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THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 1263 Session of 2002

INTRODUCED BY MOWERY, JUBELIRER, M. WHITE, TARTAGLIONE, GERLACH AND HOLL, JANUARY 23, 2002

REFERRED TO PUBLIC HEALTH AND WELFARE, JANUARY 23, 2002

AN ACT

Establishing a health care quality assurance authority; providing for its powers and duties; requiring patient safety plans; mandating serious event reporting; defining peer review and quality review activities; establishing privileges and confidentiality afforded to peer review and quality review activities and records; and allocating staffing and funds for physician oversight.

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

CHAPTER 1

GENERAL PROVISIONS

Section 101. Short title.

This act shall be known and may be cited as the Patient Safety and Quality Assurance Act.

Section 102. Statement of purpose.

It is the purpose of this act to promote, preserve and protect the health, safety and welfare of patients by the effective management of patient safety and quality improvement activities through:

(1) The creation of a health care environment that encourages error identification and the implementation of remedial steps to reduce the likelihood of future serious events by minimizing the use of blame or retribution as a means of addressing individual involvement in a medical error. This includes encouraging organizational learning about medical errors and supports the sharing of that knowledge to effect behavioral changes in itself and other health care organizations to improve patient safety.

(2) The creation of a health care quality assurance authority to identify those conditions that minimize medical errors, improve patient outcomes and enhance health care delivery.

(3) The establishment of a process for confidential, effective and appropriate peer review and quality review activities.

(4) The imposition of mandatory serious event reporting by all licensed health care facilities.

(5) The allocation of staffing and funds to the State Board of Medicine and the State Board of Osteopathic Medicine

in order to strengthen oversight of physician practice.

Section 103. Definitions.

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

"Act." The Patient Safety and Quality Assurance Act.

"Adverse event." An injury caused by medical management rather than the underlying condition of the patient.

"Adverse outcome." An outcome that results from an adverse event.

"Authority." The Health Care Quality Assurance Authority established in section 301.

"Clinical privileges." Permission to provide specific care services in an organization within well-defined limits, based on the following factors, including: license, education, training, experience, competence, health status and judgment.

"Credentialing." The process of obtaining, verifying and assessing the qualifications of a health care practitioner to provide patient care services in or for a health care organization.

"Electronic communication" or "e-mail." The process whereby information is transferred electronically between information systems, replacing traditional paper, mail and verbal communication of this information.

"Error." The failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.

"Fund." The Health Care Quality Assurance Trust Fund established in section 304.

"Health care insurer." Any insurance company, association or exchange authorized to transact the business of insurance in

this Commonwealth that provides coverage for health care services. This shall also include any entity operating under any of the following:

(1) Section 630 of the act of May 17, 1921 (P.L.682, No.284), known as The Insurance Company Law of 1921.

(2) The act of December 29, 1972 (P.L.1701, No.364), known as the Health Maintenance Organization Act.

(3) The act of December 14, 1992 (P.L.835, No.134), known as the Fraternal Benefit Societies Code.

(4) 40 Pa.C.S. Ch. 61 (relating to hospital plan corporations).

(5) 40 Pa.C.S. Ch. 63 (relating to professional health services plan corporations).

(6) 40 Pa.C.S. Ch. 67 (relating to beneficial societies).

"Health care organization." A licensed health care facility, group practice, integrated delivery system, health care insurer or any entity which is authorized by the laws of this Commonwealth to deliver, contract to deliver or arrange for the delivery of health care services.

"Health care practitioner." An individual who is licensed, certified or otherwise authorized to provide health care services within this Commonwealth.

"Licensed health care facility." Those entities operating under the act of October 20, 1966 (3rd Sp.Sess., P.L.96, No.6), known as the Mental Health and Mental Retardation Act of 1966, the act of June 13, 1967 (P.L.31, No.21), known as the Public Welfare Code and the act of July 19, 1979 (P.L.130, No.48), known as the Health Care Facilities Act.

"Licensure board." The State Board of Medicine or the State

Board of Osteopathic Medicine.

"Medical staff." The organization of physicians or dentists who are credentialed and have privileges at a licensed health care facility.

"Medication error." Any preventable event that may cause or lead to inappropriate medication use or patient harm. Such events may be related to professional practice, health care products, procedures and systems, including: prescribing; order communication; product labeling, packaging and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.

"Near error." Used to describe any process variation which did not affect the outcome but for which a recurrence carries a significant chance of a serious adverse outcome.

"Original source document." A document that was created outside the scope of any quality review, including peer review, activities and for a purpose unrelated to quality review, including peer review.

"Patient safety officer." An individual designated by a medical facility to coordinate the activities set forth in the patient safety plan under Chapter 5.

"Peer review." The procedure for evaluation by professional health care providers of the performance of other similar health care providers for the purposes of:

(1) evaluating the quality of health care rendered;

(2) review of patient outcomes; or

(3) evaluating the cost of providing health care services.

"Peer review action." An action or recommendation of a peer review committee which affects, or may affect, adversely the

medical staff membership or clinical privileges, or membership in a professional society, of the professional health care provider. The term includes a formal decision of a peer review committee not to take an action or make a recommendation described in the previous sentence and also includes quality review activities relating to a peer review action.

"Peer review activity." An activity of a licensed health care facility, professional society, group practice, integrated delivery system or other professional health care provider with respect to an individual physician to:

(1) determine whether the physician may have clinical privileges with respect to or membership in the entity;

(2) determine the scope and conditions of such privilege or membership; or

(3) change or modify such privileges or membership.

"Peer review committee."

(1) A licensed health care facility, professional society, group practice, integrated delivery system or other professional health care provider and the governing body thereof, engaging in peer review activities.

(2) Any individual or committee engaging in, or assisting in, peer review activities on behalf of a licensed health care facility, professional society, group practice, integrated delivery system or other professional health care provider.

"Privileging." The process whereby clinical privileges are granted for a health care practitioner by a health care organization.

"Professional health care provider." An individual or organization which is approved, licensed, certified or otherwise

regulated to practice or operate in the health care field under the laws of this Commonwealth, including the following individuals or organizations:

(1) Health care practitioners.

(2) An administrator of a licensed health care facility.

(3) A corporation or other organization operating a licensed health care facility or any not-for-profit corporation that is a member or corporate affiliate of the licensed health care facility or of which the health care facility is a member.

"Professional society." An organization of health care practitioners.

"Quality improvement." An approach to the continuous study and improvement of the process of providing health care services to meet the needs of individuals and others.

"Quality of care" or "quality of health care." The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.

"Quality review." The process of review and evaluation by a review organization or review committee of the quality of services provided by a professional health care provider for the purposes of:

(1) evaluating and improving the quality of health care rendered;

(2) reducing morbidity or mortality;

(3) evaluating the cost of providing health care services;

(4) engaging in self-critical analysis;

(5) evaluating and conducting reporting to Federal or

State regulatory agencies, national accrediting organizations or organizations serving as repositories or clearinghouses for voluntary medical error reporting programs, including reports contemplated under this act;

(6) compiling aggregate data concerning the procedures and the outcomes of care of professional health care providers for the purposes of evaluating the quality and efficiency of health care services, including practice analysis, review of incident reports, inpatient and outpatient utilization review, medical audit, claims review and compliance review of a licensed health care facility with applicable laws, rules and regulations; or

(7) peer review.

"Quality review activities." All activities, including peer review, engaged in by a review organization or a review committee, or an employee, agent or contractor thereof, or by the person or entity which is the subject of the quality review, or an employee, agent or contractor thereof, as part of the quality review process.

"Quality review records." All data, information, reports, documents, findings, compilations and summaries, testimony and any other records generated by, acquired by, created for or given to a review organization or review committee, either oral or written, as a part of any quality review, including peer review, regardless of when the record is created. The term does not include original source documents.

"Review organization" or "review committee."

(1) Any person, panel, national accrediting organization or committee of a health care organization or organizations engaging in quality review, including peer review, to gather

and review information relating to the care and treatment of patients.

(2) Any licensed health care facility's board, committee or individual reviewing the professional qualifications or activities of its medical staff or applicants for admission thereto.

(3) A committee of an association comprised in large part of professional health care providers reviewing the operation of a licensed health care facility or facilities, including an organization established by such associations that contracts with a licensed health care facility or facilities to assist in performing quality review, including peer review.

"Self-critical analysis." All procedures a professional health care provider uses or functions it performs to undergo self-evaluation to identify, investigate and eliminate safety problems and medical or system errors in order to change and improve health care practices and patient care.

CHAPTER 3

HEALTH CARE QUALITY ASSURANCE AUTHORITY

Section 301. Establishment of authority.

(a) Establishment.--There is hereby established a body corporate and politic to be known as the Health Care Quality Assurance Authority.

(b) Appointments.--

(1) The authority shall consist of 17 members appointed in accordance with the following:

(i) The Physician General of the Department of Health who shall act as chair.

(ii) Eight members appointed by the Governor.

(iii) Two members appointed by the President pro tempore of the Senate and two members appointed by the Minority Leader of the Senate.

(iv) Two members appointed by the Speaker of the House of Representatives and two members appointed by the Minority Leader of the House of Representatives.

(2) No authority member may act or attend through a designee or a proxy.

(3) All of the appointments shall be individuals knowledgeable in or experienced with patient safety or quality improvement practices, philosophies and initiatives.

(c) Composition.--The authority shall be comprised of the following:

(1) Six of the members appointed to the authority by the Governor must possess expertise in health care, with representation by institution-based, practicing pharmacists, nurses, physicians and risk managers/quality improvement personnel. At least three of these members shall be physicians.

(2) Two of the members appointed to the authority by the Governor shall be health care consumers.

(3) Members appointed to the authority by the legislature must be representatives of licensed health care facilities. At least three of these members shall represent hospitals and at least two of these members shall represent long-term care.

(4) The members of the authority shall not receive any compensation for serving but shall be reimbursed at established Commonwealth rates for necessary expenses incurred in the performance of their duties.

(d) Terms.--

(1) With the exception of the Physician General, members of the authority shall serve for terms of four years. No appointed member shall be eligible to serve more than two full consecutive terms.

(2) All members to the authority shall be appointed within 90 days of the effective date of this act, and the operations of the authority shall begin immediately upon constitution of the full authority. The Physician General shall convene the first meeting within 30 days after constitution of the full authority.

(e) Quorum.--A majority of the members of the authority shall constitute a quorum. Notwithstanding any other provision of law, action may be taken by the authority at a meeting upon a vote of the majority of its members present in person or through the use of amplified telephonic equipment.

(f) Meetings.--

(1) The authority shall meet at least four times a year and may provide for special meetings as may be necessary. Meetings of the authority may be held anywhere within this Commonwealth.

(2) All meetings of the authority shall be advertised and conducted pursuant to 65 Pa.C.S. Ch. 7 (relating to open meetings) and shall be subject to the act of June 21, 1957 (P.L.390, No.212), referred to as the Right-to-Know Law.

Section 302. Confidentiality and privilege.

The authority established to carry out the functions specified in this chapter shall constitute a "review organization" or "review committee" as defined in section 103. All data, logs, information, documents, findings, compilations

and summaries, testimony and any other record generated by, acquired by, created for or given to the authority under this section shall constitute "quality review records" as defined in section 103 and shall be afforded the statutory protections for quality review records set forth in section 1101.

Section 303. Powers and duties.

The authority shall do all of the following:

(1) Employ staff as necessary to implement this act.

(2) Receive reports and recommendations from the list of approved organizations recognized as experts in collecting, independently reviewing and analyzing information regarding patient safety and medical errors under section 503.

(3) Establish a list of approved organizations recognized as experts for licensed health care facilities to choose from for the purposes of collecting, independently reviewing and analyzing information submitted by health care organizations and practitioners regarding improving patient outcomes, reducing medical errors and increasing patient safety.

(4) Identify those conditions that improve patient outcomes and enhance health care delivery, reduce medical errors and increase patient safety. Develop strategies, goals and action plans for achieving improvements in these areas.

(5) Identify new technologies which enhance the delivery of health care by improving patient outcomes, reducing medical errors and increasing patient safety.

(6) Set priorities on what medical conditions could benefit from systems-wide approaches to improving health care outcomes.

(7) Report as necessary to all licensed health care

facilities on trends and recommendations to improve patient outcomes, reduce medical errors and increase patient safety.

(8) Apply for, solicit, receive, establish priorities for, allocate, disburse, 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 act.

(9) Advise the State Treasurer in relation to the investment of any money held in the fund and advise the State Treasurer in relation to the use of depositories for moneys of the fund.

(10) Receive reports and recommendations from the Department of Health and the Department of Public Welfare regarding the reportable events collected under Chapter 7.

(11) Evaluate the effectiveness of the State's mandatory serious event reporting system. Identify known and suspected obstacles to reporting, recommend alternative methods that will enhance reporting and assess the reporting system's utility in improving patient safety in licensed health care facilities.

(12) Make recommendations to the General Assembly and the executive branch of government regarding changes in the delivery of health care that improve patient outcomes, reduce medical errors and increase patient safety.

(13) Meet at least quarterly with the Department of Health and the Department of Public Welfare to advise and assist them in implementing this act.

(14) Prepare and publish annually a report of its findings, conclusions and activities conducted under this act, including a list of priorities of key issues relating to patient safety and quality improvement that need to be

addressed in this Commonwealth and a plan on how to implement these recommendations. This report shall be submitted to the members of the following standing committees of the General Assembly: the Public Health and Welfare Committee of the Senate; the Consumer Protection and Professional Licensure Committee of the Senate; the Health and Human Services Committee of the House of Representatives; and the Professional Licensure Committee of the House of Representatives; and posted on the Department of Health's and the Department of Public Welfare's Would Wide Web sites.

(15) Sponsor two educational forums each year to facilitate the sharing and exchange of information among licensed health care facilities and health care practitioners regarding patient safety issues.

Section 304. Health Care Quality Assurance Trust Fund.

(a) Establishment.--There is hereby established a separate account in the State Treasury to be known as the Health Care Quality Assurance Trust Fund. The fund shall be administered by the State Treasurer with the advice of the authority. All interest earned from the investment or deposit of moneys accumulated in the fund shall be deposited in the fund for the same use.

(b) Funds.--All moneys deposited into the fund shall be held in trust and shall not be considered general revenue of the Commonwealth but shall be used only to effectuate the purposes of this act as determined by the authority.

(c) Receipts and other credits.--There shall be paid or credited to the fund:

(1) Amounts appropriated to the fund in the manner provided by law.

(2) The following surcharges, which are hereby imposed:

(i) A surcharge upon the health care facility licensure application and renewal fees of the Department of Health established under section 807(b) of the act of July 19, 1979 (P.L.130, No.48), known as the Health Care Facilities Act, in the amount of 10% of each such fee.

(ii) A surcharge upon the civil penalties collected by the Department of Health established under section 817(b) of the Health Care Facilities Act, in the amount of 25% of each such fee.

(iii) A surcharge upon the licensing, examination, registration, certificates and other fees of all health care-related professionals of the Bureau of Professional and Occupational Affairs of the Department of State in the amount of 10% of each such fee.

(d) Expenditures.--Moneys in the fund may be expended by the authority to implement this act.

CHAPTER 5

PATIENT SAFETY

Section 501. Patient safety plans.

(a) Development.--Licensed health care facilities shall develop and implement a patient safety plan that incorporates mechanisms and internal, organization-wide systems for identification and reporting of incidents or occurrences relating to patient safety and medical errors and the implementation of remedial steps to reduce the likelihood of future serious events. The plan shall be developed in consultation with the medical staff, nursing staff and other health care practitioners and employees providing health care services in the facility. The medical staff shall have the

primary role in developing and implementing the patient safety plan as a result of its responsibility for the quality of medical care provided at the facility.

(b) Requirements.--The licensed health care facility's patient safety plan shall:

(1) Establish a system for employees and independent contractors to report incidents or occurrences relating to patient safety and medical errors as defined in subsection (c).

(2) Be accessible 24 hours a day, 7 days a week.

(3) Utilize any method or form of information exchange to receive reports from employees and independent contractors, including, but not limited to, hotlines, including anonymous hotlines, electronic communication or e-mails and written memoranda, including event reporting forms. If the licensed health care facility establishes a hotline, the telephone number shall be made readily available to all employees and independent contractors, such as by conspicuously posting the telephone number in common work areas.

(4) Develop more than one communication reporting path for an employee or independent contractor to report incidents or occurrences relating to patient safety and medical errors. One of the reporting modes must allow for anonymous reporting.

(5) Notify all employees and independent contractors of the existence of the mechanisms and internal, organization-wide systems for performance improvement that include the identification and reporting of incidents or occurrences relating to patient safety and medical errors.

(6) Incorporate findings and recommendations under the patient safety plan, where appropriate, into the health care facility's existing processes and structures for quality review, quality improvement or other performance measurement and analysis activities.

(7) Designate and individual within the licensed health care facility to serve as a patient safety officer. This person shall be responsible for coordinating the activities set forth in the patient safety plan.

(c) Scope of reporting.--The types of incidents or occurrences that shall be reported shall include, but not be limited to:

(1) Events that cause no harm to patients but are categorized as "near errors."

(2) Serious events which could compromise quality assurance or patient safety as defined in section 701.

(3) Those events with serious adverse outcomes.

(d) Investigations.--Matters reported shall be documented and investigated through the licensed health care facility's process of self-critical analysis with the active involvement of its medical staff. Data shall be maintained by the licensed health care facility that includes:

(1) The specific report made.

(2) The nature of any investigation or analysis.

(3) The results of any investigation or analysis.

(e) Retaliatory action prohibited.--Licensed health care facilities shall:

(1) Establish policies and procedures which provide that all employees, medical staff members, and independent contractors must be involved in identifying deficiencies in

current care delivery processes and in designing and executing solutions needed to create safer systems.

(2) Develop and distribute nonretaliation policies to all employees, medical staff members and independent contractors to encourage the identification and reporting of incidents or occurrences relating to patient safety and medical errors under this chapter.

(3) Include the identification and reporting of incidents or occurrences relating to patient safety and medical errors as a factor in evaluating the performance of all employees and independent contractors, and in reviewing and acting upon matters relating to the medical staff membership and privileges of its medical staff.

(4) Develop methods to encourage reporting of errors or patient safety concerns which shall include, but not be limited to:

(i) Incorporating accountability for patient safety into employee position descriptions and establishing a comparable mechanism that does the same with members of the licensed health care facility's medical staff.

(ii) Developing a policy setting forth the degrees of disciplinary actions that may be imposed on all employees and independent contractors and the types of corrective action that may be imposed on members of its medical staff for failing to report identified incidents or occurrences relating to patient safety and medical errors.

(f) Disciplinary action.--Nothing in this section shall limit a licensed health care facility's ability to take appropriate disciplinary action against an employee or

independent contractor for not meeting defined performance expectations or to take corrective action against medical staff members for unprofessional conduct consistent with medical staff bylaws, including making false reports regarding errors, near errors or complaints related to patient safety.

(g) Report to the governing body.--At least quarterly, after review by and input from the medical staff consistent with the licensed health care facility's medical staff bylaws, and in accordance with the process set forth in the patient safety plan, a report to the licensed health care facility's governing body shall be made on the occurrence of medical errors and actions taken by the facility to improve patient safety. Such report shall include information generated from the licensed health care facility's internal, organization-wide systems for the identification and reporting of incidents or occurrences relating to patient safety and medical errors.

(h) Records.--All data, logs, reports, information, documents, findings, compilations and summaries and any other records generated by, acquired by, created for or given to the licensed health care facility's governing body under this section shall constitute "quality review records" as defined in section 103 and shall be afforded the statutory protections for quality review records set forth in Chapter 11.

Section 502. Confidentiality and privilege.

Any committee established to carry out the functions specified in this chapter shall constitute a "review organization" or "review committee" as defined in section 103. All data, logs, information, documents, findings, compilations and summaries, testimony and any other record generated by, acquired by, created for or given to the review organization or

review committee under this section shall constitute "quality review records" as defined in section 103 and shall be afforded the statutory protections for quality review records set forth in section 1101.

Section 503. External reporting and information exchange.

(a) Establishment.--Performance monitoring and improvement in health care are data driven. As part of the patient safety plan, licensed health care facilities shall:

(1) Establish a mechanism and participate in the voluntary reporting and sharing of information or knowledge with an organization that has been approved for use in collecting, independently reviewing and analyzing information submitted by health care organizations and practitioners for the purpose of education and organizational learning about improving patient outcomes, reducing medical errors and increasing patient safety.

(2) Each licensed health care facility shall choose at least one organization to voluntarily report to and share information with that which is listed by the authority as acceptable for use as set forth in section 302. The licensed health care facility shall maintain the relationship with this organization for at least two years.

(3) Each licensed health care facility shall notify the authority of any changes in its relationship with the selected organization or the selection of a new or additional organization used to meet the external reporting and information exchange requirements.

(b) Data collection.--Licensed health care facilities shall plan and design information management processes to meet internal and external information needs. Licensed health care

facilities shall choose which types of data and information are important to monitor and voluntarily report based on its mission, the scope of care and services provided and populations served, and which meets the data reporting requirements of the organization it chooses to voluntarily report to and share information with.

(c) Submission of reports.--Each licensed health care facility shall ensure that aggregate data and trending information based on the expert organization's findings and analysis is submitted to the authority at least quarterly. The data and trending information shall be reported to the authority directly by the expert organization.

(d) Mandatory participation.--To effectively implement processes for reporting and sharing of information or knowledge with organizations recognized as experts in collecting, independently reviewing and analyzing information submitted by health care organizations and practitioners for the purpose of education and organizational learning about medical errors and to effect behavioral changes to improve patient safety, participation by licensed health care facilities shall be voluntary for two years. At the expiration of two years, participation with at least one of these organizations shall be mandatory by all licensed health care facilities.

CHAPTER 7

MANDATORY REPORTING OF SERIOUS EVENTS

Section 701. Reporting requirements.

(a) Establishment.--If a licensed health care facility is aware of a situation or the occurrence of an event at the facility which could seriously compromise quality assurance or patient safety, the facility shall notify the Department of

Health for facilities operating under the act of July 19, 1979 (P.L.130, No.48), known as the Health Care Facilities Act, and the Department of Public Welfare for facilities operating under the act of October 20, 1966 (3rd Sp.Sess., P.L.96, No.6), known as the Mental Health and Mental Retardation Act of 1966, and the act of June 13, 1967 (P.L.31, No.21), known as the Public Welfare Code, collectively, the applicable State agency with licensure jurisdiction.

"Seriously compromise quality assurance or patient safety" when used in this chapter means an unexpected occurrence involving death or serious physical or psychological injury. Serious injury specifically includes loss of limb or function.

(b) Reportable events.--For purposes of this chapter, the following events shall be reported to the Department of Health or the Department of Public Welfare:

(1) Clinical treatment or medical intervention-related events, not related to the natural course of the patient's illness or underlying condition or pursuant to a patient directive:

(i) Unanticipated death or major permanent loss of function.

(ii) Deaths due to malnutrition, dehydration or sepsis that occurred following conduct on the part of the licensed health care facility or its staff, employees or independent contractors.

(iii) Deaths or serious injuries related to a medication error.

(iv) Transfers to a hospital from another licensed health care facility as a result of injuries or accidents occurring in the facility and not reportable under any

other category. Transferring facilities are responsible for making the report.

(v) Substantiated complaints of patient abuse.

(vi) Surgery performed on the wrong patient or on the wrong body part.

(vii) Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities.

(2) Nonclinical patient safety and security events:

(i) Suicide of a patient that occurred at the licensed health care facility.

(ii) Elopements from the licensed health care facility resulting in death or serious injury. The term "elopement" includes instances where a resident or inpatient of a licensed health care facility leaves without the knowledge of such facility. The term does not include instances where a patient leaves against medical advice (AMA) or leaves a hospital emergency department before being registered or admitted.

(iii) Rape that occurred on the premises of the licensed health care facility. Reporting shall occur once a licensed health care facility has substantial evidence that a rape has occurred. An allegation of rape is not reportable.

(iv) Infant abduction or infant discharged to the wrong family.

(v) Unlicensed practice of a regulated profession.

(vi) A health care facility going on "divert status" when the diversion is for eight continuous hours or over 12 hours in a 24-hour period. Reporting shall include

when the facility went on divert status, when the facility went off divert status, the reasons for divert status and what the facility did to avoid the divert status.

(3) Threats to the continuation of health care services:

(i) Significant disruption of services due to disaster such as fire, storm, flood or other occurrence. This includes instances where the disruption of services can not be remedied by alternative back-up or support systems, such as auxiliary generators. It also includes instances where the licensed health care facility must transfer all or a portion of its patients or residents to other licensed health care facilities.

(ii) Notification of termination of any services vital to the continued safe operation of the facility or the health and safety of its patients and personnel, including the anticipated or actual termination of electric, gas, steam heat, water, sewer and local exchange telephone service.

(iii) Receipt of a strike notice.

(c) Changes.--Modification of this list or requirements for reporting of additional events shall only be done based on the recommendations of the authority. These changes shall be made by statement of policy following a 60-day public comment period and publication in the Pennsylvania Bulletin.

(d) Notification.--Reporting to the Department of Health or the Department of Public Welfare shall:

(1) Be made within seven calendar days following recognition by the licensed health care facility of any matter reportable under section 702.

(2) Be made by telephone, facsimile or electronic communication or e-mail.

(e) Agency responsibilities.--The Department of Health and the Department of Public Welfare shall:

(1) Have in place systems capable of receiving reports 24 hours a day, 7 days a week.

(2) Use the information contained in the notification from the licensed health care facility only in connection with the enforcement of its licensure responsibilities.

(f) Report details.--Initial notification shall include sufficient detail and information to alert the Department of Health or the Department of Public Welfare as to the nature of the event and the preliminary steps which the licensed health care facility intends to take to further investigate or rectify the situation. Within 60 calendar days of making the initial notification to the Department of Health or the Department of Public Welfare, the licensed health care facility shall conclude its internal investigation regarding the event and provide to the applicable State agency with licensure jurisdiction a final written report that shall include the following information:

(1) a description of the event;

(2) any steps the facility has taken to rectify the situation; and

(3) any steps the facility intends to implement to reduce the risk of similar events occurring in the future.

(g) Confidentiality.--The notification requirements of this section do not require a facility to include information which is deemed confidential and not reportable to the Department of Health or the Department of Public Welfare under other provisions of Federal or State law or regulations.

Section 702. Confidentiality and privilege.

All data, information, documents, findings, compilations and summaries, testimony and any other record generated by, acquired by, created for or given to the Department of Health or the Department of Public Welfare under this section shall be held in confidence and shall not be disclosed to any person except to the extent necessary to carry out the purposes of this chapter. Information contained in section 701 shall not be subject to discovery or introduction into evidence in any civil, administrative or arbitration action or proceeding except a proceeding of the Bureau of Professional and Occupational Affairs of the Department of State brought under this chapter. No person who participated in any review, investigation or subsequent action taken by the Department of Health or the Department of Public Welfare regarding an event reported under this chapter shall be permitted or required to testify in any civil, administrative or arbitration action or proceeding as to any evidence or other matters relating to such review, investigation or subsequent action except in a proceeding of the Bureau of Professional and Occupational Affairs of the Department of State brought under this chapter.

Section 703. Duties of Department of Health and Department of Public Welfare.

Following notification of a serious event, receipt of a final written report and after an investigation, if warranted, if the Department of Health or the Department of Public Welfare has reasonable cause to believe that practices occurred involving moral turpitude, dishonesty or corruption or were outside of the scope of the profession involving an individual or individuals who are licensed, certified or otherwise regulated to practice

or operate in the health care field under the laws of the Commonwealth, the agency shall refer the matter to the Bureau of Professional and Occupational Affairs of the Department of State for investigation.

Section 704. Reports to public and General Assembly.

(a) Annual reporting.--The Department of Health and the Department of Public Welfare shall prepare and publish on an annual basis a report regarding the information collected under this chapter. These reports shall be posted on the Department of Health's and the Department of Public Welfare's World Wide Web sites and submitted to the members of the following standing committees of the General Assembly: the Public Health and Welfare Committee of the Senate and the Consumer Protection and Professional Licensure Committee of the Senate, and the Health and Human Services Committee of the House of Representatives and the Professional Licensure Committee of the House of Representatives.

(b) Content.--The reports shall only contain the following aggregate information:

(1) the total number of reports received by type of licensed health care facility;

(2) the total number of referrals for investigation made to the Bureau of Professional and Occupational Affairs of the Department of State; and

(3) the total number of reports made for each specified category listed in this chapter.

(c) Licensure actions.--The Department of Health and the Department of Public Welfare shall publish on its respective World Wide Web site any licensure actions taken against a licensed health care facility relating to any of the reportable

events listed under section 701.

Section 705. Sanctions for failure to report.

Any licensed health care facility that fails to report any matter under section 701 shall be subject to all available sanctions by the applicable State agency with licensure jurisdiction as set forth in the act of October 20, 1966 (3rd Sp.Sess., P.L.96, No.6), known as the Mental Health and Mental Retardation Act of 1966, the act of June 13, 1967 (P.L.31, No.21), known as the Public Welfare Code, and the act of July 19, 1979 (P.L.130, No.48), known as the Health Care Facilities Act.

CHAPTER 9

PEER REVIEW ACTIVITIES

Section 901. Standards for peer review activities.

(a) Peer review activities.--For purposes of the protection set forth in section 902, peer review activities must be taken:

(1) in the reasonable belief that the action was in the furtherance of quality health care;

(2) with a reasonable effort to obtain the facts of the matter; and

(3) in the case of a peer review action:

(i) after adequate notice and hearing procedures are afforded to the professional health care provider involved or after such other procedures as are fair to the professional health care provider under the circumstances; and

(ii) in the reasonable belief that the action was warranted by the facts known after such reasonable effort to obtain facts and after meeting the requirement of this paragraph.

Peer review activities shall be presumed to have met the preceding standards necessary for the protection set out in section 902 unless the presumption is rebutted by a preponderance of the evidence. The standard of review shall be an objective one which looks to the totality of the circumstances.

(b) Notice and hearing.--Peer review activities are deemed to have met the adequate notice and hearing requirement of subsection (a)(3) with respect to a professional health care provider if the conditions set forth in the Health Care Quality Improvement Act of 1986 (Public Law 99-660, 42 U.S.C. § 11112(2)(a) and (b)) are met. Nothing in this section precludes the use of alternative dispute resolution consistent with medical staff and hospital bylaws.

(c) Construction of section.--For purposes of section 902, nothing in this section shall be construed as:

(1) requiring the procedures referred to in subsection (a)(3):

(i) where there is no adverse peer review action taken; or

(ii) in the case of a suspension or restriction of clinical privileges, for a period of not longer than 14 days, during which an investigation is being conducted to determine the need for a peer review action; or

(2) precluding an immediate suspension or restriction of clinical privileges, subject to subsequent notice and hearing or other adequate procedures, where the failure to take such an action may result in an imminent danger to the health of any individual.

Section 902. Immunity from liability.

(a) Immunity.--If peer review action or peer review activities meet all the standards specified in section 901, notwithstanding any other provision of law, the following persons or entities shall not be held to have violated any criminal law or to be civilly liable under any law for money damages by reason of having participated in such review, by furnishing professional counsel or services or by reason of having provided such information:

(1) The peer review committee.

(2) Any person acting as a member or staff to the peer review committee.

(3) Any person under contract or other agreement with the peer review committee.

(4) Any person who participates with or assists the peer review committee.

(5) Any person providing information to the peer review committee.

(b) Applicability.--The immunity provisions in subsection (a) shall apply unless:

(1) the information provided is unrelated to the performance of the duties and functions of such peer review committee;

(2) the information provided is false and the person providing such information knew, or had reason to believe, that such information was false; or

(3) any actions taken by such peer review committee were motivated by malice toward any person affected by such action.

CHAPTER 11

QUALITY REVIEW RECORDS

Section 1101. Confidentiality and privilege.

(a) Review activities.--All quality review activities, including peer review, and all records of a review organization or review committee, including a peer review committee, shall be held in confidence and shall not be disclosed to any person except to the extent necessary to carry out the functions of the review committee or review organization or as provided in sections 1102 and 1104. Except as provided for in subsection (c), quality review records shall not be subject to discovery or introduction into evidence in any civil, administrative or arbitration action or proceeding, and no person who participated in any quality review activities of such review organization or review committee shall be permitted or required to testify in any civil, administrative or arbitration action or proceeding as to any evidence or other matters relating to such quality review activities.

(b) Use of records.--A review organization or review committee may not use quality review records for any purpose other than conducting quality review or quality review activities except as provided in subsection (c).

(c) Actions and proceedings.--Notwithstanding the provisions of subsections (a) and (b), in a civil action or fair hearing procedure brought by the practitioner who is the subject of the peer review to challenge the outcome of the peer review, the presiding officer or judge may upon a showing of good cause by the practitioner or licensed health care facility order the disclosure to the practitioner or permit the licensed health care facility the use of such records of the peer review committee as are necessary in order to enable the practitioner or licensed health care facility to adequately prepare and

present its case. If disclosure is ordered, such disclosure shall not constitute a waiver of the quality review privilege for any purpose, and the practitioner or licensed health care facility to whom the records are disclosed shall be bound to maintain their confidentiality in accordance with the terms of this act.

Section 1102. Aggregate data.

Under no circumstances shall any aggregate data concerning the procedures and outcomes of professional health care providers compiled for the purposes of evaluating the quality and efficiency of health care services be disclosed or released to any person or entity other than a review organization or review committee without the express prior written consent of such professional health care provider. Such aggregate data and other quality review records shall be used for quality review purposes only, and in no event shall such aggregate data or any other quality review records be sold or otherwise similarly distributed, but a review organization or review committee shall be authorized to utilize the services of and/or pay a fee to another person or entity to compile or analyze such aggregate data. Notwithstanding the former provisions, a review organization or review committee shall have the authority to publish aggregate data in blinded form so long as the published data does not disclose any information identifying any patient or professional health care provider. Such publication shall not constitute a waiver of the quality review privilege or any other privilege.

Section 1103. Exceptions.

Notwithstanding the confidentiality provisions of sections 1101 and 1102:

(1) information, documents or records which constitute original source documents may be obtained from their original sources to the extent otherwise disclosable or discoverable; and

(2) information or testimony otherwise disclosable or discoverable may be elicited from any person as to matters within that person's knowledge provided that the information was not obtained or opinions formed by the person as a result of the person's participation in any quality review activities.

Section 1104. Waiver.

Except as provided in this section, the evidentiary privileges created by this chapter shall be invoked by all witnesses, licensed health care facilities, review organizations and review committees in all judicial, administrative, civil or arbitration actions or proceedings. The disclosure of confidential privileged quality review records between a review organization or review committee and any of the following does not constitute a waiver of the privilege:

(1) a professional health care provider under review;

(2) another review organization or review committee performing a quality review function whether affiliated or not;

(3) a State agency with licensing jurisdiction and authority;

(4) any Federal or State agency requiring by law the disclosure of confidential privileged quality review records or information contemplated by Chapter 5; or

(5) a credentials verification organization gathering information relating to applications.

The organization or witness invoking the privilege shall be granted a protective order preventing the release of its proceedings, records and files or the testimony of the witness as applicable. The unintentional or mistaken disclosure of confidential privileged quality review records does not constitute a waiver of the privilege.

CHAPTER 13

PHYSICIAN OVERSIGHT

Section 1301. Staffing and salaries.

(a) General counsel.--The State Board of Medicine and the State Board of Osteopathic Medicine shall each employ a board general counsel and each shall also employ an executive director who in turn shall employ such qualified investigators and attorneys and administrative staff as are necessary to fully implement the boards' authority to revoke, suspend, limit and otherwise regulate the licenses of physicians and to issue reprimands and fines, to require refresher educational courses or require licensees to submit to independent medical examination or medical treatment. The boards shall each set salary ranges for such positions as are sufficient, in their sole discretion and without reference to other government pay scales, to attract and retain top quality individuals, nor shall the selection of particular individuals be subject to the approval of the administrative, judicial or legislative branches of government and shall be made entirely on merit.

(b) Hearing examiners.--The boards shall also each employ with the approval of the Governor such hearing examiners as are necessary to conduct hearings in accordance with the disciplinary authority granted the boards and may adopt rules and regulations setting forth the powers, standards and duties

of such examiners. The hearing examiners shall have the power to conduct hearings, administer oaths and to issue subpoenas in accordance with such regulations.

Section 1302. Disciplinary committee.

Each board shall appoint a five to nine member disciplinary committee composed primarily of physicians to oversee the disciplinary process. The disciplinary committee shall review complaints and requests from investigators and prosecuting attorneys to determine which complaints and requests require investigation and which after investigation warrants the issuance of an order to show cause. The disciplinary committee may require additional investigation and shall require expert reports on issues that require such unless expertise in that specialty is available from a committee member. The disciplinary committee shall receive its legal advice from the board counsel. The disciplinary committee shall also review requests for temporary immediate suspension without hearing and make recommendation to the board.

Section 1303. Temporary immediate suspensions.

On recommendations and findings of the disciplinary committee and findings by the board that:

(1) the conduct of a physician poses an immediate risk of harm to patients; and

(2) the likelihood is that a successful prosecution will lead to license revocation and not to some lesser penalty,

the boards may impose an immediate temporary suspension of up to ten days. The physician shall receive notice and a statement of findings prior to any immediate suspension and a hearing shall be held before a hearing examiner within ten days of the effective date of the immediate suspension at which hearing the

issues of risk of immediate risk of harm to patients and the likelihood that a successful prosecution shall lead to licensure revocation shall be heard. In no case, by waiver of the physician or otherwise, shall an immediate temporary suspension exceed 60 days.

Section 1304. Appropriations.

The activities of the boards shall not be the financial obligation of the Commonwealth but shall be supported by license and other fees and charges and fines collected by the medical board and by the osteopathic medical board respectively, and such amounts are hereby specifically appropriated for the exclusive use by the State Board of Medicine and the State Board of Osteopathic Medicine respectively in carrying out the provisions of this act. Further each board shall set fees, charges and fines at such levels as are reasonably necessary to carry out the provisions of this act.

CHAPTER 15

MISCELLANEOUS PROVISIONS

Section 1501. Severability.

The provisions of this act are severable, except with respect to the provisions contained in Chapters 5, 9 and 11. Except with respect to Chapters 5, 9 and 11, if any provision of this act or its application to any person or circumstance is held invalid, the invalidity shall not affect other provisions or applications of this act which can be given effect without the invalid provision or application. In the case of Chapters 5, 9 and 11, if one or more of these chapters are held invalid, none of the provisions in the remaining chapters shall be given effect.

Section 1502. No private right of action.

No private right of action is created through the adoption of

this act.

Section 1503. Repeals.

All acts and parts of acts are repealed insofar as they are inconsistent with this act.

Section 1504. Regulations.

The Department of Health and the Department of Public Welfare shall promulgate regulations necessary to carry out the provisions of this act.

Section 1505. Applicability.

Chapters 9 and 11 shall apply to peer review and quality review activities occurring on or after the effective date of this act.

Section 1506. Effective date.

This act shall take effect in 120 days.