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 Health Regulation Committee

BILL:	SB 1892
INTRODUCER:	Senator Bennett
SUBJECT:	Health Care
DATE:	April 9, 2011
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Stovall	HR	**Unfavorable**
2.			BC	
3.				
4.				
5.				
6.				

I. Summary:

The bill requires a physician or osteopathic physician who provides expert testimony concerning the prevailing professional standard of care of a physician or osteopathic physician to be licensed in this state under ch. 458, The Medical Practice Act, or ch. 459, F.S., The Osteopathic Medical Practice Act, or possess an expert witness certificate issued by the Board of Medicine (BOM) or the Board of Osteopathic Medicine (BOOM).

The bill extends the period of time immediately preceding the date of the occurrence that is the basis for the action within which an expert witness must have performed certain activities in order to qualify as an expert witness. The time frames are extended to 5 years if the health care provider against whom or on whose behalf the testimony is offered is a specialist or a health care provider other than a specialist or general practitioner.

A patient's informed consent for cataract surgery must include a properly executed standard informed consent form that sets forth the recognized specific risks related to cataract surgery. This form must be developed by the BOM and the BOOM. If this consent form is properly executed, it creates a rebuttable presumption that the physician properly disclosed the risks associated with cataract surgery.

An advance registered nurse practitioner (ARNP) is authorized to order and administer controlled substances under certain conditions and a certificated registered nurse anesthetist is authorized to order the administration of drugs that are commonly used to alleviate pain.

The bill requires a clause in 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 authority for a self-insurance policy or insurance policy for medical malpractice to grant authority for the insurer to bring the case to closure without the permission of the insured if the action is within the policy limits.

The bill changes the burden of proof to clear and convincing evidence for an action for recovery of damages based on death or personal injury resulting from medical negligence.

The bill requires a claimant to submit, along with the other required information, an executed authorization form, that is set forth in the bill, 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 provides consequences for failing to submit the authorization form, revoking the authorization, or not completing the form in good faith.

A defendant or his or her legal representative may interview a claimant's treating physician without notice to the claimant.

The bill establishes in law that hospitals, ambulatory surgical centers, and mobile surgical facilities are not liable for the medical negligence of contracted health care providers, other than an employee, unless the entity expressly directs or exercises actual control over the specific conduct that caused injury.

This bill substantially amends the following sections of the Florida Statutes: 458.3175, 458.331, 458.351, 459.0066, 459.015, 459.026, 464.012, 627.4147, 766.102, 766.106, 766.206, and 768.0981.

This bill creates s. 766.1065, F.S.

II. Present Situation:

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.[1]

Presuit Investigation[2]

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.

[1] S. 766.102, F.S.
[2] S. 766.203, F.S.

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.

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.

Medical Experts[3]

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.

[3] S. 766.102(5), (9), and (12), F.S.

- 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:
  - 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;
  - 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.[4] 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.[5]

The court shall 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.[6]

Disciplinary action may be taken against a medical physician or osteopathic physician who has been found by any court in this state to have provided corroborating written medical expert

[4] Sections 90.702 and 90.704, F.S.
[5] Fla. R. Civ. P. 1.390(a).
[6] S. 766.206, F.S.

opinion attached to any statutorily required notice of claim or intent or to any statutorily required response rejecting a claim, without reasonable investigation.[7]

After Claimant's Presuit Investigation[8]

After completion of 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. 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 must conduct a presuit investigation to determine the liability of the defendant. Each insurer or self-insurer must have a procedure for the prompt investigation, review, and evaluation of claims during the 90-day period.

Each insurer or self-insurer shall investigate the claim in good faith, and both the claimant and prospective defendant shall 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 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 must 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 is to be delivered to the claimant if not represented by counsel or to the claimant's attorney. Failure of the prospective defendant or insurer or self-insurer to reply to the notice within 90 days after receipt is deemed a final rejection of the claim.

[7] *See* s. 458.331(jj), F.S., and s. 459.015(mm), F.S.
[8] S. 766.106, F.S.

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.[9]

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:[10]

- 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. 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.

Advanced Registered Nurse Practitioners

Chapter 464, F.S., the Nurse Practice Act, governs the licensure and regulation of nurses in Florida. Nurses are licensed by the Department of Health (Department) and are regulated by the Board of Nursing (BON).

"Advanced registered nurse practitioner" means any person licensed in Florida to practice professional nursing and certified in advanced or specialized nursing practice, including certified registered nurse anesthetists, certified nurse midwives, and nurse practitioners.[11]

[9] S. 766.106(5), F.S.
[10] S. 766.106(6), F.S.
[11] S. 464.003(3), F.S.

Any nurse desiring to be certified as an ARNP must apply to the Department and submit proof that he or she holds a current license to practice professional nursing and that he or she meets one or more of the following requirements as determined by the BON:

- Satisfactory completion of a formal postbasic educational program of at least one academic year, the primary purpose of which is to prepare nurses for advanced or specialized practice.
- Certification by an appropriate specialty board.
- Graduation from a program leading to a master's degree in a nursing clinical specialty area with preparation in specialized practitioner skills.[12]

The BON is required to provide by rule the appropriate requirements for ARNPs in the categories of certified registered nurse anesthetist, certified nurse midwife, and nurse practitioner.[13]

An ARNP must perform authorized functions within the framework of an established protocol that is filed with the BON upon biennial license renewal and within 30 days after entering into a supervisory relationship with a physician or changes to the protocol. Within the protocol, an ARNP may:

- Monitor and alter drug therapies.
- Initiate appropriate therapies for certain conditions.
- Perform additional functions as may be determined by rule.
- Order diagnostic tests and physical and occupational therapy.[14]

In addition to the above functions, an ARNP may perform the following acts within his or her specialty:

- The certified registered nurse anesthetist may, to the extent authorized by established protocol approved by the medical staff of the facility in which the anesthetic service is performed, perform any or all of the following:
  - Determine the health status of the patient as it relates to the risk factors and to the anesthetic management of the patient through the performance of the general functions.
  - Based on history, physical assessment, and supplemental laboratory results, determine, with the consent of the responsible physician, the appropriate type of anesthesia within the framework of the protocol.
  - Order under the protocol preanesthetic medication.
  - Perform under the protocol procedures commonly used to render the patient insensible to pain during the performance of surgical, obstetrical, therapeutic, or diagnostic clinical procedures. These procedures include ordering and administering regional, spinal, and general anesthesia; inhalation agents and techniques; intravenous agents and techniques; and techniques of hypnosis.
  - Order or perform monitoring procedures indicated as pertinent to the anesthetic health care management of the patient.
  - Support life functions during anesthesia health care, including induction and intubation procedures, the use of appropriate mechanical supportive devices, and the management of fluid, electrolyte, and blood component balances.

[12] S. 464.012(1), F.S.
[13] S. 464.012(2), F.S.
[14] S. 464.012(3), F.S.

  - Recognize and take appropriate corrective action for abnormal patient responses to anesthesia, adjunctive medication, or other forms of therapy.
  - Recognize and treat a cardiac arrhythmia while the patient is under anesthetic care.
  - Participate in management of the patient while in the postanesthesia recovery area, including ordering the administration of fluids and drugs.
  - Place special peripheral and central venous and arterial lines for blood sampling and monitoring as appropriate.
- The certified nurse midwife may, to the extent authorized by an established protocol which has been approved by the medical staff of the health care facility in which the midwifery services are performed, or approved by the nurse midwife's physician backup when the delivery is performed in a patient's home, perform any or all of the following:
  - Perform superficial minor surgical procedures.
  - Manage the patient during labor and delivery to include amniotomy, episiotomy, and repair.
  - Order, initiate, and perform appropriate anesthetic procedures.
  - Perform postpartum examination.
  - Order appropriate medications.
  - Provide family-planning services and well-woman care.
  - Manage the medical care of the normal obstetrical patient and the initial care of a newborn patient.
- The nurse practitioner may perform any or all of the following acts within the framework of established protocol:
  - Manage selected medical problems.
  - Order physical and occupational therapy.
  - Initiate, monitor, or alter therapies for certain uncomplicated acute illnesses.
  - Monitor and manage patients with stable chronic diseases.
  - Establish behavioral problems and diagnosis and make treatment recommendations.[15]

During the 2008-2009 legislative interim, staff of the Senate Health Regulation Committee researched the issues surrounding expanding the scope of practice for ARNPs to prescribe controlled substances. Among other things, staff reported that 47 states authorize ARNPs to prescribe controlled substances, 39 states authorize the prescribing of controlled substances in Schedule II through Schedule V, and 8 states authorize the prescribing of controlled substances in Schedule III through Schedule V. Many states place further limitations on the drugs that ARPNs may prescribe. These limitations may be set in one of more of the following ways: establishing the limitations within the terms of agreements between ARPNs and their supervising/collaborating physicians or dentists; requiring the ARNP to prescribe within established formularies; requiring the drugs prescribed to be within the ARPN's and collaborating physician's scope of practice; or prohibiting the prescribing of specific drugs by law. The reported findings and recommendations are available in Interim Report 2009-117, AUTHORIZATION FOR ADVANCED REGISTERED NURSE PRACTITIONERS TO PRESCRIBE CONTROLLED SUBSTANCES.[16]

[15] Section 464.012(4), F.S.
[16] *See* AUTHORIZATION FOR ADVANCED REGISTERED NURSE PRACTITIONERS TO PRESCRIBE CONTROLLED SUBSTANCES, Interim Report 2009-117, by the Florida Senate Health Regulation Committee, published October 2008, available at:

Cataract Surgery[17]

A cataract is a clouding of the lens in the eye that affects vision. Most cataracts are related to aging. By age 80, more than half of all Americans either have a cataract or have had cataract surgery.

The lens is a clear part of the eye that helps to focus light, or an image, on the retina. In a normal eye, light passes through the transparent lens to the retina. Once it reaches the retina, light is changed into nerve signals that are sent to the brain. The lens must be clear for the retina to receive a sharp image. If the lens is cloudy from a cataract, the image will be blurred.

Although most cataracts are related to aging, there are other types of cataract:

- Secondary cataract. Cataracts can form after surgery for other eye problems, such as glaucoma. Cataracts also can develop in people who have other health problems, such as diabetes. Cataracts are sometimes linked to steroid use.
- Traumatic cataract. Cataracts can develop after an eye injury, sometimes years later.
- Congenital cataract. Some babies are born with cataracts or develop them in childhood, often in both eyes. These cataracts may be so small that they do not affect vision. If they do, the lenses may need to be removed.
- Radiation cataract. Cataracts can develop after exposure to some types of radiation.

There are two types of cataract surgery.

- Phacoemulsification, or phaco. A small incision is made on the side of the cornea. A tiny probe is inserted into the eye. This device emits ultrasound waves that soften and break up the lens so that it can be removed by suction. Most cataract surgery today is done by phacoemulsification, also called "small incision cataract surgery."
- Extracapsular surgery. A longer incision is made on the side of the cornea and the cloudy core of the lens is removed in one piece. The rest of the lens is removed by suction. After the natural lens has been removed, it often is replaced by an artificial lens, called an intraocular lens (IOL).

Although this may not be an all inclusive list, some of the risks of cataract surgery include: infection, bleeding, and increased risk of retinal detachment. Serious infection can result in loss of vision. A retinal detachment is a medical emergency; even if treated promptly, some vision may be lost.

Florida Medical Consent Law

The Florida Medical Consent Law provides that no recovery shall be allowed in any court in this state against, among other medical practitioners, a medical physician or osteopathic physician in

http://archive.flsenate.gov/data/Publications/2009/Senate/reports/interim_reports/pdf/2009-117hr.pdf, (Last visited on April 9, 2011).

[17] *See* National Eye Institute, National Institutes of Health, Facts about Cataract, found at: http://www.nei.nih.gov/health/cataract/cataract_facts.asp, (Last visited on April 9, 2011).

an action brought for treating, examining, or operating on a patient without his or her informed consent when:

- The action of the physician in obtaining the consent of the patient or another person authorized to give consent for the patient was in accordance with an accepted standard of medical practice among members of the medical profession with similar training and experience in the same or similar medical community as that of the person treating, examining, or operating on the patient for whom the consent is obtained; and
- A reasonable individual, from the information provided by the physician, under the circumstances, would have a general understanding of the procedure, the medically acceptable alternative procedures or treatments, and the substantial risks and hazards inherent in the proposed treatment or procedures, which are recognized among other physicians in the same or similar community who perform similar treatments or procedures;
  Or
- The patient would reasonably under all the surrounding circumstances, have undergone such treatment or procedure had he or she been advised by the physician in accordance with the provisions described above.

A written consent which meets these requirements and is signed by the patient or another authorized person raises a rebuttable presumption of a valid consent. A valid signature on the consent is one which is given by a person who under all the surrounding circumstances is mentally and physically competent to give consent.

Medical physicians and osteopathic physicians may be subject to disciplinary action for performing professional services which have not been authorized by the patient or his or her legal representative.[18]

Administrative Rulemaking and Legislative Ratification

Chapter 2010-279, Laws of Florida (L.O.F.), became effective on November 17, 2010,[19] when the Legislature over-rode the Governor's veto of CS/CS/HB 1565, which was passed during the 2010 Regular Session. This law requires a proposed administrative rule that has an adverse impact or regulatory costs that exceed certain thresholds to be submitted to the Legislature for ratification before the rule can take effect. The Legislature provided for a statement of estimated regulatory costs (SERC) as the tool to assess a proposed rule's impact.

An agency proposing a rule is required to prepare a SERC of the proposed rule if the proposed rule:[20]

- Will have an adverse impact on small business; or
- Is likely to directly or indirectly increase regulatory costs in excess of $200,000 in the aggregate in this state within 1 year after the implementation of the rule.

[18] *See* s. 458.331(1)(p) and (u), F.S., and s. 459.015(s) and (y), F.S.
[19] House Joint Resolution 9-A passed during the 2010A Special Session on November 16, 2010.
[20] *See* s. 120.54(3)(b)1., F.S.

A SERC is required to include:[21]

- An economic analysis showing whether the rule directly or indirectly:
  - Is likely to have an adverse impact on economic growth, private sector job creation or employment, or private sector investment in excess of $1 million in the aggregate within 5 years after the implementation of the rule;
  - Is likely to have an adverse impact on business competitiveness, including the ability of persons doing business in the state to compete with persons doing business in other states or domestic markets, productivity, or innovation in excess of $1 million in the aggregate within 5 years after the implementation of the rule; or
  - Is likely to increase regulatory costs, including any transactional costs, in excess of $1 million in the aggregate within 5 years after the implementation of the rule.

  If the adverse impact or regulatory costs of the rule exceed any of these criteria, then the rule may not take effect until it is ratified by the Legislature;

- A good faith estimate of the number of individuals and entities likely to be required to comply with the rule, together with a general description of the types of individuals likely to be affected by the rule;
- A good faith estimate of the cost to the agency, and to any other state and local government entities, of implementing and enforcing the proposed rule, and any anticipated effect on state or local revenues;
- A good faith estimate of the transactional costs likely to be incurred by individuals and entities, including local government entities, required to comply with the requirements of the rule. "Transactional costs" are direct costs that are readily ascertainable based upon standard business practices, and include filing fees, the cost of obtaining a license, the cost of equipment required to be installed or used or procedures required to be employed in complying with the rule, additional operating costs incurred, the cost of monitoring and reporting, and any other costs necessary to comply with the rule;
- An analysis of the impact on small businesses,[22] and an analysis of the impact on small counties and small cities.[23] The impact analysis for small businesses must include the basis for the agency's decision not to implement alternatives that would reduce adverse impacts on small businesses;
- Any additional information that the agency determines may be useful; and
- A description of any regulatory alternative submitted by a substantially affected person and a statement adopting the alternative or a statement of the reasons for rejecting the alternative in favor of the proposed rule.

[21] *See* s. 120.541(2), F.S.

[22] "Small business" is defined to mean an independently owned and operated business concern that employs 200 or fewer permanent full-time employees and that, together with its affiliates, has a net worth of not more than $5 million or any firm based in this state which has a Small Business Administration 8(a) certification. As applicable to sole proprietorships, the $5 million net worth requirement shall include both personal and business investments.

[23] "Small county" and "small city" are defined to mean any county that has an unincarcerated population of 75,000 or less and any municipality that has an unincarcerated population of 10,000 or less, respectively, according to the most recent decennial census.

III. Effect of Proposed Changes:

Section 1 and section 4 create s. 458.3175, F.S., and s. 459.0066, F.S., respectively, to authorize the BOM or the BOOM to issue a certificate to a physician or osteopathic physician who is licensed to practice medicine or osteopathic medicine in another state or a province of Canada to provide expert testimony in this state pertaining to medical negligence litigation against a physician. The expert witness certificate authorizes the physician or osteopathic physician 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 against a physician licensed under ch. 458, F.S., or ch. 459, F.S.

A physician who is not licensed in this state but intends to provide expert testimony in this state must submit a completed application and pay an application fee in an amount not to exceed $50. The BOM or the BOOM may not issue a certificate to a physician who has had a previous expert witness certificate revoked by the BOM or the BOOM. The BOM or the BOOM is required to approve or deny the application within 5 business days after receipt of the completed application and fee, otherwise the application is approved by default. If a physician intends to rely on a certificate that is approved by default, he or she must notify the BOM or the BOOM in writing. An expert witness certificate is valid for 2 years.

An expert witness certificate does not authorize the physician to practice medicine or osteopathic medicine in this state, and a physician who does not otherwise practice medicine in this state is not required to obtain a license to practice medicine in this state, or pay other fees, including the neurological injury compensation assessment.

The BOM and the BOOM are required to adopt rules to administer their respective section of law.

Section 2 and section 5 amend s. 458.331, F.S., and s. 459.015, F.S., respectively, to add that providing misleading, deceptive, or fraudulent expert witness testimony related to the practice of medicine is grounds for denial of a license or other disciplinary action against a physician or osteopathic physician.

The bill adds a provision that the purpose of the respective section relating to grounds for disciplinary action and action by the board and department, is to facilitate uniform discipline for those acts made punishable under this section. And, to that end, a reference to the section constitutes a general reference under the doctrine of incorporation by reference. The effect of this provision is to avoid having to republish and reenact laws referencing this section to incorporate by reference all subsequent changes to it.

Section 3 and section 6 amend s. 458.351, F.S., and s. 459.026, F.S., respectively, relating to reports of adverse incidents in office practice settings. The BOM and the BOOM are required to adopt rules establishing a standard informed consent form that sets forth the recognized specific risks related to cataract surgery. As a part of this process, the boards are required to consider information from Florida-licensed physicians regarding recognized specific risks related to cataract surgery and the standard informed consent forms adopted for use in the medical field by

other states. These rules must be proposed by October 1, 2011, and are exempted from the provisions of s. 120.541, F.S., relating to adverse impacts, estimated regulatory costs, and legislative ratification of rules.

A patient's informed consent must include the patient's signature, or the signature of a person authorized by the patient to give consent, and the signature of a competent witness on the form adopted by the respective board. A properly executed consent form adopted by the applicable board is admissible as evidence and creates a rebuttable presumption that the physician properly disclosed the risks associated with cataract surgery. The rebuttable presumption must be included in the charge to the jury in a civil action against a physician based on his or her alleged failure to properly disclose the risks of cataract surgery.

This section provides that an incident resulting from recognized specific risks described in the signed consent form is not considered an adverse incident. Therefore such an incident is not required to be reported to the applicable board or by a hospital, ambulatory surgical center, or mobile surgical facility to the Agency for Health Care Administration.

Section 7 amends s. 464.012, F.S., to authorize an ARNP to order and administer any drug or drug therapies that are necessary for the proper medical care and treatment of a patient. This includes controlled substances in Schedule II through Schedule V if:

- The drugs are ordered or administered in accordance with the protocol between the supervising practitioner and the ARNP,
- The drugs ordered are consistent with the ARNP's educational preparation or for which clinical competency has been established and maintained,
- The protocol specifies:
  - The name of the ARNP, the drugs that may be ordered and the circumstances under which they may be ordered,
  - The extent of the practitioner's supervision of the ARNP and the method of periodic review of the ARNP's competence, including peer review, and
  - The illness, injury, or condition for which a Schedule II controlled substance is administered, if Schedule II controlled substances are authorized in the protocol,
- The administering or ordering of the drugs by the ARNP occurs under practitioner supervision, as defined to mean a collaboration between the ARNP and the supervising practitioner on the development of the protocol and the availability of the supervising practitioner via telephonic contact at the time the patient is examined by the ARNP. Physical presence is not required,
- The controlled substances are administered or ordered in accordance with a patient-specific protocol approved by the treating or supervising practitioner if Schedule II or Schedule III controlled substances are administered or ordered by the ARNP, and
- The board has certified that the ARNP has satisfactorily completed at least 6 months of direct supervision in the administering and ordering of drugs and a course in pharmacology covering the order, use, administration, and dispensing of controlled substances.

A practitioner may not supervise more than four ARNPs at any one time.

In addition, as a part of managing a patient in the postanesthesia recovery area, a certified registered nurse anesthetist may order the administration of drugs that are commonly used to alleviate pain.

Section 8 amends s. 627.4147, F.S., to repeal the authority for a self-insurance policy or insurance policy that provides coverage for medical malpractice to allow 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 the policy to clearly state whether or not the insured has the exclusive right of veto if the offer is within policy limits, which is currently the law that applies for dentists.

Section 9 amends s. 766.102, F.S., to change the burden of proof for an action for recovery of damages based on death or personal injury allegedly resulting from the negligence of a health care provider.[24] The claimant must prove by clear and convincing evidence, rather than the greater weight of evidence, that the alleged actions of the health care provider represented a breach of the prevailing professional standard of care for that health care provider. Similarly, the bill adds, if an action for damages is based on death or personal injury allegedly resulting from the failure of a health care provider to order, perform, or administer supplemental diagnostic tests, the claimant has the burden of proving by clear and convincing evidence that the alleged actions of the health care provider represented a breach of the prevailing professional standard of care.

The bill provides that any records, policies, or testimony of an insurer's reimbursement policies or reimbursement determination regarding the care provided to the plaintiff are not admissible as evidence in any civil action. Definitions are provided for the terms "insurer", "reimbursement determination", and "reimbursement policies."

The bill extends the period of time immediately preceding the date of the occurrence that is the basis for the action within which the expert witness must have performed certain activities. If the health care provider against whom or on whose behalf the testimony is offered is:

- A specialist, in addition, to other things, the expert witness must have devoted professional time during the 5 years, rather than 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,

[24] The health care providers to which this provision apply are defined in s. 766.202(4) to include: any hospital, ambulatory surgical center, or mobile surgical facility as defined and licensed under chapter 395; a birth center licensed under chapter 383; any person licensed under chapter 458 (medical practice), chapter 459 (osteopathic medicine), chapter 460 (chiropractic medicine), chapter 461 (podiatric medicine), chapter 462 (naturopathy), chapter 463 (optometry), part I of chapter 464 (nursing), chapter 466 (dentistry), chapter 467 (midwifery), or chapter 486 (physical therapy); a clinical lab licensed under chapter 483; a health maintenance organization certificated under part I of chapter 641; a blood bank; a plasma center; an industrial clinic; a renal dialysis facility; or a professional association partnership, corporation, joint venture, or other association for professional activity by health care providers.

  - Instructing students in an accredited health professional school or accrediting 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.
- A health care provider other than a specialist or a general practitioner, the expert witness must have devoted professional time during the 5 years, rather than 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,
  - Instructing students in an accredited health professional school or accrediting residency program in the same or similar health profession as 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.

In addition, this section requires a physician or osteopathic physician who provides expert testimony concerning the prevailing professional standard of care of a physician or osteopathic physician to be licensed in this state under The Medical Practice Act or The Osteopathic Medical Practice Act, or possess an expert witness certificate issued by the BOM or the BOOM.

A health care provider's failure to comply with or a breach of any federal requirement is not admissible as evidence in any medical negligence case in this state.

Section 10 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 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 physician who is licensed under the Medical Practice Act or the Osteopathic Medical Practice Act 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 or osteopathic medicine.

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 (referred to as ex parte interview in the bill). 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 11 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;[25] 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 12 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 13 amends s. 768.0981, F.S., to add hospitals, ambulatory surgical centers, and mobile surgical facilities to the group of insurers, prepaid limited health service organizations, health maintenance organizations, and prepaid health clinics that are not liable for the medical negligence of a health care provider within whom the entity has entered into a contract, other than an employee, unless the entity expressly directs or exercises actual control over the specific conduct that caused injury.

Section 14 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.

[25] 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.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Claimants who choose 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 Florida BOM or the Florida BOOM. This requirement, 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 BOM and the 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.

VI. Technical Deficiencies:

None.

VII. Related Issues:

Sections 3 and 6 create a new subsection relating to informed consent for cataract surgery. These provisions are unrelated to reports of adverse incidents in office practice settings and the placement within these sections of law may create confusion. If placed in another section of law, paragraph (d) that refers to an adverse incident could easily include a cross-reference to s. 4458.351, F.S., or s. 459.026, F.S.

VIII. Additional Information:

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

None.

B. Amendments:

None.

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