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.)

	Р	repared B	y: The Profession	al Staff of the Budg	get Committee				
BILL:	CS/SB 1590								
INTRODUCER:	Banking and Insurance Committee and Senators Hays and Gaetz								
SUBJECT:	Medical Malpractice Actions								
DATE:	April 21, 2011		REVISED:						
ANALYST Stovall Knudson/Arzillo Bradford A		STAFF DIRECTOR Stovall Burgess Meyer, C.		REFERENCE HR BI BC	ACTION Favorable Fav/CS Pre-meeting				
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	Please A. COMMITTE B. AMENDMEN	E SUBST	TITUTE X	for Addition Statement of Subs Technical amendn Amendments were Significant amend	stantial Changes nents were reco	s mmended			

I. Summary:

Senate bill 1590 revises statutes related to medical malpractice claims. The bill requires a physician, osteopathic physician, or dentist who provides expert testimony concerning the prevailing professional standard of care of a physician, osteopathic physician, or dentist to be licensed in this state or possess an expert witness certificate issued by the Department of Health (DOH). Florida licensed physicians and dentists will be subject to disciplinary action for offing false or misleading information as an expert witness, while physicians outside Florida will be subject to revocation of the expert witness certificate for offering such testimony.

The bill requires an insurance policy or self-insurance policy for medical malpractice coverage to clearly state whether or not the insured has the exclusive right of veto of any admission of liability or offer of judgment. The bill repeals the requirement that a self-insurance policy or insurance policy for medical malpractice must authorize the insurer to make this decision without the permission of the insured medical provider if the action is within the policy limits.

The bill exempts a licensed hospital from liability for the medical negligence of a health care provider with whom the hospital has contracted, unless the hospital expressly directs or exercise

actual control over the conduct that caused the injury. The exemption from liability does not apply to the negligent act of a hospital employee.

In a civil action involving the failure of a health care provider to order supplemental diagnostic tests, the bill requires the plaintiff to prove by clear and convincing evidence that the health care provider breached the prevailing professional standard of care.

The bill makes inadmissible all evidence related to an insurer's reimbursement policies or reimbursement determination regarding medical care provided to the Plaintiff. The bill also prohibits the introduction of federal standards and regulations into evidence to establish that the medical provider breached the prevailing professional standard of care.

The bill requires a claimant to submit, along with the other required information, an executed authorization form for the release of protected health information that is potentially relevant to the claim of personal injury or wrongful death when he or she notifies each prospective defendant of his or her intent to initiate litigation for medical negligence.

The bill authorizes a prospective defendant or his or her legal representative access to conduct ex-parte interviews of the claimant's treating health care providers without notice to, or the presence of, the claimant or the claimant's legal representative.

The bill requires the Board of Medicine to create by rule a standardized informed consent form setting forth the risks of cataract surgery. An executed informed consent form creates a rebuttable presumption that the physician properly disclosed the risks of cataract surgery in a civil action or administrative proceeding. Risks described in the signed informed consent form may not be classified as an "adverse incident" pursuant to s. 395.0197, F.S.

The Board Of Medicine (BOM) and the Board Of Osteopathic Medicine (BOOM) will be required to develop application forms and rules to administer the certification program for expert witnesses. Additional regulatory and enforcement activities may emerge as a result of the bill. According to DOH, this will require additional resources and budget authority, including 1 FTE and 2 OPS positions. The bill authorizes the BOM and the BOOM to establish an application fee not to exceed \$50 for the expert witness certificate, which should be sufficient to cover the cost of this regulation.

This bill substantially amends the following sections of the Florida Statutes: 458.331, 459.015, 627.4147, 766.102, 766.106, and 766.206. The bill creates the following sections of the Florida Statutes: 458.3175, 459.0066, and 766.1065.

II. Present Situation:

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. 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." Consequently, other statutes, such as license disciplinary statutes, require a heightened standard of proof called "clear and convincing evidence." 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 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.³

Presuit Investigation⁴

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 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
- That negligence resulted in injury to the claimant.

Corroboration of reasonable grounds to initiate medical negligence litigation must be provided by the claimant's submission of a verified written medical expert opinion from a medical expert.

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
- That negligence resulted in injury to the claimant.

² Castillo v. E.I. Du Pont De Nemours & Co., Inc., 854 So. 2d 1264, 1277 (Fla. 2003).

¹ S. 766.102, F.S.

³ *Inquiry Concerning Davey*, 645 So. 2d 398, 404 (Fla. 1994)(quoting *Slomowitz v. Walker*, 429 So. 2d 797, 800 (Fla. 4th DCA 1983).

⁴ S. 766.203, F.S.

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.

These expert opinions are subject to discovery. Furthermore, the opinion must specify whether any previous opinion by that medical expert has been disqualified and if so, the name of the court and the case number in which the ruling was issued.

Qualification of Medical Expert⁵ Witnesses

A person may not give expert testimony concerning the prevailing professional standard of care unless that person is a licensed health care provider and meets the following criteria:

- If the health care provider against whom or on whose behalf the testimony is offered is a specialist, the expert witness must:
 - Specialize in the same specialty as the health care provider against whom or on whose behalf the testimony is offered; or specialize in a similar specialty that includes the evaluation, diagnosis, or treatment of the medical condition that is the subject of the claim and have prior experience treating similar patients; and
 - Have devoted professional time during the 3 years immediately preceding the date of the occurrence that is the basis for the action to:
 - The active clinical practice of, or consulting with respect to, the same or similar specialty that includes the evaluation, diagnosis, or treatment of the medical condition that is the subject of the claim and have prior experience treating similar patients;
 - Instruction of students in an accredited health professional school or accredited residency or clinical research program in the same or similar specialty; or
 - A clinical research program that is affiliated with an accredited health professional school or accredited residency or clinical research program in the same or similar specialty.
- If the health care provider against whom or on whose behalf the testimony is offered is a general practitioner, the expert witness must have devoted professional time during the 5 years immediately preceding the date of the occurrence that is the basis for the action to:
 - o The active clinical practice or consultation as a general practitioner;
 - The instruction of students in an accredited health professional school or accredited residency program in the general practice of medicine; or
 - A clinical research program that is affiliated with an accredited medical school or teaching hospital and that is in the general practice of medicine.
- If the health care provider against whom or on whose behalf the testimony is offered is a health care provider other than a specialist or a general practitioner, the expert witness must have devoted professional time during the 3 years immediately preceding the date of the occurrence that is the basis for the action to:
 - The active clinical practice of, or consulting with respect to, the same or similar health profession as the health care provider against whom or on whose behalf the testimony is offered:

⁵ S. 766.102(5), (9), and (12), F.S.

The instruction of students in an accredited health professional school or accredited residency program in the same or similar health profession in which the health care provider against whom or on whose behalf the testimony is offered; or

- A clinical research program that is affiliated with an accredited medical school or teaching hospital and that is in the same or similar health profession as the health care provider against whom or on whose behalf the testimony is offered.
- If the claim of negligence is against a physician licensed under chapter 458, osteopathic physician licensed under chapter 459, podiatric physician licensed under chapter 461, or chiropractic physician licensed under chapter 460 providing emergency medical services in a hospital emergency department, the court shall admit expert medical testimony only from physicians, osteopathic physicians, podiatric physicians, and chiropractic physicians who have had substantial professional experience within the preceding 5 years while assigned to provide emergency medical services in a hospital emergency department.

These provisions do not limit the power of the trial court to disqualify or qualify an expert witness on grounds other than the qualifications in this section (s. 766.102, F.S.). Relevant portions of the Florida Evidence Code provide requirements for expert opinion testimony. The Florida Rules of Civil Procedure define "expert witness" as a person duly and regularly engaged in the practice of a profession who holds a professional degree from a university or college and has had special professional training and experience, or one possessed of special knowledge or skill about the subject upon which called to testify.

The court must refuse to consider the testimony or opinion attached to any notice of intent or to any response rejecting a claim of an expert who has been disqualified three times.⁸

After Claimant's Presuit Investigation9

After completion of the presuit investigation and prior to filing a complaint for medical negligence, a claimant shall notify each prospective defendant by certified mail, return receipt requested, of intent to initiate litigation for medical negligence. 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, and copies of all of the medical records relied upon by the expert in signing the affidavit. The requirement of providing the list of known health care providers may not serve as grounds for imposing sanctions for failure to provide presuit discovery. 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. Each insurer or self-insurer shall have a procedure for the prompt investigation, review, and evaluation of claims during the 90-day period.

⁶ Sections 90.702 and 90.704, F.S.

⁷ Fla. R. Civ. P. 1.390(a).

⁸ S. 766.206, F.S.

⁹ S. 766.106, F.S.

Each insurer or self-insurer must investigate the claim in good faith, and both the claimant and prospective defendant must cooperate with the insurer in good faith. If the insurer requires, a claimant shall appear before a pretrial screening panel or before a medical review committee and shall submit to a physical examination. Unreasonable failure of any party to comply with this section justifies dismissal of claims or defenses. There is no civil liability for participation in a pretrial screening procedure if done without intentional fraud.

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.

The response shall be delivered to the claimant if not represented by counsel or to the claimant's attorney, by certified mail, return receipt requested. Failure of the prospective defendant or insurer or self-insurer to reply to the notice within 90 days after receipt shall be deemed a final rejection of the claim for purposes of this section.

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. 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. ¹⁰

Upon receipt by a prospective defendant of a notice of claim, the parties are required to make discoverable information available without undertaking formal discovery. Informational discovery may be used to obtain unsworn statements, the production of documents or things, and physical and mental examinations as follows:¹¹

- 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 of behalf of all potential defendants.

¹⁰ S. 766.106(5), F.S.

¹¹ S. 766.106(6), F.S.

The examination report is available to the parties and their attorney 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.
- Medical information release The claimant must execute a medical information release that allows a prospective defendant or his or her legal representative to take unsworn statements of the claimant's treating physicians that address areas that are potentially relevant to the claim of personal injury or wrongful death. 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.

Informed Consent

The doctrine of informed consent requires a physician to advise his or her patient of the material risks of undergoing a medical procedure. Physicians and osteopathic physicians are required to obtain informed consent of patients before performing procedures and are subject to discipline for failing to do so. Florida has codified informed consent in the Florida Medical Consent Law, s. 766.103, F.S, in relevant part:

- (4)(a) **A consent which** is evidenced in writing and meets the requirements of subsection (3) shall, if validly signed by the patient or another authorized person, **raise a rebuttable presumption of a valid consent.**
- (b) A valid signature is one which is given by a person who under all the surrounding circumstances is mentally and physically competent to give consent. (emphasis added).

The Florida Supreme Court discussed the effect of the rebuttable presumption in the Medical Consent Law in *Pub. Health Trust of Dade County v. Valcin*, 507 So. 2d 596 (Fla. 1987). In that case, the patient signed two consent forms, one acknowledging that no guarantees had been made concerning the results of the operation and one stating that the surgery had been explained to her. ¹⁴ The patient argued that the doctor made oral representations that contradicted the consent forms and made other statements that were not addressed by the consent forms. The court found that such claims could overcome the presumption because no conclusive presumption of valid consent, rebuttable only upon a showing of fraud, will apply to the case. The alleged oral warranties, of course, if accepted by the jury may properly rebut a finding of valid informed consent. ¹⁵

A second issue in Valcin was not related to informed consent, but concerned which type of presumption should apply when surgical records related to the surgery are unavailable or lost. There are two types of presumptions, a shift in the burden of producing or a shift in the burden of

¹² See State v. Presidential Women's Center, 937 So. 2d 114, 116 (Fla. 2006)("The doctrine of informed consent is well recognized, has a long history, and is grounded in the common law and based in the concepts of bodily integrity and patient autonomy").

¹³ See ss. 458.331, F.S., and 459.015, F.S.

¹⁴ See Pub. Health Trust of Dade County v. Valcin, 507 So. 2d 596, 598 (Fla. 1987).

¹⁵ See id. at 599.

proof.16 In the former, as applied to this case, the hospital would bear the initial burden of going forward with the evidence establishing its nonnegligence. If it met this burden by the greater weight of the evidence, the presumption would vanish, requiring resolution of the issues as in a typical case.17 The jury is never told of the presumption.

The second type of rebuttable presumption, as recognized in s. 90.302(2), F.S., affects the burden of proof, shifting the burden to the party against whom the presumption operates to prove the nonexistence of the fact presumed. When evidence rebutting such a presumption is introduced, the presumption does not automatically disappear. It is not overcome until the trier of fact believes that the presumed fact has been overcome by whatever degree of persuasion is required by the substantive law of the case. Rebuttable presumptions which shift the burden of proof are expressions of social policy, rather than mere procedural devices employed to facilitate the determination of the particular action. A section 90.302(2) presumption shifts the burden of proof, ensuring that the issue of negligence goes to the jury.¹⁸

Medical Malpractice Insurance Policies

Section 627.4147, F.S., provides that medical malpractice insurance policies must authorize the insurer or self-insurer to make decisions without the permission of the insured regarding any offer of admission of liability and for arbitration, settlement offer, or offer of judgment, if the offer is within the policy limits. The statute states that it is against public policy to give the insured exclusive right to veto the insurer or self-insurer's decision when the offer is within policy limits. However, malpractice insurance policies issued to licensed dentists provide dentists with an exclusive right to veto, as long as it is clearly stated in the policy, and the policy states that the insurer or self-insurer may not make admissions to liability and arbitration, settlement offer or offer of judgment that are outside the policy limits. Nevertheless, in both instances, the insurer or self-insurer must make a good faith admission of liability, settlement offer, or offer of judgment and it must be in the best interest of the insured.

Hospital Liability for Independent Contractors

Generally, a hospital may not be held liable for the negligence of independent contractor physicians to whom it grants staff privileges. ¹⁹ "Vicarious liability does not therefore necessarily attach to the hospital for the doctors' acts or omissions." ²⁰

The Florida Supreme Court has described the doctrine of vicarious liability:

The concept of vicarious liability can be described as follows: A person whose liability is imputed based on the tortuous acts of another is liable for the entire share of comparative responsibility assigned to the other. Vicarious liability is often justified on the policy grounds that it ensures that a financially responsible party will cover damages. Thus, the vicariously liable party is liable for the entire share of the fault assigned to the active

¹⁶ See ss. 90.302(1) and (2), F.S.

¹⁷ See Gulle v. Boggs, 174 So.2d 26 (Fla.1965); C. Ehrhardt, Florida Evidence § 302.1 (2d ed. 1984).

¹⁸ See supra note 19 at 600-01.

¹⁹ See Insinga v. LaBella, 543 So. 2d 209 (Fla. 1989).

²⁰ Pub. Health Trust of Dade County v. Valcin, 507 So. 2d 596, 601 (Fla. 1987).

tortfeasor. The vicariously liable party has not breached any duty to the plaintiff; its liability is based solely on the legal imputation of responsibility for another party's tortuous acts. The vicariously liable party is liable only for the amount of liability apportioned to the tortfeasor. In sum, the doctrine of vicarious liability takes a party that is free of legal fault and visits upon that party the negligence of another.²¹

However, a hospital may be held vicariously liable for the acts of independent contractor physicians if the physicians act with the apparent authority of the hospital.²² Apparent authority exists only if all three of the following elements are present: (a) a representation by the purported principal; (b) a reliance on that representation by a third party; and (c) a change in position by the third party in reliance on the representation.²³

There are numerous cases in Florida appellate courts where courts have struggled over the issue of whether the hospital should be liable for the negligence of an independent contractor physician. Some cases involve the apparent authority issue. Others involve the issue of whether the hospital has a nondelegable duty to provide certain medical services. One court found that even where a physician is an independent contractor, however, a hospital that undertakes by [express or implied] contract to do for another a given thing is not allowed to —escape [its] contractual liability [to the patient] by delegating performance under a contract to an independent contractor."²⁴

In March 2003, the Florida Supreme Court issued its opinion in *Villazon v. Prudential Health Care Plan*, 843 So. 2d 842 (Fla. 2003). In *Villazon*, the court considered whether vicarious liability theories could make an HMO liable for the negligence of a physician who had a contract with the HMO. The court held that the HMO Act did not provide a cause of action against the HMO for negligence of the physician but that a suit could proceed under common law theories of negligence under certain circumstances.²⁵ It noted that the "existence of an agency relationship is normally one for the trier of fact to decide."²⁶ The court explained that the physician's contractual independent contractor status does not alone preclude a finding of agency and remanded the case for consideration of whether the insurer exercised sufficient control over the physician's actions such that an agency relationship existed or whether agency could be established under an apparent agency theory.²⁷

Appellate courts in Florida have more recently examined the nondelegable duty issue, with differing opinions. As a result, the law is unsettled across the state regarding the liability of hospitals for the negligent acts or omissions of medical providers with whom they contract to provide medical services within the hospital, but over whom they do not have direct control of the manner in which the services are provided.

²¹ American Home Assur. Co. v. National Railroad Passenger Corp., 908 So. 2d 459, 467-468 (Fla. 2005)(internal citations omitted).

²² See Stone v. Palms West Hosp., 941 So. 2d 514 (Fla. 4th DCA 2006).

²³ See Roessler v. Novak, 858 So. 2d 1158, 1161 (Fla. 2d DCA 2003).

²⁴ Shands Teaching Hosp. and Clinic, Inc. v. Juliana, 863 So. 2d 343, 349 n. 9 (Fla. 1st DCA 2003). But see Jones v. Tallahassee Memorial Regional Healthcare, Inc. 923 So. 2d 1245 (Fla. 1st DCA 2006)(refusing to extend the nondelegable duty doctrine to physicians).

²⁵ See Villazon v. Prudential Health Care Plan, Inc., 843 So. 2d 842, 852 (Fla. 2003).

²⁶ See id. at 853.

²⁷ See id. at 855-56.

In Wax v. Tenet Health System Hospitals, Inc., 955 So.2d 1 (Fla. 4th DCA 2006)²⁸, the wife of a deceased patient brought a medical malpractice action against the surgeon who operated on her husband, the hospital where the surgery was completed and others. Specifically, for purposes of this analysis, the wife alleged that the hospital had a nondelegable duty to provide anesthesiology services and was directly liable for the negligence of the anesthesiologist with whom the hospital had contracted to provide services.²⁹ The *Wax* court agreed with the plaintiff that the statutory definition of hospital³⁰ and a specific regulation of hospitals established under statutory authority by the Agency for Health Care Administration (AHCA)³¹ established that the hospital had an express legal duty to furnish anesthesia services to patients that were consistent with established standards.³² The court found that the imposition of this duty on all surgical hospitals to provide non-negligent anesthesia services was important enough to be nondelegable without the express consent to the contrary of the patient.³³

However, in Tarpon Springs Hospital Foundation, Inc. v. Reth, 40 So.3d 823 (Fla. 2nd DCA 2010), the Second District Court of Appeal considered the same argument of the plaintiff related to the identical statutes and rules as were presented to the Fourth District Court of Appeal in Wax and concluded that, while the hospital had a statutory obligation to maintain an anesthesia department within the hospital that is directed by a physician member of the hospital's professional staff, the statutes and rules do not impose a nondelegable duty to provide non-negligent anesthesia services to surgical patients of the hospital.³⁴

Noting the conflict among the District Courts of Appeal regarding the applicability of the theory of nondelegable duty to the contractual relationship between hospital and medical provider in medical negligence claims, the Second District certified the conflict to the Florida Supreme Court for further review. 35 However, as of the date of this analysis, the Florida Supreme Court has not resolved the conflict.

Risk Management Programs

Pursuant to section 395.0197, Florida Statutes, each licensed facility (hospital, ambulatory surgical center, or mobiles surgical facility) must establish an internal risk management program. The risk management program must develop protocols to prevent adverse incidents and a system for investigating, analyzing, and reporting any adverse incidents that occur. The program must investigate and analyze the frequency and causes of adverse incidents to patients, develop

²⁸ The case was originally heard in 2006. Following the filing of a Motion for Rehearing and a Motion for Rehearing En Banc by appellees, both of which were denied, the Court realized that it failed to resolve all issues and delivered an opinion regarding the hospital's liability for the alleged negligence of the anesthesiologist. The opinion was issued on May 7, 2007. See Wax, 955 So.2d at 6. 29 See Wax v. Tenet Health System Hospitals, Inc., 955 So.2d 1, 3, 6 (Fla. 4th DCA 2006).

³⁰ See s. 395.002(13)(b), F.S. (2005) defining "hospital" as an establishment that, among other things, regularly makes available "treatment facilities for surgery."

³¹ Rule 59A-3.2085(4), F.A.C. states "[e]ach Class I and Class II hospital, and each Class III hospital providing surgical or obstetrical services, shall have an anesthesia department, service or similarly titled unit directed by a physician member of the organized professional staff."

³² See supra note 22 at 8.

³³ See supra note 22 at 9.

³⁴ See Tarpon Springs Hospital Foundation, Inc. v. Reth, 40 So.3d 823, 823-24 (Fla. 2nd DCA 2010).

³⁵ See id. at 824.

appropriate measures to minimize the risk of adverse incidents, analyze patient grievances regarding patient care and medical services, inform patients of adverse incidents, and implement a system of reporting adverse incidents to the risk manager.

Each year, the licensed facility must submit an annual report to the Agency for Health Care Administration (AHCA) listing the total number of adverse incidents and detailed information regarding the incidents including the medical procedures causing the injuries, types of injuries caused, the license number of each health care professional directly involved in the adverse incident, and a description of all malpractice claims against the licensed facility. The report is exempt from the public records law³⁶ and is not discoverable or admissible in any civil or administrative actions unless used in a disciplinary proceeding by AHCA or the medical provider's licensing board. However, AHCA must publish a quarterly report on its website summarizing the adverse incident reports it has received, but that does not identify the patient, the facility where the incident occurred, or the health care practitioners involved.

III. Effect of Proposed Changes:

Sections 1, 4, and 6 create s. 458.3175, F.S., s. 459.0066, F.S., and s. 466.005, F.S., respectively, to authorize the Department of Health (DOH) to issue a certificate to a physician, osteopathic physician, or dentist who is licensed to practice in another state or a Canadian province authorizing that person to provide expert testimony in this state pertaining to medical negligence litigation. The expert witness certificate authorizes the physician, osteopathic physician or dentist to provide a verified written medical opinion for purposes of presuit investigation of medical negligence claims and provide expert testimony about the prevailing professional standard of care in connection with medical negligence litigation pending in this state. An expert witness certificate is valid for 2 years.

To obtain an expert witness certificate, the physician, osteopathic physician, or dentist must submit a completed application and pay an application fee in an amount not to exceed \$50. A certificate may not be issued to a physician or dentist who has had a previous expert witness certificate revoked by the department. The department must approve or deny the application within 7 business days after receipt of the completed application and fee; otherwise the application is approved by default. If a physician or dentist intends to rely on a certificate that is approved by default, he or she must notify the department in writing.

The expert witness certificate does not authorize the physician or dentist to practice medicine, osteopathic medicine or dentistry in this state. An out of state and Canadian physician, osteopathic physician, or dentist who obtains an expert witness certificate is not required to obtain a license to practice medicine in this state, or pay other fees, including the neurological injury compensation assessment.

Physicians Providing Misleading, Deceptive or Fraudulent Expert Witness Testimony

Sections 2, 5, and 7 amend s. 458.331, F.S., s. 459.015, F.S., and s. 466.028, F.S. respectively, to add that a physician or osteopathic physician providing misleading, deceptive, or fraudulent

³⁶ s. 119.07(1), F.S.

expert witness testimony related to the practice of medicine or dentist providing such testimony regarding dentistry is subject to denial of a license or other disciplinary action.

Informed Consent Form for Cataract Surgery

Section 3 and 8 amends s. 458.351, F.S., and s. 459.026, F.S., directing the BOM to create by rule a standardized informed consent form setting forth the risks of cataract surgery. The form will be used by physicians licensed under ch. 458, F.S., and osteopathic physicians licensed under ch. 459, F.S. The BOM is directed to consider information from physicians licensed and licensed osteopathic physicians prior to formally proposing the rule. The rules establishing the form must be proposed within 90 days of July 1, 2011.

The section also provides statutory guidelines regarding the contents and execution of the informed consent form. The patient (or a person authorized to give consent) and a witness must sign the form in order to execute the patient's informed consent. An executed informed consent form creates a rebuttable presumption that the physician properly disclosed the risks of cataract surgery in a civil action or administrative proceeding.

Risks described in the signed informed consent form may not be classified as an "adverse incident" pursuant to s. 395.0197, F.S.

Section 9 amends s. 627.4147, F.S., to repeal the requirement that a self-insurance policy or insurance policy that provides coverage for medical malpractice must authorize the insurer or self-insurer to determine, make, and conclude any offer of admission of liability and for arbitration, settlement offer, or offer of judgment if the offer is within the policy limits without the permission of the insured. The bill also repeals the statement that it is against public policy for an insurance or self-insurance policy to contain a clause giving the insured the exclusive right to veto an offer for admission of liability and for arbitration, settlement offer, or offer of judgment, when the offer is within the policy limits.

Instead, the bill requires a clause in all malpractice insurance policies that clearly states whether or not the insured has the exclusive right of veto if the offer is within policy limits. The policy must also prohibit the insurer or self-insurer from making or concluding, without the permission of the insured, any offer of admission of liability and for arbitration, settlement offer, or offer of judgment, if such offer is outside the policy limit. In current law, these provisions only apply policies covering licensed dentists.

Section 10 amends s. 766.102, F.S., regarding evidentiary rules and standards in medical malpractice claims.

Inadmissible Evidence – The bill makes inadmissible all evidence related to an insurer's reimbursement policies or reimbursement determination regarding medical care provided to the Plaintiff. The bill defines "insurer" to include all public and private insurers, including the Centers for Medicare and Medicaid Services. The "reimbursement determination" is defined as the insurer's determination of the amount the insurer reimburses a health care provider for health care services. "Reimbursement policies" are defined as the insurer's policies that governing its

decisions regarding health care coverage and method of payment and all data upon which these decisions are made.

The bill also makes inadmissible evidence regarding a health care provider's breach of or failure to comply with any federal requirement. This will prevent the introduction of federal standards and regulations to establish that the medical provider breached the prevailing professional standard of care.

Standard of Proof – The bill requires the plaintiff to prove by clear and convincing evidence that the health care provider breached the prevailing professional standard of care involving the failure of a health care provider to order supplemental diagnostic tests. The change places a more difficult burden of proof on the Plaintiff in these cases than under current law, which requires the claimant to prove a breach of the standard of care by the greater weight of the evidence.

Eligibility to Provide Expert Testimony – The bill states that a person may not give expert testimony concerning the prevailing professional standard of care unless that person's license is active and valid and the person has conducted a complete review of all medical records. In addition, this section requires a physician, osteopathic physician, or dentist who provides expert testimony concerning the prevailing professional standard of care of a physician, osteopathic physician or dentist to be licensed in this state or possess an expert witness certificate issued by the DOH.

Section 11 amends s. 766.106, F.S., to require a claimant to submit, along with the other required information, an executed authorization form for the release of protected health information that is potentially relevant to the claim of personal injury or wrongful death when he or she notifies each prospective defendant of his or her intent to initiate litigation for medical negligence. This expands the current requirement that the claimant provide 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, and copies of all of the medical records relied upon by the expert in signing the affidavit.

This section provides that notwithstanding the immunity from civil liability arising from participation in the presuit screening process that is currently afforded under the law, a licensed physician, licensed osteopathic physician, or licensed dentist who submits a verified written expert medical opinion is subject to denial of a license or disciplinary action for providing misleading, deceptive, or fraudulent expert witness testimony related to the practice of medicine, osteopathic medicine, or dentistry.

Unlike the current requirement to request permission from the plaintiff to perform an unsworn interview with the claimant's health care providers, the bill authorizes a prospective defendant or his or her legal representative access to interview the claimant's treating health care providers without notice to or the presence of the claimant or the claimant's legal representative. However, a prospective defendant or his or her legal representative who takes an unsworn statement from a claimant's treating physicians must provide reasonable notice and opportunity to be heard to the claimant or the claimant's legal representative before taking unsworn statements. Unsworn

statements are used for presuit screening and are not discoverable or admissible in a civil action for any purpose by any party.

Section 12 creates s. 766.1065, F.S., to establish an authorization form for the release of protected health information that is potentially relevant to the claim of personal injury or wrongful death. The bill sets forth the specific content of the form, including identification of the parties; authorizing the disclosure of protected health information for specified purposes; description of the information and the health care providers from whom the information is available; identification of health care providers to whom the authorization for disclosure does not apply because the health care information is not potentially relevant to the claim of personal injury or wrongful death; the persons to whom the patient authorizes the information to be disclosed; a statement regarding the expiration of the authorization; acknowledgement that the patient understands that he or she has the right to revoke the authorization in writing, the consequences for the revocation, signing the authorization is not a condition for health plan benefits, and that the information authorized for disclosure may be subject to additional disclosure by the recipient and may not be protected by federal HIPAA privacy regulations;³⁷ and applicable signature by the patient or his or her representative.

The bill provides that the presuit notice is void if this authorization does not accompany the presuit notice and other materials required by s. 766.106(2), 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 the applicable statute-of-limitations period is retroactively rendered void.

Section 13 amends s. 766.206, F.S., to authorize the court to dismiss the claim if the court finds that the authorization form accompanying the notice of intent to initiate litigation for medical negligence was not completed in good faith by the claimant. If the court dismisses the claim, the claimant or the claimant's attorney is personally liable for all attorney's fees and costs incurred during the investigation and evaluation of the claim, including the reasonable attorney's fees and costs of the defendant or the defendant's insurer.

Section 14 amends s. 768.0981, F.S., to exempt a licensed hospital from liability for the medical negligence of a health care provider with whom the hospital has contracted, unless the hospital expressly directs or exercise actual control over the conduct that caused the injury. The exemption from liability does not apply to the negligent act of a hospital employee.

Section 15 provides an effective date of July 1, 2011.

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.

³⁷ HIPAA is the federal Health Insurance Portability and Accountability Act of 1996 (Public Law 104-194) and generally include the privacy rules adopted thereunder. With certain exceptions, the HIPAA privacy rules preempt contrary provisions in state law, unless the state law is more stringent than the federal rules. *See* 45 C.F.R. Part 164.

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.

D. Other Constitutional Issues:

Section 1 and section 3 of the bill change provisions relating to expert witnesses. Article V, s. 2(a), Fla. Const., provides that the Florida Supreme Court "shall adopt rules for the practice and procedure" in all courts. The Florida Supreme Court has interpreted this provision to mean that the court has the exclusive power to create rules of practice and procedure. Section 1 and section 3 provide requirements for expert witnesses who do not possess a Florida license. If a court were to find that any of these requirements encroached on the court's rulemaking power, it could hold the provisions invalid.

V. Fiscal Impact Statement:

A Tax/Fee Issues:

None.

B. Private Sector Impact:

The bill requires physicians and dentists licensed in another state or Canada to pay a fee of not more than \$50 to obtain an expert witness certificate in order to provide an expert witness opinion or provide expert testimony relating to the standard of care in a medical malpractice case involving a physician or dentist. The department estimates that during the first year there will be approximately 2,478 expert witness certificates applied for, thereby resulting in revenues of \$123,900 to be deposited within the Medical Quality Assurance Trust Fund.

A party seeking to use an expert witness who is not a physician or osteopathic physician licensed in this state may only use an expert witness who has a certificate from the DOH. Proponents of the bill assert that this will help ensure that medical expert witness testimony is accurate. Opponents of the bill assert that this requirement, and the reduced timeframe in which substantial professional experience qualifies a person as an expert witness, might limit or delay a claimant's ability to engage an expert witness to conduct a presuit investigation and proceed with a claim for medical negligence.

The specific HIPAA-compliant form will facilitate the release and disclosure of protected health information and more clearly protect persons who release that information. The defense will have an additional discovery tool with the authorization to conduct ex parte interviews of treating health care providers.

The changes to insurance and self-insurance policies provide physicians with greater control over the disposition of medical malpractice claims.

C. Government Sector Impact:

The DOH will be required to develop application forms and rules to administer the certification program for expert witnesses. Additional regulatory and enforcement activities may emerge as a result of the bill.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Additional Information:

A. Committee Substitute – Statement of Substantial Changes: (Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Banking and Insurance on April 12, 2011

The Committee Substitute deleted all provisions of the bill to conform to its companion bill, HB 479. The Committee Substitute makes the following changes:

- Exempts a licensed hospital from liability for the medical negligence of a health care provider with whom the hospital has contracted, unless the hospital expressly directs or exercise actual control over the conduct that caused the injury.
- Requires the plaintiff to prove by clear and convincing evidence that the health care provider breached the prevailing professional standard of care involving the failure of a health care provider to order supplemental diagnostic tests.
- Makes inadmissible all evidence related to an insurer's reimbursement policies or reimbursement determination regarding medical care provided to the Plaintiff.
- Prohibits the introduction of federal standards and regulations into evidence to establish that the medical provider breached the prevailing professional standard of care.
- Requires the Board of Medicine to create by rule a standardized informed consent form setting forth the risks of cataract surgery. Risks described in the signed informed consent form may not be classified as an "adverse incident" pursuant to s. 395.0197, F.S.
- Creates a rebuttable presumption in a civil action that the physician properly disclosed the risks of cataract surgery or administrative proceeding when there is an executed informed consent form.
- Changes the authority to issue certificates from out of state expert witnesses from the BOM and BOOM to the Department of Health.

• Specifies the information that must be provided on the registration application for the out of state expert witness certificate.

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None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.