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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 521 Session of 2009

INTRODUCED BY DeLUCA, BARRAR, BRENNAN, CALTAGIRONE, D. COSTA, CREIGHTON, DONATUCCI, FRANKEL, GINGRICH, GOODMAN, HALUSKA, HENNESSEY, JOSEPHS, KORTZ, KOTIK, MELIO, MICOZZIE, MOUL, MUNDY, MURT, MYERS, PYLE, SIPTROTH, K. SMITH, SOLOBAY AND WHITE, FEBRUARY 19, 2009

REFERRED TO COMMITTEE ON INSURANCE, FEBRUARY 19, 2009

AN ACT

Amending the act of March 20, 2002 (P.L.154, No.13), entitled "An act reforming the law on medical professional liability; providing for patient safety and reporting; establishing the Patient Safety Authority and the Patient Safety Trust Fund; abrogating regulations; providing for medical professional liability informed consent, damages, expert qualifications, limitations of actions and medical records; establishing the Interbranch Commission on Venue; providing for medical professional liability insurance; establishing the Medical Care Availability and Reduction of Error Fund; providing for medical professional liability claims; establishing the Joint Underwriting Association; regulating medical professional liability insurance; providing for medical licensure regulation; providing for administration; imposing penalties; and making repeals," further providing for declaration of policy, for patient safety definitions, for powers and duties of the Patient Safety Authority and for powers and duties of the Department of Health; and providing for whistleblower protection.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. Section 102 of the act of March 20, 2002 (P.L. 154, No.13), known as the Medical Care Availability and Reduction of Error (Mcare) Act, is amended to read:

Section 102. Declaration of policy.

The General Assembly finds and declares as follows:

(1) It is the purpose of this act to ensure that medical care is available in this Commonwealth through a comprehensive and high-quality health care system.

(2) Access to a full spectrum of hospital services and to highly trained physicians in all specialties must be available across this Commonwealth.

(3) To maintain this system, medical professional liability insurance has to be obtainable at an affordable and reasonable cost in every geographic region of this Commonwealth.

(4) A person who has sustained injury or death as a result of medical negligence by a health care provider must be afforded a prompt determination and fair compensation.

(5) Every effort must be made to reduce and eliminate medical errors by identifying problems and implementing solutions that promote patient safety.

(6) Recognition and furtherance of all of these elements is essential to the public health, safety and welfare of all the citizens of Pennsylvania.

<u>(7) It is the purpose of this act to enhance patient safety by establishing meaningful whistleblower protection and a reporting system for medical errors which is responsive to legitimate concerns.</u>

Section 2. Section 302 of the act is amended by adding definitions to read:

Section 302. Definitions.

The following words and phrases when used in this chapter shall have the meanings given to them in this section unless the context clearly indicates otherwise:

* * *

"Disciplinary action." An action against an individual which has a negative impact on the individual in relation to salary or terms of employment or professional affiliation. The term includes discharge and loss or alteration of privileges of affiliation.

* * *

"Health care facility." A facility licensed under the act of July 19, 1979 (P.L.130, No.48), known as the Health Care Facilities Act.

"Health care practitioner." An individual who is authorized to practice some component of the healing arts by a license, permit, certificate or registration, issued by a Commonwealth licensing agency.

* * *

Section 3. Section 304(a) and (b) of the act are amended to read:

Section 304. Powers and duties.

(a) General rule.--The authority shall do all of the following:

(1) Adopt bylaws necessary to carry out the provisions of this chapter.

(2) Employ staff as necessary to implement this chapter.

(3) Make, execute and deliver contracts and other instruments.

(4) Apply for, solicit, receive, establish priorities for, allocate, disburse, contract for, administer and spend funds in the fund and other funds that are made available to the authority from any source consistent with the purposes of this chapter.

(5) Contract with a for-profit or registered nonprofit entity or entities, other than a health care provider, to do the following:

(i) Collect, analyze and evaluate data regarding reports of serious events and incidents, including the identification of performance indicators and patterns in frequency or severity at certain medical facilities or in certain regions of this Commonwealth.

(ii) Transmit to the authority recommendations for changes in health care practices and procedures which may be instituted for the purpose of reducing the number and severity of serious events and incidents.

(iii) Directly advise reporting medical facilities of immediate changes that can be instituted to reduce serious events and incidents.

(iv) Conduct reviews in accordance with subsection (b).

(6) Receive and evaluate recommendations made by the entity or entities contracted with in accordance with paragraph (5) and [report] <u>advise the department of</u> those recommendations [to the department, which shall have no more than 30 days to approve or disapprove the recommendations].

(7) [After consultation and approval by the department, issue] <u>Issue</u> recommendations to medical facilities on a facility-specific or on a Statewide basis regarding changes, trends and improvements in health care practices and procedures for the purpose of reducing the number and severity of serious events and incidents. Prior to issuing recommendations, consideration shall be given to the following factors that include expectation of improved

quality care, implementation feasibility, other relevant implementation practices and the cost impact to patients, payors and medical facilities. Statewide recommendations shall be issued to medical facilities on a continuing basis and shall be published and posted on the department's publicly accessible Internet website and the authority's publicly accessible [World Wide Web site] Internet website.

(8) Meet with the department for purposes of implementing this chapter.

(9) Upon receipt of a complaint under subsection (b), do all of the following:

(i) Distribute copies of the complaint to each director on the board.

(ii) Within ten business days, require the department to investigate the complaint under section 306(a)(6).

(iii) Maintain the confidentiality of all information resulting from the complaint and the investigation. Information under this subparagraph may be released only when sanctions are pursued under section 306(a)(7) or until section 316(d) is invoked by a health care practitioner.

(10) Disseminate, through publications and training sessions, information about patient safety reporting under subsection (b)(2).

(b) [Anonymous reports] Reports to the authority.--

(1) A health care worker who has complied with section 308(a) may file an anonymous report regarding a serious event with the authority. Upon receipt of the report, the authority shall give notice to the affected medical facility that a

report has been filed. [The authority shall conduct its own review of the report unless the medical facility has already commenced an investigation of the serious event.] The medical facility [shall] may provide the authority with the results of its investigation no later than 30 days after receiving notice pursuant to this subsection. [If the authority is dissatisfied with the adequacy of the investigation conducted by the medical facility, the authority shall perform its own review of the serious event and may refer a medical facility and any involved licensee to the department for failure to report pursuant to section 313(e) and (f).] This paragraph shall not preclude a direct report to the authority under paragraph (2).

(2) The authority shall maintain a Statewide confidential, toll-free telephone line to enable health care practitioners to report on patient safety and the quality of patient care provided by a health care facility. If a health care practitioner who files a complaint under this paragraph requests anonymity, the authority shall, except to the extent necessary to verify credentials, maintain anonymity.

* * *

Section 4. Section 306 of the act, amended May 1, 2006 (P.L. 103, No.30), is amended to read:

Section 306. Department responsibilities.

(a) General rule.--The department shall do all of the following:

(1) Review and approve patient safety plans in accordance with section 307.

(2) Receive reports of serious events and infrastructure failures under section 313.

(3) Investigate serious events and infrastructure failures.

(4) In conjunction with the authority, analyze and evaluate existing health care procedures and approve recommendations issued by the authority pursuant to section 304(a)(6) and (7).

(5) Meet with the authority for purposes of implementing this chapter.

(6) Upon referral of a complaint under section 304(a)(9), do all of the following:

(i) Within ten business days, investigate the complaint. In order to carry out the investigation under this subparagraph, the department shall consult with one, or, if the department deems necessary, a second, independent, external quality review team to examine the team's recommendations and findings. A team under this subparagraph shall consider the appropriate use of patient care standards in the situation under investigation and make recommendations based upon its findings. The following apply to a team under this subparagraph:

(A) The team shall consist of at least all of the following:

(I) A registered nurse who holds a license under the act of May 22, 1951 (P.L.317, No.69), known as The Professional Nursing Law; is engaged in active practice for at least 20 hours per week; and holds a specialty-specific certification from the American Nurses Credentialing Center.

(II) A physician or an osteopath who is engaged in active practice for at least 20 hours per week and who is board-certified in a specialty which is recognized by the American Board of Medical Specialties or the American Osteopathic Association and which is specific to the situation under investigation.

(III) A pharmacist who is engaged in active practice for at least 20 hours per week and who is board-certified as a clinical pharmacist.

(B) A member of the team may not:

(I) be an employee or a contractor of the health care facility or the health care practitioner under investigation;

(II) be a past or current colleague of the health care practitioner under investigation;

(III) have a past or current financial or practice relationship with the health care practitioner under review, that practitioner's group, that practitioner's employer or that practitioner's privilege-granting health care facility;

(IV) have a past or current financial or practice relationship with the health care facility under investigation; or

(V) reside within 75 miles of the health care facility under investigation.

(ii) If warranted by the investigation:

(A) Seek sanctions under paragraph (7).

(B) Recommend sanctions or other action to the

appropriate licensing board under Chapter 9. A licensing board or agency which receives a recommendation under this clause shall report to the authority concerning its action every 30 days until the matter is finally disposed of. A report under this clause shall be available to each director of the board upon request.

(C) Recommend sanctions or other action to any other appropriate Commonwealth agency.

(iii) Maintain the confidentiality of all information resulting from the complaint and the investigation until sanctions are sought under paragraph (7) or until section 316(d) is invoked by a health care practitioner.

(7) Impose an administrative penalty of up to $5,000 upon a health care facility for acts or omissions which impair patient safety or the quality of patient care or, at the department's discretion, take other remedial actions as authorized by law. This paragraph is subject to 2 Pa.C.S. Ch. 5 Subch. A (relating to practice and procedure of Commonwealth agencies) and Ch. 7 Subch. A (relating to judicial review of Commonwealth agency action).

(b) Department consideration.--The recommendations made to medical facilities pursuant to subsection (a)(4) may be considered by the department for licensure purposes under the act of July 19, 1979 (P.L.130, No.48), known as the Health Care Facilities Act, and, in the case of abortion facilities, for approval or revocation purposes pursuant to 28 Pa. Code § 29.43 (relating to facility approval), but shall not be considered mandatory unless adopted by the department as regulations

pursuant to the act of June 25, 1982 (P.L.633, No.181), known as the Regulatory Review Act.

Section 5. The act is amended by adding a section to read:

Section 316. Whistleblower protection.

(a) Applicability.--This section applies to a health care practitioner who does any of the following:

(1) Files a complaint under section 304(b).

(2) Makes a report to an agency which has jurisdiction over patient safety, health care or the quality of patient care provided by any health care facility or health care professional.

(3) Makes a report to a health care facility on patient safety or the quality of patient care provided by the health care facility. This paragraph includes a report to any employer, supervisor, coworker or other person with privileges.

(b) Prohibition.--A health care facility that employs or grants conditional or unconditional privileges to a health care practitioner may not take disciplinary action against the health care practitioner in retaliation for filing a complaint in good faith or making a report in good faith under subsection (a).

(c) Immunity.--A health care practitioner who in good faith files a complaint or makes a report under subsection (a) shall be immune from civil liability arising from filing the complaint or making the report.

(d) Remedy.--A health care practitioner who is aggrieved by a violation of subsection (b) may recover damages proximately caused by the violation, including pain and suffering; cost of the litigation; and attorney fees. Notwithstanding any other provision of law, in an action under this subsection, all

patient records relating to the complaint under this subsection, including peer review documents, shall be available to the court and each party for possible use as documentary evidence.

(e) Deterring complaints and reports.--Any provision of a contract or a professional affiliation arrangement, including a document granting privileges, entered into with a health care practitioner which limits the health care practitioner's ability to file a complaint or make a report under subsection (a) or which contains any threat, implicit or otherwise, or contains any penalty for filing a complaint or making a report under subsection (a) is against public policy and shall be void.

(f) Notification to health care practitioners.--Within 12 months of the effective date of this section, every Commonwealth licensing agency that licenses, permits, certifies or registers health care practitioners within this Commonwealth shall notify the health care practitioners of the Statewide confidential, toll-free telephone line and the whistleblower protection provided through this act through already scheduled newsletters, annual notices and other mailings.

Section 6. This act shall take effect in 90 days.