CHAMBER ACTION

The Health Care Regulation Committee recommends the following:

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Council/Committee Substitute

Remove the entire bill and insert:

A bill to be entitled

An act relating to medical malpractice insurance; providing a short title; creating the Patient Safety and Provider Liability Act; providing legislative findings; amending s. 766.110, F.S.; specifying certain authorized insurers who may make available liability insurance; amending s. 766.118, F.S.; providing a limitation on noneconomic damages for a hospital facility that complies with certain patient-safety measures; creating s. 766.401, F.S.; providing definitions; creating s. 766.402, F.S.; authorizing an eligible hospital to petition the agency for an order certifying the hospital as a certified patient-safety facility; providing requirements for certification as a patient-safety facility; authorizing the agency to conduct onsite examinations; providing for revocation of an order certifying approval of a certified patient-safety facility; providing that an order certifying the approval of a certified patient-safety facility is conclusive evidence of compliance with Page 1 of 19

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statutory patient-safety requirements; providing that evidence of noncompliance is not admissible for any action for medical malpractice; creating s. 766.403, F.S.; providing requirements for a hospital to demonstrate that it is engaged in a common enterprise for the care and treatment of patients; specifying required patient-safety measures; prohibiting a report or document generated under the act from being admissible or discoverable as evidence; creating s. 766.404, F.S.; requiring a certified patientsafety facility to submit an annual report to the agency and the Legislature; providing requirements for the annual report; providing that the annual report may include certain information from the Office of Insurance Regulation within the Department of Financial Services; providing that the annual report is subject to publicrecords requirements but is not admissible as evidence in a legal proceeding; creating s. 766.405, F.S.; providing for limitations on damages for eligible hospitals that are certified for compliance with certain patient-safety measures; creating s. 766.406, F.S.; providing rulemaking authority; providing for severability; providing for broad statutory view of the act; providing for self-execution of the act; providing an effective date.

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

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Section 1. Short title.--This act may be cited as the "Patient Safety and Provider Liability Act."

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Section 2. <u>Legislative findings.--The Legislature finds</u> that:

- (1) This state is in the midst of a prolonged medical malpractice insurance crisis that has serious adverse effects on patients, practitioners, licensed health care facilities, and all residents of this state.
- (2) Hospitals are central components of the modern health care delivery system.
- (3) The medical malpractice insurance crisis in this state can be alleviated by the adoption of innovative approaches for patient safety in teaching hospitals, which can lead to a reduction in medical errors coupled with a limitation on noneconomic damages that can be awarded against a teaching hospital that implements such innovative approaches.
- (4) Statutory incentives are necessary to facilitate innovative approaches for patient safety in hospitals and that such incentives and patient-safety measures will benefit all persons seeking health care services in this state.
- (5) Coupling patient safety measures and a limitation on provider liability in teaching hospitals will lead to a reduction in the frequency and severity of incidents of medical malpractice in hospitals.
- (6) A reduction in the frequency and severity of incidents of medical malpractice in hospitals will reduce attorney's fees and other expenses inherent in the medical liability system.
- (7) There is no alternative method that addresses the overwhelming public necessity to implement patient-safety measures and limit provider liability.

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(8) Making high-quality health care available to the residents of this state is an overwhelming public necessity.

- (9) Medical education in this state is an overwhelming public necessity.
- (10) Statutory teaching hospitals are essential for highquality medical care and medical education in this state.
- (11) The critical mission of statutory teaching hospitals is severely undermined by the ongoing medical malpractice crisis.
- (12) Teaching hospitals are appropriate health care facilities for the implementation of innovative approaches to enhancing patient safety and limiting provider liability.
- reasonable limitations on actions for medical malpractice against teaching hospitals in furtherance of the critical public interest in promoting access to high-quality medical care, medical education, and innovative approaches to patient safety and provider liability.
- (14) There is an overwhelming public necessity for teaching hospitals to implement innovative measures for patient safety and limit provider liability in order to generate empirical data for state policymakers concerning the effectiveness of these measures. Such data may lead to broader application of these measures in a wider array of hospitals after a reasonable period of evaluation and review.
- (15) There is an overwhelming public necessity to promote the academic mission of teaching hospitals. Furthermore, the Legislature finds that the academic mission of these medical

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facilities is materially enhanced by statutory authority for the implementation of innovative approaches to promoting patient safety and limiting provider liability. Such approaches can be carefully studied and learned by medical students, medical school faculty, and affiliated physicians in appropriate clinical settings, thereby enlarging the body of knowledge concerning patient safety and provider liability which is essential for advancement of patient safety, reduction of expenses inherent in the medical liability system, and curtailment of the medical malpractice insurance crisis in this state.

Section 3. Subsection (2) of section 766.110, Florida Statutes, is amended to read:

766.110 Liability of health care facilities.--

(2) Every hospital licensed under chapter 395 may carry liability insurance or adequately insure itself in an amount of not less than \$1.5 million per claim, \$5 million annual aggregate to cover all medical injuries to patients resulting from negligent acts or omissions on the part of those members of its medical staff who are covered thereby in furtherance of the requirements of ss. 458.320 and 459.0085. Notwithstanding s. 626.901, a licensed hospital may extend insurance and self-insurance coverage to members of the medical staff, including physicians' practices, individually or through a professional association, as defined in chapter 621, and other health care practitioners, as defined in s. 456.001(4), including students preparing for licensure. Such coverage shall be limited to legal liability arising out of medical negligence within the hospital

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premises as defined under s. 766.401. Self-insurance Coverage
extended hereunder to a member of a hospital's medical staff
meets the financial responsibility requirements of ss. 458.320
and 459.0085 if the physician's coverage limits are not less
than the minimum limits established in ss. 458.320 and 459.0085
and the hospital is a verified trauma center that has extended
self insurance coverage continuously to members of its medical
staff for activities both inside and outside of the hospital.
Any approved insurer, authorized insurer as defined in s.
624.09, risk retention group as defined in s. 627.942, or joint
underwriting association established under s. 627.351(4) which
is approved or authorized to write casualty insurance may make
available, but $\underline{\text{is}}$ $\underline{\text{shall}}$ not $\underline{\text{be}}$ required to write, such coverage.
The hospital may assess on an equitable and pro rata basis the
following individuals to whom it extends coverage pursuant to
this section professional health care providers for a portion of
the total hospital insurance cost for this coverage: physicians
licensed under chapter 458, osteopathic physicians licensed
under chapter 459, podiatric physicians licensed under chapter
461, dentists licensed under chapter 466, and nurses licensed
under part I of chapter 464, and other health professionals. The
hospital may provide for a deductible amount to be applied
against any individual health care provider found liable in a
law suit in tort or for breach of contract. The legislative
intent in providing for the deductible to be applied to
individual health care providers found negligent or in breach of
contract is to instill in each individual health care provider
the incentive to avoid the risk of injury to the fullest extent Page 6 of 19

and ensure that the citizens of this state receive the highest quality health care obtainable.

Section 4. Present subsections (6) and (7) of section 766.118, Florida Statutes, are renumbered as subsections (7) and (8), respectively, and a new subsection (6) is added to that section, to read:

766.118 Determination of noneconomic damages.--

(6) LIMITATION ON NONECONOMIC DAMAGES FOR NEGLIGENCE OF CERTAIN HOSPITALS.--With respect to a complaint for personal injury or wrongful death arising from medical negligence, a hospital that has received an order from the Agency for Health Care Administration pursuant to s. 766.402 which certifies that the facility complies with patient-safety measures specified in s. 766.403 shall be liable for no more than \$500,000 in noneconomic damages, regardless of the number of claimants, number of claims, or theory of liability, including vicarious liability, arising from the same nucleus of operative fact, notwithstanding any other provision of this section.

Section 5. Section 766.401, Florida Statutes, is created to read:

 $\underline{766.401}$ Definitions.--As used in this section and ss. 766.402-766.405, the term:

- (1) "Affected patient" means a patient of a certified patient-safety facility.
- (2) "Affected practitioner" means any person, including a physician, who is credentialed by the eligible hospital to provide health care services in a certified patient-safety facility.

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(3) "Agency" means the Agency for Health Care Administration.

- (4) "Certified patient-safety facility" means any eligible hospital that, in accordance with an order from the Agency for Health Care Administration, has adopted a patient-safety plan.
- (5) "Clinical privileges" means the privileges granted to a physician or other licensed health care practitioner to render patient-care services in a hospital.
- (6) "Eligible hospital" or "licensed facility" means a statutory teaching hospital, as defined by s. 408.07, which maintains at least seven different accredited programs in graduate medical education and has 100 or more full-time equivalent resident physicians.
 - (7) "Health care provider" or "provider" means:
 - (a) An eligible hospital.
- (b) A physician or a physician assistant licensed under chapter 458.
- (c) An osteopathic physician or an osteopathic physician assistant licensed under chapter 459.
- (d) A registered nurse, nurse midwife, licensed practical nurse, or advanced registered nurse practitioner licensed or registered under part I of chapter 464 or any facility that employs nurses licensed or registered under part I of chapter 464 to supply all or part of the care delivered by that facility.
- (e) A health care professional association and its employees or a corporate medical group and its employees.

(f) Any other medical facility in which the primary purpose is to deliver human medical diagnostic services or to deliver nonsurgical human medical treatment, including an office maintained by a provider.

- (g) A free clinic that delivers only medical diagnostic services or nonsurgical medical treatment free of charge to low-income persons not otherwise covered by Medicaid or other programs for low-income persons.
- (h) Any other health care professional, practitioner, or provider, including a student enrolled in an accredited program, who prepares the student for licensure as any one of the professionals listed in this subsection.
- (i) Any person, organization, or entity that is vicariously liable under the theory of respondent superior or any other theory of legal liability for medical negligence committed by any licensed professional listed in this subsection.
- (j) Any nonprofit corporation qualified as exempt from federal income taxation under s. 501(a) of the Internal Revenue Code and described in s. 501(c) of the Internal Revenue Code, including any university or medical school that employs licensed professionals listed in this subsection or which delivers health care services provided by licensed professionals listed in this subsection, any federally funded community health center, and any volunteer corporation or volunteer health care provider that delivers health care services.

(8) "Health care practitioner" or "practitioner" means any
person, entity, or organization identified in subsection (7),
except for a hospital.

- (9) "Medical incident" or "adverse incident" has the same meaning as provided in ss. 381.0271, 395.0197, 458.351, and 459.026.
- (10) "Medical negligence" means medical malpractice, whether grounded in tort or in contract, arising out of the rendering of or failure to render medical care or services.
- (11) "Person" means any individual, partnership, corporation, association, or governmental unit.
- (12) "Premises" means those buildings, beds, and equipment located at the address of the licensed facility and all other buildings, beds, and equipment for the provision of the hospital, ambulatory surgical, mobile surgical care, primary care, or comprehensive health care under the dominion and control of the licensee, including offices and locations where the licensed facility offers medical care and treatment to affected patients.
- (13) "Statutory teaching hospital" or "teaching hospital" has the same meaning as provided in s. 408.07.
- Section 6. Section 766.402, Florida Statutes, is created to read:
 - 766.402 Agency approval of patient-safety plans.--
- (1) An eligible hospital that has adopted a patient-safety plan may petition the agency to enter an order certifying approval of the hospital as a certified patient-safety facility.

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(2) In accordance with chapter 120, the agency shall enter an order certifying approval of the certified patient-safety facility upon a showing that, in furtherance of an approach to patient safety:

- (a) The petitioner has established safety measures for the care and treatment of patients.
- (b) The petitioner satisfies requirements for patient-protection measures, as specified in s. 766.403.
- (c) The petitioner satisfies all other requirements of ss. 766.401-766.405.
- (3) Upon entry of an order approving the petition, the agency may conduct onsite examinations of the licensed facility to ensure continued compliance with the terms and conditions of the order.
- remains in effect until revoked. The agency may revoke the order upon reasonable notice to the eligible hospital that it fails to comply with material requirements of s. 766.403 and that the hospital has failed to cure stated deficiencies upon reasonable notice. Revocation of an agency order pursuant to s. 766.403 applies prospectively to any cause of action for medical negligence which arises on or after the effective date of the order of revocation.
- (5) An order approving a petition under this section is, as a matter of law, conclusive evidence that the hospital complies with the applicable patient-safety requirements of s. 766.403. A hospital's noncompliance with the requirements of s. 766.403 does not affect the limitations on damages conferred by

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this section. Evidence of noncompliance with s. 766.403 is not admissible for any purpose in any action for medical malpractice. This section, or any portion thereof, may not give rise to an independent cause of action for damages against any hospital.

Section 7. Section 766.403, Florida Statutes, is created to read:

766.403 Patient-safety plans.--

- (1) In order to satisfy the requirements of s. 766.402, the licensed facility shall have a patient-safety plan, which provides that the facility shall:
- (a) Have in place a process, either through the facility's patient-safety committee or a similar body, for coordinating the quality control, risk management, and patient-relations functions of the facility and for reporting to the facility's governing board at least quarterly regarding such efforts.
- (b) Establish within the facility a system for reporting near misses and agree to submit any information collected to the Florida Patient Safety Corporation. Such information must be submitted by the facility and made available by the Patient Safety Corporation in accordance with s. 381.0271(7).
- (c) Design and make available to facility staff, including medical staff, a patient-safety curriculum that provides lecture and web-based training on recognized patient-safety principles, which may include training in communication skills, teamperformance assessment and training, risk-prevention strategies, and best practices and evidence-based medicine. The licensed

facility shall report annually the programs presented to the agency.

- (d) Implement a program to identify health care providers on the facility's staff who may be eligible for an early-intervention program that provides additional skills assessment and training and offer such training to the staff on a voluntary and confidential basis with established mechanisms to assess program performance and results.
- (e) Implement a simulation-based program for skills

 assessment, training, and retraining of a facility's staff in
 those tasks and activities that the agency identifies by rule.
- (f) Designate a patient advocate who coordinates with members of the medical staff and the facility's chief medical officer regarding the disclosure of adverse medical incidents to patients. In addition, the patient advocate shall establish an advisory panel, consisting of providers, patients or their families, and other health care consumers or consumer groups to review general patient-safety concerns and other issues related to relations among and between patients and providers and to identify areas where additional education and program development may be appropriate.
- (g) Establish a procedure to biennially review the facility's patient-safety program and its compliance with the requirements of this section. Such review shall be conducted by an independent patient-safety organization as defined in s.

 766.1016(1) or other professional organization approved by the agency. The organization performing the review shall prepare a written report that contains detailed findings and

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recommendations. The report shall be forwarded to the facility's risk manager or patient-safety officer, who may make written comments in response. The report and any written comments shall be presented to the governing board of the licensed facility. A copy of the report and any of the facility's responses to the findings and recommendations shall be provided to the agency within 60 days after the date that the governing board reviewed the report. The report is confidential and exempt from production or discovery in any civil action. Likewise, the report and the information contained therein are not admissible as evidence for any purpose in any action for medical negligence.

- (h) Establish a system for the trending and tracking of quality and patient-safety indicators that the agency may identify by rule and a method for review of the data at least semiannually by the facility's patient-safety committee.
- (2) This section does not constitute an applicable standard of care in any action for medical negligence or otherwise create a private right of action, and evidence of noncompliance with this section is not admissible for any purpose in any action for medical negligence against any health care provider.
- (3) This section does not prohibit the licensed facility from implementing other measures for promoting patient safety within the premises. This section does not relieve the licensed facility from the duty to implement any other patient-safety measure that is required by state law. The Legislature intends that the patient-safety measures specified in this section are

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in addition to all other patient-safety measures required by

state law, federal law, and applicable accreditation standards

for licensed facilities.

- (4) A review, report, or other document created, produced, delivered, or discussed pursuant to this section is not discoverable or admissible as evidence in any legal action.
- Section 8. Section 766.404, Florida Statutes, is created to read:

766.404 Annual report.--

- (1) Each certified patient-safety facility shall submit an annual report to the agency containing information and data reasonably required by the agency to evaluate performance and effectiveness of its patient-safety plan. However, information may not be submitted or disclosed in violation of any patient's right to privacy under state or federal law.
- submitted by all certified patient-safety facilities, and each year, on or before March 1, the agency shall submit a report to the President of the Senate and the Speaker of the House of Representatives which evaluates the performance and effectiveness of the approach to enhancing patient safety and limiting provider liability in certified patient-safety facilities. The report must include, but need not be limited to, pertinent data concerning:
- (a) The number and names of certified patient-safety facilities;
- (b) The number and types of patient-protection measures
 currently in effect in these facilities;

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411	(c) The number of affected patients;
412	(d) The number of surgical procedures on affected
413	patients;
414	(e) The number of medical incidents, claims of medical
415	malpractice, and claims resulting in indemnity;
416	(f) The average time for resolution of contested and
417	uncontested claims of medical malpractice;
418	(g) The percentage of claims which result in civil trials;
419	(h) The percentage of civil trials which result in adverse
420	judgments against affected facilities;
421	(i) The number and average size of an indemnity paid to
422	claimants;
423	(j) The estimated liability expense, inclusive of medical
424	liability insurance premiums; and
425	(k) The percentage of medical liability expense, inclusive
426	of medical liability insurance premiums, which is borne by
427	affected practitioners in certified patient-safety facilities.
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429	The report may also include other information and data that the
430	agency deems appropriate to gauge the cost and benefit of
431	<pre>patient-safety plans.</pre>
432	(3) The agency's annual report to the President of the
433	Senate and the Speaker of the House of Representatives may
434	include relevant information and data obtained from the Office
435	of Insurance Regulation within the Department of Financial
436	Services concerning the availability and affordability of
437	enterprise-wide medical liability insurance coverage for
438	affected facilities and the availability and affordability of

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insurance policies for individual practitioners which contain coverage exclusions for acts of medical negligence in facilities that indemnify health practitioners. The Office of Insurance Regulation shall cooperate with the agency in the reporting of information and data specified in this subsection.

- (4) Reports submitted to the agency by certified patient-safety facilities pursuant to this section are public records under chapter 119. However, these reports, and the information contained therein, are not admissible as evidence in a court of law in any action.
- Section 9. Section 766.405, Florida Statutes, is created to read:
- 766.405 Damages in malpractice actions against certain
 hospitals that meet patient-safety requirements; agency approval
 of patient-safety measures.--
- (1) In recognition of their essential role in training future health care providers and in providing innovative medical care for this state's residents, in recognition of their commitment to treating indigent patients, and further in recognition that teaching hospitals, as defined in s. 408.07, provide benefits to the residents of this state through their roles in improving the quality of medical care, training of health care providers, and caring for indigent patients, the limits of liability for medical malpractice arising out of the rendering of, or the failure to render, medical care by all such hospitals shall be determined in accordance with the requirements of this section.

(2) Upon entry of an order and for the entire period of time that the order remains in effect, the damages recoverable from an eligible hospital covered by the order and from its full-time physician employees, full-time and part-time nonphysician employees, and agents in actions arising from medical negligence shall be determined in accordance with the following provisions:

- (a) Noneconomic damages shall be limited to a maximum of \$500,000, regardless of the number of claimants, number of claims, or the theory of liability pursuant to s. 766.118(6).
- (b) Awards of economic damages shall be offset by payments from collateral sources, as defined by s. 766.202(2), and any set-offs available under ss. 46.015 and 768.041. Awards for future economic losses shall be offset by future collateral source payments.
- (c) After being offset by collateral sources, awards of future economic damages shall, at the option of the eligible hospital, be reduced by the court to present value or paid through periodic payments in the form of an annuity or a reversionary trust. A company that underwrites an annuity to pay future economic damages shall have a rating of "A" or higher by A.M. Best Company. The terms of the reversionary instrument used to periodically pay future economic damages must be approved by the court. Such approval may not be unreasonably withheld.
- (3) The limitations on damages in subsection (2) apply prospectively to causes of action for medical negligence which arise on or after the effective date of the order.

Section 10. Section 766.406, Florida Statutes, is created to read:

766.406 Rulemaking authority.--The agency may adopt rules pursuant to ss. 120.536(1) and 120.54 to administer ss. 766.401-766.405.

Section 11. If any provision of this act or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the act which can be given effect without the invalid provision or application, and to this end, the provisions of this act are severable.

Section 12. If a conflict exists between any provision of this act and s. 456.052, s. 456.053, s. 456.054, s. 458.331, s. 459.015, or s. 817.505, Florida Statutes, the provisions of this act shall govern. The provisions of this act shall be broadly construed in furtherance of the overriding legislative intent to facilitate innovative approaches for enhancing patient protection and limiting provider liability in eligible hospitals.

Section 13. <u>It is the intention of the Legislature that</u> the provisions of this act are self-executing.

Section 14. This act shall take effect upon becoming a law.