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 Judiciary Committee

BILL:	CS/SB 1506
INTRODUCER:	Health Regulation Committee and Senator Thrasher
SUBJECT:	Health Care
DATE:	February 15, 2012 REVISED: 2/16/12

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Wilson	Stovall	HR	**Fav/CS**
2.	O'Connor	Cibula	JU	**Favorable**
3.			BC	
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:

The bill authorizes certified optometrists to administer and prescribe oral, in addition to topical, ocular medications related to the diagnosis and treatment of ocular conditions. Certified optometrists are authorized to prescribe controlled substances other than Schedule I or II substances, if they hold a valid federal controlled substance registry number. Before a certified optometrist may administer or prescribe oral ocular medications, he or she must complete a course and subsequent examination on general and ocular pharmacology.

The bill alters the composition of the committee that maintains the formulary of topical drugs certified optometrists are permitted to prescribe to specify that the two optometrists on the committee must be certified optometrists. The bill creates a statutory formulary of oral ocular medications that certified optometrists may prescribe. The standards of practice of optometry are amended to include requirements related to the administration and prescription of oral ocular medications, co-management of post-operative care, and referral of patients to physicians in certain situations. The bill also requires optometrists to report adverse incidents to the Department of Health.

With respect to clinical laboratories, the bill includes optometrists in the list of licensed practitioners who are permitted to operate such laboratories, adds optometrists to the definition of licensed practitioner, and requires laboratories to accept specimens for examination from optometrists.

The bill changes the burden of proof for a claimant in an action alleging a breach of the prevailing professional standard of care in an action for damages based on death or personal injury that allegedly resulted from the failure of a health care provider to order, perform, or administer supplemental diagnostic tests. The burden of proof is increased from a greater weight of the evidence to clear and convincing evidence.

The bill also authorizes a prospective defendant, or his or her legal representative, to conduct ex parte interviews of the claimant's treating health care providers without the presence of the claimant or the claimant's legal representative. Notice of any intended interviews must be provided to the claimant at least 10 days before the date of the interview.

The bill authorizes certain health care providers and a patient or prospective patient to agree in writing to submit to arbitration any claim for medical negligence which may currently exist or which may accrue in the future which would otherwise be brought under ch. 766, F.S., relating to medical malpractice. An arbitration agreement entered into under this section would be governed by the Florida Arbitration Code. Such an arbitration agreement may contain a provision that would limit the available damages in any arbitration award.

This bill substantially amends the following sections of the Florida Statutes: 463.002, 463.005, 463.0055, 463.0057, 463.006, 463.0135, 463.014, 483.035, 483.041, 483.181, 766.102, 766.106, 893.02, and 893.05. The bill creates ss. 463.0141 and 766.1091, F.S.

II. Present Situation:

Optometrists and Ophthalmologists

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

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.[2]

Ophthalmologists are medical physicians who specialize in diseases of the eye. Ophthalmologists provide a full spectrum of eye care, from prescribing corrective lenses and other medications to performing eye surgery. Ophthalmologists also care for patients with more advanced and complicated diseases than do optometrists. Ophthalmologist training involves an undergraduate

[1] Section 463.014(4), F.S.
[2] American Optometric Association, *What is a Doctor of Optometry?* Found at: <http://www.aoa.org/x4891.xml> (Last visited on February 10, 2102).

degree, 4 years of medical school, and completion of at least 4 years of residency training in ophthalmology.[3]

Florida law requires optometrists who diagnose patients with certain diseases to refer such patients to ophthalmologists for further treatment.[4] 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.[5]

Administration of Medications by Optometrists

Licensed optometrists may administer and prescribe topical ocular pharmaceutical agents if they are appropriately certified by the Board of Optometry (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. Medications approved for prescription by certified optometrists are listed in a formulary maintained by the board.[6,7]

To be certified for prescribing privileges, an optometrist must satisfy all of the following:[8]

- Complete at least 100 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 1 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.[9]
- Pay a $500 fee.[10]

Certification for prescribing privileges is a required component of the general licensure process for optometrists and has been so for the last 25 years.[11, 12] Optometrists who are not certified may use topical anesthetics for glaucoma examinations.[13]

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[3] American Academy of Ophthalmology, *About Ophthalmology and Eye M.D.s*. Found at: <http://www.aao.org/about/eyemds.cfm> (Last visited on February 10, 2012).
[4] 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.
[5] Section 463.0135, F.S.
[6] Section 463.0055, F.S.
[7] The formulary is listed in Rule 64B13-18.002, F.A.C., and includes agents to dilate and constrict pupils, local anesthetics, antibiotics, anti-inflammatory agents, antihistamines, antivirals, and anti-glaucoma medications. All medications are for topical ocular use only.
[8] Rule 64B13-10.001, F.A.C.
[9] This examination consists of 60 simulated patient cases to assess the examinee's performance in clinical practice situations. Found at: <http://www.optometry.org/part_2_pam.cfm> (Last visited on February 10, 2012).
[10] Rule 64B13-6.001(9), F.A.C.
[11] Section 463.006, F.S.
[12] Department of Health, *2012 Bill Analysis, Economic Statement, and Fiscal Note for SB 788*. A copy is on file with the Senate Health Regulation Committee.
[13] Section 463.0055(1), F.S.

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. ss. 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.[14]

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. Prescribing numbers must be renewed every 3 years.[15]

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.[16]

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.[17] Practitioners authorized to operate their own clinical laboratories exclusively to diagnose and treat their own patients are physicians, chiropractors, podiatrists, naturopaths, and dentists.

[14] DEA, Office of Diversion Control, *Controlled Substance Schedules.* Found at: <http://www.deadiversion.usdoj.gov/schedules/#define> (Last visited on February 10, 2012).
[15] DEA, *Questions and Answers.* Found at: <http://www.deadiversion.usdoj.gov/drugreg/faq.htm> (Last visited on February 10, 2012).
[16] Sections 893.02 and 893.05, F.S.
[17] Section 483.041, F.S.

Laboratories must be biennially licensed and inspected by the Agency for Health Care Administration to ensure quality standards in examination of specimens, equipment, sanitation, staffing, and other measures.[18]

A clinical laboratory may examine human specimens at the request of the following licensed practitioners:[19]

- 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.

Standard of Proof in Medical Malpractice Actions

In any action for recovery of damages based on the death or personal injury of any person in which it is alleged that the death or injury resulted from the negligence of a health care provider, the claimant has the burden of proving by the greater weight of evidence that the alleged action of the health care provider represented a breach of the prevailing professional standard of care for that health care provider. The prevailing professional standard of care is that level of care, skill, and treatment which, in light of all relevant surrounding circumstances, is recognized as acceptable and appropriate by reasonably prudent similar health care providers.[20] Nevertheless, s. 766.102(4), F.S., provides that the "failure of a health care provider to order, perform, or administer supplemental diagnostic tests shall not be actionable if the health care provider acted in good faith and with due regard for the prevailing professional standard of care."

Greater weight of the evidence means the "more persuasive and convincing force and effect of the entire evidence in the case."[21] Other statutes, such as license disciplinary statutes involving the revocation or suspension of a license, require a heightened standard of proof called "clear and convincing evidence."[22] Clear and convincing evidence has been described as follows:

> [C]lear and convincing evidence requires that the evidence must be found to be credible; the facts to which the witnesses testify must be distinctly remembered; the testimony

[18] Section 483.051, F.S.
[19] Section 483.181, F.S.
[20] Section 766.102, F.S.
[21] *Castillo v. E.I. Du Pont De Nemours & Co., Inc.*, 854 So. 2d 1264, 1277 (Fla. 2003).
[22] *See e.g.*, ss. 458.331(3), and 459.015(3), F.S.

> must be precise and explicit and the witnesses must be lacking in confusion as to the facts in issue. The evidence must be of such weight that it produces in the mind of the trier of fact a firm belief or conviction, without hesitancy, as to the truth of the allegations sought to be established.[23]

Medical Malpractice Presuit Investigation

Prior to the filing of a lawsuit, the person allegedly injured by medical negligence or a party bringing a wrongful death action arising from an alleged incidence of medical malpractice (the claimant) and the defendant (the health care professional or health care facility) are required to conduct presuit investigations to determine whether medical negligence occurred and what damages, if any, are appropriate.

The claimant is required to conduct an investigation[24] to ascertain that there are reasonable grounds to believe that:

- A named defendant in the litigation was negligent in the care or treatment of the claimant; and
- The claimant was injured as the result of negligence.

After completion of the presuit investigation and prior to filing a complaint for medical negligence, a claimant shall notify each prospective defendant of intent to initiate litigation for medical negligence.[25] Notice to each prospective defendant must include, if available, a list of all known health care providers seen by the claimant for the injuries complained of subsequent to the alleged act of negligence, all known health care providers during the 2-year period prior to the alleged act of negligence who treated or evaluated the claimant, copies of all of the medical records relied upon by the expert in signing the affidavit, and an executed authorization for release of protected health information. The presuit notice is void if this authorization does not accompany the presuit notice.[26]

A suit may not be filed for a period of 90 days after notice is mailed to any prospective defendant. The statue of limitations is tolled during the 90-day period. During the 90-day period, the prospective defendant or the defendant's insurer or self-insurer shall conduct a presuit investigation to determine the liability of the defendant.

Before the defendant issues his or her response, the defendant or his or her insurer or self-insurer is required to ascertain whether there are reasonable grounds to believe that:

- The defendant was negligent in the care or treatment of the claimant; and
- The claimant was injured as a result of negligence.

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[23] *Inquiry Concerning Davey*, 645 So. 2d 398, 404 (Fla. 1994) (quoting *Slomowitz v. Walker*, 429 So. 2d 797, 800 (Fla. 4th DCA 1983)).
[24] Section 766.203, F.S.
[25] Section 766.106, F.S.
[26] Section 766.1065(1), F.S. If the authorization is revoked, the presuit notice is deemed retroactively void from the date of issuance, and any tolling effect that the presuit notice may have had on any applicable statute-of-limitations period is retroactively rendered void.

Corroboration of the lack of reasonable grounds for medical negligence litigation must be provided by submission of a verified written medical expert opinion which corroborates reasonable grounds for lack of negligent injury sufficient to support the response denying negligent injury.

At or before the end of the 90 days, the prospective defendant or the prospective defendant's insurer or self-insurer shall provide the claimant with a response:

- Rejecting the claim;
- Making a settlement offer; or
- Making an offer to arbitrate in which liability is deemed admitted and arbitration will be held only on the issue of damages. This offer may be made contingent upon a limit of general damages.

Failure of the prospective defendant, insurer, or self-insurer to reply to the notice within 90 days after receipt is deemed a final rejection of the claim for purposes of this provision.

Discovery and Admissibility of Evidence

Statements, discussions, written documents, reports, or other work product generated by the presuit screening process are not discoverable or admissible in any civil action for any purpose by the opposing party.[27] All participants, including, but not limited to, physicians, investigators, witnesses, and employees or associates of the defendant, are immune from civil liability arising from participation in the presuit screening process.[28]

Upon receipt by a prospective defendant of a notice of claim, the parties are required to make discoverable information available without undertaking formal discovery. Informal discovery may be used to obtain unsworn statements, the production of documents or things, and physical and mental examinations as follows:[29]

- Unsworn statements – Any party may require other parties to appear for the taking of an unsworn statement. Unsworn statements may be used only for the purpose of presuit screening and are not discoverable or admissible in any civil action for any purpose by any party.
- Documents or things – Any party may request discovery of documents or things. This includes medical records.
- Physical and mental examination – A prospective defendant may require an injured claimant to be examined by an appropriate health care provider. Unless otherwise impractical, a claimant is required to submit to only one examination on behalf of all potential defendants. The examination report is available to the parties and their attorneys and may be used only for the purpose of presuit screening. Otherwise the examination is confidential.
- Written questions – Any party may request answers to written questions.

[27] However, the presuit expert witness opinions are subject to discovery under s. 766.203(4), F.S.
[28] Section 766.106(5), F.S.
[29] Section 766.106(6), F.S.

- Unsworn statements of treating health care providers – The statements must be limited to those areas that are potentially relevant to the claim. Reasonable notice and an opportunity to be heard must be given to the claimant before taking unsworn statements. The claimant, or claimant's legal representative, has the right to attend the taking of these unsworn statements.

The failure to cooperate on the part of any party during the presuit investigation may be grounds to strike any claim made, or defense raised in the suit.[30]

Arbitration Generally

For many years, courts and legislatures have utilized arbitration as an alternative method to resolve disputes between parties in an expedient, efficient, and inexpensive manner.[31] However, when parties agree to participate in arbitration, they concede some of the safeguards that are traditionally afforded to those who proceed to court, one of which is the right to have the evidence weighed in accordance with established legal principles.[32] Arbitration may be defined as "a process that allows parties voluntarily to refer their disputes to an impartial third person, an arbitrator, selected by them to determine the parties' rights and liabilities."[33] Typically, a decision rendered by arbitrators is as binding and conclusive as the judgment of a court.[34] Because of the federal policy favoring and encouraging the use of arbitration to resolve disputes, the use of pre-dispute arbitration agreements has expanded beyond use in commercial contexts between large businesses and those with equal bargaining power, to use in many noncommercial consumer contracts.[35]

Florida Arbitration Code

Florida traditionally has favored arbitration. In 1957, the Legislature enacted the Florida Arbitration Code (FAC),[36] which prescribes a framework governing the rights and procedures under arbitration agreements, including the enforceability of arbitration agreements. The FAC governs arbitration clauses where interstate commerce is not implicated.[37] The FAC governs the arbitration process in its entirety, including, but not limited to the scope and enforceability of arbitration agreements, the appointment of arbitrators, the arbitration hearing process and procedure, the entry and enforcement of arbitration awards, and appeals.

Under the FAC, Florida courts have held that the determination of whether any dispute is subject to arbitration should be resolved in favor of arbitration.[38] A court's role in deciding whether to compel arbitration is limited to three gateway issues to determine the enforceability of an arbitration agreement: (1) whether a valid written agreement to arbitrate exists; (2) whether an

[30] Section 766.106(7), F.S.
[31] Elizabeth K. Stanley, *Parties' Defenses to Binding Arbitration Agreements in the Health Care Field & the Operation of the McCarran-Ferguson Act*, 38 ST. MARY'S L.J. 591, 591-92 (2007).
[32] *Affiliated Marketing, Inc. v. Dyco Chemicals & Coatings, Inc*., 340 So. 2d 1240 (Fla. 2d DCA 1976).
[33] Stanley, *supra* note 31, at 592 (internal citations omitted).
[34] *Capital Factors, Inc. v. Alba Rent-A-Car, Inc*., 965 So. 2d 1178, 1182 (Fla. 4th DCA 2007).
[35] Stanley, *supra* note 31, at 592.
[36] *See* ch. 682. F.S.
[37] *O'Keefe Architects, Inc. v. CED Construction Partners, Ltd.*, 944 So. 2d 181, 184 (Fla. 2006).
[38] Michael Cavendish, *The Concept of Arbitrability Under the Florida Arbitration Code*, 82 FLA. B.J. 18, 20 (Nov. 2008) (citing *Waterhouse Constr. Group, Inc. v. 5891 S.W. 64th Street, LLC*, 949 So. 2d 1095, 1099 (Fla. 3d DCA 2007)).

arbitrable issue exists; and (3) whether the right to arbitration has been waived.[39] The FAC applies in arbitration cases only to the extent that it is not in conflict with federal law.[40]

Voluntary Binding Arbitration

Section 766.207, F.S., related to medical malpractice, establishes a procedure for voluntary binding arbitration of damages upon the completion of presuit investigation with preliminary reasonable grounds for a medical negligence claim. A proceeding for voluntary binding arbitration is an alternative to jury trial and does not supersede the right of any party to a jury trial.[41] Either party may initiate the election for voluntary binding arbitration of damages. A claimant's offer to arbitrate must be made to each defendant and each defendant's offer to arbitrate must be made to each claimant.[42] The arbitration panel's decision is subject to the limitations on damages that are provided in s. 766.207, F.S.

If the defendant refuses a claimant's offer of voluntary binding arbitration and the claimant proves medical negligence, the claimant is entitled to recover damages subject to the limitations in s. 766.118, F.S., prejudgment interest, and reasonable attorney's fees up to 25 percent of the award reduced to present value. If a claimant rejects a defendant's offer of voluntary binding arbitration, the damages awardable at trial are limited to net economic damages, plus noneconomic damages not to exceed $350,000 per incident.[43]

Arbitration Agreements in Contracts for Medical Services

Insurance companies and physicians are more frequently requiring patients to enter into arbitration agreements regarding any potential medical malpractice claims resulting from the medical treatment or care.[44] Therefore, some patients may face a choice when seeking medical treatment or care—sign an arbitration agreement or forego treatment with a particular physician or other health care provider.[45] These arbitration agreements may apply to all medical negligence and professional malpractice claims arising out of the physician-patient relationship, and bind the patient, as well as the spouse and heirs of the patient.[46]

Some patients have challenged the enforceability of arbitration agreements in this context by asserting that the agreements are void as against public policy, are too broad, are essentially contracts of adhesion, and are unconscionable.[47] Generally, courts will closely scrutinize

[39] *Seifert v. U.S. Home Corp*., 750 So. 2d 633, 636 (Fla. 1999).
[40] *Powertel, Inc. v. Bexley*, 743 So. 2d 570, 573 (Fla. 1st DCA 1999), *review denied*, 763 So. 2d 1044 (Fla. 2000), and *Florida Power Corp. v. Casselberry*, 793 So. 2d 1174, 1179 (Fla. 5th DCA 2001).
[41] Section 766.209, F.S.
[42] Section 766.207(7)(k), F.S.
[43] Section 766.209, F.S.
[44] Jennifer Gillespie, *Physician-Patient Arbitration Agreements: Procedural Safeguards May Not Be Enough*, 1997 J. DISP. RESOL. 119, 119 (1997).
[45] *Id*.
[46] *Id*. at 120.
[47] *See Buraczynski v. Eyring*, 919 S.W.2d 314 (Tenn. 1996). In *Buraczynski*, a patient signed an arbitration agreement in the context of medical services prior to a knee-replacement operation. The agreement covered all medical negligence and malpractice claims arising out of the surgery, and provided that the patient would have 30 days to revoke the agreement by providing written notice to the physician. After a challenge by the patient's heirs to avoid participation in arbitration, the Tennessee Supreme Court found that the agreement was consistent with public policy, was not overly broad, and was an

physician-patient arbitration agreements under general contract principles to determine if the agreements are unenforceable contracts of adhesion.[48] In *Jonathan M. Frantz, M.D., P.A. v. Shedden*, a Florida eye patient brought a medical malpractice action against an eye clinic after complication arose from elective eye surgery.[49] The eye clinic moved to stay litigation and enforce arbitration. During a preoperative visit, the plaintiff had signed an arbitration agreement that was separate from other documents, was afforded the opportunity to review the agreement, and was advised that he could ask staff questions regarding the agreement. The court concluded that, because the agreement was neither procedurally nor substantively unconscionable, the litigation should be stayed in favor of arbitration.[50] In a recent First District Court of Appeal case, the court found that the arbitration clause in question afforded meaningful relief and was consistent with the legislative intent of ch. 766, F.S., which "imposes limitations on non-economic damages, and provides for arbitration as a means of dispute resolution."[51]

Medical Malpractice Insurance & Claims

The Office of Insurance Regulation (OIR) publishes a report annually on medical malpractice insurance and claims.[52] According to the most recent report of 2010 data that was published on October 1, 2011:

- In 2010, the Florida medical malpractice insurance companies reported 2,520 closed claims in Florida. This continues the annual decline in the number of closed claims reported by Florida medical malpractice insurance companies. For 2009, 2087 closed claims were reported; for 2008, 3,336 were reported; for 2007, 3,553 were reported; and for 2006, 3,811 closed claims were reported. [53]
- As in previous reports, the most commonly reported claims location was hospital inpatient facilities with 1,204 claims closed. The emergency room ranked third in the injury location with 318 closed claims (see page 44).

III. Effect of Proposed Changes:

Section 1 amends s. 463.002, F.S., to allow certified optometrists to administer and prescribe oral medications related to the diagnosis and treatment of ocular conditions, not just those which are topically applied to the eye.

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enforceable adhesion contract because it was supported by consideration and was not oppressive or unconscionable. *Id.* at 321.

[48] *See Broemmer v. Abortion Services of Phoenix Ltd.*, 840 P.2d 1013 (Ariz. 1992); *Leong by Leong v. Kaiser Foundation Hosp.*, 788 P.2d 164 (Haw. 1990); and *Obstetrics and Gynecologists William G. Wixted, M.D., Patrick M. Flanagan, M.D., William F. Robinson, M.D. Ltd. v. Pepper*, 693 P.2d 1259 (Nev. 1985).

[49] *Jonathan M. Frantz, M.D., P.A. v. Shedden*, 974 So. 2d 1193 (Fla. 2d DCA 2008).

[50] *Id*. at 1198.

[51] *Franks v. Bowers*, 62 So. 3d 16, 18 (Fla 1st DCA 2011), *cert. granted*, 74 So. 3d 1083(2011).

[52] Florida OIR 2011 Annual Report – October 1, 2011 *Medical Malpractice Financial Information Closed Claim Database and Rate Filings*, available at: <http://www.floir.com/siteDocuments/MedicalMalReport10012011.pdf > (Last visited on February 8, 2012).

[53] Florida OIR 2010 Annual Report – October 1, 2010 *Medical Malpractice Financial Information Closed Claim Database and Rate Filings*, available at: < http://www.floir.com/siteDocuments/MedicalMalReport10012010.pdf> (Last visited on February 10, 2012). *See also* Senate Bill *Analysis and Fiscal Impact Statement for SB 1474* (2010), available at: <http://archive.flsenate.gov/session/index.cfm?BI_Mode=ViewBillInfo&Mode=Bills&ElementID=JumpToBox&SubMenu=1&Year=2010&billnum=1474> (Last visited on February 10, 2012).

Section 2 amends s. 463.005, F.S., to allow the Board of Optometry to promulgate rules related to administration of all ocular pharmaceutical agents, not only topical agents.

Section 3 amends s. 463.0055, F.S., to require a certified optometrist, before he or she prescribes oral pharmaceutical agents, to complete a course and subsequent examination on general and ocular pharmacology with particular emphasis on the ingestion and side effects of oral pharmaceuticals. The bill provides specifics concerning the format of the courses and examinations and requires the Florida Medical Association and the Florida Optometric Association to jointly develop and administer the course and examination.

The bill also alters the composition of the committee that maintains the formulary of topical drugs such optometrists are permitted to prescribe to specify that the two optometrists on the committee must be certified optometrists. The bill specifies that the formulary of topical ocular pharmaceutical agents will consist of those topical agents that are appropriate to treat and diagnose ocular diseases and disorders. The bill also establishes a statutory formulary of oral pharmaceutical agents that certified optometrists are permitted to prescribe.

Section 4 amends s. 463.0057, F.S., to prohibit holders of faculty certificates from prescribing ocular pharmaceutical agents unless they take a course on general and ocular pharmacology, pass an examination, and are licensed and certified optometrists.

Section 5 amends s. 463.006, F.S., to require that the licensure examination for optometrists include questions on the use and side effects of all ocular pharmaceutical agents, not just topical agents. Anyone who passes this examination and fulfills other licensure and certification provisions will be permitted to administer and prescribe pharmaceutical agents in the diagnosis and treatment of ocular conditions.

Section 6 amends s. 463.0135, F.S., to state that 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. The bill also provides that optometrists who diagnose neovascular glaucoma, in addition to other types of glaucoma currently listed in statute, must promptly and without unreasonable delay refer the patient to a licensed physician skilled in diseases of the eye. In addition, an optometrist must timely refer to such a physician any patient who experiences progressive glaucoma due to failed pharmaceutical management by the optometrist.

The bill also requires co-management of post-operative care to be conducted pursuant to an established protocol which governs the relationship between the operating surgeon and the optometrist. The patient must be informed that either physician will be available for emergency care throughout the post-operative period, and the patient must consent to the co-management relationship in writing.

Section 7 amends s. 463.014, F.S., to prohibit optometrists from prescribing or otherwise distributing any drug for the purpose of treating a systemic disease, except that optometrists may use commonly-accepted methods to immediately treat anaphylaxis. The bill also further clarifies the definition of surgery in ch. 463, F.S., which prohibits optometrists from conducting surgery.

Section 8 creates s. 463.0141, F.S., to require and provide specifications for reporting of adverse incidents in the practice of optometry.

Section 9 amends s. 483.035, F.S., to include optometrists in the list of licensed practitioners who are permitted to operate clinical laboratories exclusively in connection with the diagnosis and treatment of their own patients.

Section 10 amends s. 483.041, F.S., to include optometrists in the definition of licensed practitioner with respect to clinical laboratories.

Section 11 amends s. 483.181, F.S., to require clinical laboratories to accept specimens for examination submitted by optometrists.

Section 12 amends s. 766.102, F.S., to change the burden of proof for a claimant in an action alleging a breach of the prevailing professional standard of care in an action for damages based on death or personal injury that allegedly resulted from the failure of a health care provider to order, perform, or administer supplemental diagnostic tests. The burden of proof is increased from greater weight of the evidence to clear and convincing evidence.

Section 13 amends s. 766.106, F.S., to authorize a prospective defendant, or his or her legal representative, to conduct ex parte interviews of the claimant's treating health care providers without the presence of the claimant or the claimant's legal representative. Notice of any intended interviews must be provided to the claimant at least 10 days before the date of the interview.

Section 14 creates s. 766.1091, F.S., to authorize certain health care providers and a patient or prospective patient to agree in writing to submit to arbitration any claim for medical negligence that may currently exist or that may accrue in the future that would otherwise be brought under ch. 766, F.S., relating to medical malpractice. The health care providers include:

- Allopathic physicians;
- Osteopathic physicians;
- Certified optometrists;
- Dentists;
- Any entity owned in whole or in part by an allopathic physician, osteopathic physician, certified optometrist, or dentist; or
- A health care clinic licensed under part X of ch. 400, F.S.

An arbitration agreement entered into under this section would be governed by the FAC. Such an arbitration agreement may contain a provision that would limit the available damages in any arbitration award.

Section 15 amends s. 893.02, F.S., to include certified optometrists as authorized prescribers of controlled substances in the state, provided that they hold valid federal controlled substance registry numbers.

Section 16 amends s. 893.05, F.S., to prohibit certified optometrists from prescribing any Schedule I or II controlled substances listed in the Florida Comprehensive Drug Abuse Prevention and Control Act.

Section 17 provides an effective date of July 1, 2012.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Certified optometrists will be able to prescribe additional types of medication related to the diagnosis and treatment of ocular conditions.

C. Government Sector Impact:

The Department of Health should experience little fiscal impact as certification procedures for optometrists are already in effect. There will be an increase in workload relating to updating the formulary of drugs which certified optometrists may prescribe as well as non-recurring rulemaking costs which may be adequately absorbed with current resources.

The Agency for Health Care Administration may experience an increase in applications for clinical laboratory licenses from optometrists, although this number is estimated to be small. There will also be a slightly increased workload related to additional inspections of

such laboratories, which should be offset by an increase in revenues from licensure and renewal fees.[54]

VI. Technical Deficiencies:

None.

VII. Related Issues:

The informal discovery options include taking unsworn statements of treating health care providers. Lines 484 and 485 provide in existing law that the claimant or claimant's legal representative has the right to attend the taking of such unsworn statements. Lines 486 – 494 provide for ex parte interviews of treating health care providers without the presence of the claimant or the claimant's legal representative. Neither "unsworn statements" nor "ex parte interviews" are defined. To avoid inconsistency and potential litigation, it might be prudent to define or distinguish an unsworn statement and an ex parte interview.

VIII. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Regulation on February 9, 2012:
The committee substitute:

- Expands the types of ocular pharmaceutical agents that certified optometrist may administer and prescribe, including some controlled substances;
- Requires optometrists to report adverse incidents to the Department of Health;
- Authorizes optometrists to operate clinical laboratories;
- Requires clinical laboratories to accept specimens for examination from optometrists;
- Authorizes certain health care providers and their patients to enter into voluntary binding arbitration agreements and limit damages; and
- Removes the part of the bill extending sovereign immunity to emergency health care providers.

B. Amendments:

None.

[54] Department of Health, *2012 Bill Analysis, Economic Statement, and Fiscal Note for SB 788*. A copy is on file with the Senate Health Regulation Committee.