A party desiring to take the unsworn statement of any party must give reasonable notice in writing to all parties. The notice must state the time and place for taking the statement and the name and address of the party to be examined. Unless otherwise impractical, the examination of any party must be done at the same time by all other parties. Any party may be represented by counsel at the taking of an unsworn statement. An unsworn statement may be recorded electronically, stenographically, or on videotape. The taking of unsworn statements is subject to the provisions of the Florida Rules of Civil Procedure and may be terminated for abuses.

- 2. Documents or things.—Any party may request discovery of documents or things. The documents or things must be produced, at the expense of the requesting party, within 20 days after the date of receipt of the request. A party is required to produce discoverable documents or things within that party's possession or control. Medical records shall be produced as provided in s. 766.204.
- 3. Physical and mental examinations.—A prospective defendant may require an injured claimant to appear for examination by an appropriate health care provider. The prospective defendant shall give reasonable notice in writing to all parties as to the time and place for examination. Unless otherwise impractical, a claimant is required to submit to only one examination on behalf of all potential defendants. The practicality of a single examination must be determined by the nature of the claimant's condition, as it relates to the liability of each prospective defendant. Such examination report

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is available to the parties and their attorneys upon payment of the reasonable cost of reproduction and may be used only for the purpose of presuit screening. Otherwise, such examination report is confidential and exempt from the provisions of s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

- 4. Written questions.—Any party may request answers to written questions, the number of which may not exceed 30, including subparts. A response must be made within 20 days after receipt of the questions.
- 5. Unsworn statements of treating health care providers.—A prospective defendant or his or her legal representative may also take unsworn statements of the claimant's treating health care providers. The statements must be limited to those areas that are potentially relevant to the claim of personal injury or wrongful death. Subject to the procedural requirements of subparagraph 1., a prospective defendant may take unsworn statements from a claimant's treating physicians. Reasonable notice and opportunity to be heard must be given to the claimant or the claimant's legal representative before taking unsworn statements. The claimant or claimant's legal representative has the right to attend the taking of such unsworn statements.
- 6. Ex parte interviews of treating health care providers.—A prospective defendant or his or her legal representative may interview the claimant's treating health care providers without the presence of the claimant or the claimant's legal representative. If a prospective defendant or his or her legal representative intends to interview a claimant's health care providers, the prospective defendant must provide the claimant with notice of such interview at least 10 days before the date

494 of the interview.

Section 14. Section 766.1091, Florida Statutes, is created to read:

766.1091 Voluntary binding arbitration; damages.-

- (1) A health care provider licensed under chapter 458, chapter 459, chapter 463, or chapter 466; any entity owned in whole or in part by a health care provider licensed under chapter 458, chapter 459, chapter 463, or chapter 466; or any health care clinic licensed under part X of chapter 400, and a patient or prospective patient, may agree in writing to submit to arbitration any claim for medical negligence which may currently exist or may accrue in the future and would otherwise be brought pursuant to this chapter. Any arbitration agreement entered into pursuant to this section shall be governed by chapter 682.
- (2) Any arbitration agreement entered into pursuant to subsection (1) may contain a provision that limits the available damages in an arbitration award.

Section 15. Subsection (21) of section 893.02, Florida Statutes, is amended to read:

- 893.02 Definitions.—The following words and phrases as used in this chapter shall have the following meanings, unless the context otherwise requires:
- (21) "Practitioner" means a physician licensed pursuant to chapter 458, a dentist licensed pursuant to chapter 466, a veterinarian licensed pursuant to chapter 474, an osteopathic physician licensed pursuant to chapter 459, a naturopath licensed pursuant to chapter 462, a certified optometrist licensed under chapter 463, or a podiatric physician licensed

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pursuant to chapter 461, provided such practitioner holds a valid federal controlled substance registry number.

Section 16. Subsection (1) of section 893.05, Florida Statutes, is amended to read:

893.05 Practitioners and persons administering controlled substances in their absence.—

(1) A practitioner, in good faith and in the course of his or her professional practice only, may prescribe, administer, dispense, mix, or otherwise prepare a controlled substance, or the practitioner may cause the same to be administered by a licensed nurse or an intern practitioner under his or her direction and supervision only. A veterinarian may so prescribe, administer, dispense, mix, or prepare a controlled substance for use on animals only, and may cause it to be administered by an assistant or orderly under the veterinarian's direction and supervision only. A certified optometrist licensed under chapter 463 may not administer or prescribe pharmaceutical agents in Schedule I or Schedule II of the Florida Comprehensive Drug Abuse Prevention and Control Act.

Section 17. This act shall take effect July 1, 2012.