

Pennsylvania's Patient Safety Authority

An Overview

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ABSTRACT

Pennsylvania is at the forefront of states in addressing the problem of medical errors by enacting legislation which established a Patient Safety Authority and requires reporting of medical errors which cause injury and which are considered near misses. The need for such an entity grew out of the medical malpractice crisis and the Institute of Medicine's 1999 *Report To Err Is Human*, which identified preventable medical errors as a leading cause of death in the United States. The Patient Safety Authority is a governmental entity, mostly advisory, which encompasses many of the recommendations of by the Institute in the 1999 Report. The Patient Safety Authority contracted with a vendor to set up a reporting system for medical facilities to report medical errors which cause injury and those which are considered near misses. The Authority, in conjunction with Pennsylvania's Department of Health, analyze the data to identify ways to improve patient safety and to issue advisories. Prior to this initiative, facilities have failed to engage in such a reporting mechanism and those within the medical community attempting to correct problems have frequently been ostracized by the profession or systems within the medical community. Whistleblower protections have been created and need to be expanded. While the initiatives of the Patient Safety Authority are still greatly influenced by the stakeholders within the medical community, some progress has clearly been made toward improving patient safety by encouraging as well as requiring the reporting of medical errors.

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INTRODUCTION

This article describes Pennsylvania's Patient Safety Authority from its etiology, creation, purpose and mandate to its history, progress, potential, implications and proposed expansion.

ETIOLOGY

Medical errors kill more people annually than motor vehicle accidents, breast cancer, or

AIDS.(Emphasis added)² That is profound. Yet, unlike breast cancer, AIDS and other disabling, life-threatening and/or killer diseases, where the medical community and public join together to find a cure and promote public awareness, such as the race for the cure of breast cancer and walks to defeat ALS, diabetes, and many others, according to the Institute of Medicine, silence about medical errors prevails. While the media occasionally reports on individual medical mistakes which caused horrific consequences and circumstances, in general, medical errors as a nationwide leading cause of death escapes national attention as a collective problem.³

² Kohn LT, Corrigan JM, Donaldson MD, eds., Institute of Medicine. *To Err Is Human: Building A Safer Health System*, Institute of Medicine, (National Academy Press 2000) at 1, 26. ("1999 Report - To Err Is Human") Medical errors result in an estimated number of deaths as at least 44,000 and as high as 98,000, where motor vehicle accidents are reported as 43,458, breast cancer as 42,297 and AIDS as 16,516.

³ 1999 Report - To Err Is Human states that ". . . silence surrounds this issue . . ." and that "[m]edia coverage has been limited to reporting of anecdotal cases." *Id.* at 3.

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At the same time, issues such as tort reform, frivolous lawsuits, good doctors leaving the practice of medicine because of skyrocketing malpractice insurance premiums, capture the forefront of national debate, in the media and even as issues in the 2004 presidential campaign. Medical errors, by contrast, are not part of the conversation, even though deaths from medical errors exceed those from the eighth leading cause of death.⁴ *The 1999 Report—To Err is Human* opened dialogue about medical errors within the medical community. This ground-breaking report of the extent of medical errors and the shocking estimated number of deaths resulting from such errors, together with its recommendations for reducing medical errors, laid the groundwork for and inspired the creation of Pennsylvania's Patient Safety Authority.

Pennsylvania's Patient Safety Authority encompasses many of the types of recommendations presented by the Institute in the 1999 Report. For example, the Institute recommends ". . . identifying and learning from errors through immediate and strong mandatory reporting efforts, as well as the encouragement of voluntary efforts, both with the aim of making sure the system continues to be made safer for patients . . ." as part of its four tiered approach.⁵ Pennsylvania's Patient Safety Authority implemented and continues to oversee a statewide mandatory reporting system of serious events, which are basically medical errors which cause injury, and incidents, commonly labeled as "near misses" which are medical errors which could injure a patient.⁶ Similarly, the Institute recommends establishing a national focus for leadership, research, tools and protocols.⁷ The Patient Safety Authority attempts to establish such a state-

wide focus, as exemplified by its issuance of advisories to medical facilities subject to its mandatory reporting system.

In many ways the Patient Safety Authority embodies the underlying principles espoused by the 1999 Report which include fostering an environment conducive to widespread reporting of serious events and near misses for evaluative purposes. The Institute notes that "it is simply not acceptable for patients to be harmed by the same health care system that is supposed to offer healing and comfort."⁸ Without relieving individuals from responsibility, "[t]he focus must shift from blaming individuals for past errors to a focus on preventing future errors by designing safety into the system."⁹ The Institute points to lessons from high risk industries such as aviation as well as improvements and reduced deaths related to anesthesia which resulted from systemic approaches to reducing errors.¹⁰

LEGISLATIVE BATTLE, WHICH LED TO ACT 13

The enactment of the Medical Care Availability and Reduction of Error ("Mcare") Act, 40 P.S. §1303.101 *et seq.*, also known as Act 13, involved a legislative battle between proponents of more protections for patients against proponents of more protections for medical care providers. The Act addresses both patient safety and medical malpractice liability and insurance. The mark up of the bill enacted as the Mcare Act, House Bill 1802, reveals some of the battlegrounds. For instance, the markup reveals the removal of an entire section which provided for penalties for alterations or destruction of medical charts or records and for the failure of colleagues to report them. Similarly, liability for periodic payments changed from not terminating upon the patient's death to terminating upon the patient's death. Also, the statute of limitations was renamed a statute of repose, in an apparent attempt to avoid the tolling of the statute of limitations which applies in some instances where a patient did not know or have a reason to know or discover the injury from medical malpractice before the statute of limitations ran out. Another example is the removal of a provision regarding joint and several liability. The provision would have added a collection burden on patients' recovery as compared to other tort plaintiffs by placing the burden of collecting non-economic damages of more

⁴ 1999 *To Err is Human Report* at 1, 26.

⁵ 1999 *To Err is Human Report* at 6.

⁶ Chapter 3 of Act 13 defines "Incident" as an event, occurrence or situation involving the clinical care of a patient in a medical facility which could have injured the patient but did not either cause an unanticipated injury or require the delivery of additional health care services to the patient. The term does not include a serious event. 40 P.S. §1303.302.

The act defines "Serious event" as an event, occurrence or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional health care services to the patient. The term does not include an incident." 40 P.S. §1303.302.

⁷ 1999 *To Err is Human Report* at 6.

⁸ 1999 *To Err is Human Report* at 3.

⁹ 1999 *To Err is Human Report* at 5.

¹⁰ 1999 *To Err is Human Report* at 5, 13.

than a million dollars upon the patient, rather than allow recovery from any of the defendants with them seeking contribution from each other for each's proportion of responsibility, as is the case for defendants for torts other than medical malpractice.

The debate on patient safety and medical professional liability reform certainly continues after the enactment of Act 13. For example, with the announcement of the reporting requirements of Act 13, an article in Philadelphia Medicine expressed the intention to meet with the legislature to advocate for a constitutional amendment to allow caps on non-economic damages, to lobby for procedural rules for venue and to require experts early on in a case; to fight against court challenges and to support campaigns which will create a friendly environment for liability reform. The article failed to discuss a need to reduce medical errors or to support campaigns which will ensure patient safety.¹¹

The Patient Safety Authority was created as a result of a clear crisis in medical health care. In 1999, the Institute of Medicine, a government-based agency run by doctors and scientists, found that preventable medical errors constitute the eighth leading cause of death in this country. Thereafter, scientists and academics, including members of the medical community, indicated that preventable medical errors could be the fifth, or even the third leading cause of preventable deaths in this country. That excludes preventable deaths due to infections and other idiopathic causes.

THE MCARE ACT—ACT 13

Act 13—the Medical Care Availability & Reduction of Error (MCARE) Act, 40 P.S. §1303.101 *et seq.*, established Pennsylvania's Patient Safety Authority. The purpose of the Act is to ensure access to high quality health care in Pennsylvania, which requires affordable medical professional liability insurance and reducing medical errors to ensure patient safety.¹² The Act further declares that victims of medical malpractice must be ensured a prompt determination and fair compensation and that “[e]very effort must be made to reduce and eliminate medical errors by identifying problems and implementing solutions that promote patient safety.”¹³

The Act created the Patient Safety Authority, consisting of an eleven member board,

with the authority to carry out the mandates of the statute.¹⁴ The Act requires that the Patient Safety Authority contract with a (a) vendor to

“(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 . . .” of anonymous reports to the authority where the authority is dissatisfied with the investigation by the medical facility.

The Act mandates the Authority to review and evaluate recommendations made by the vendor and report them to the department of Health of Pa for approval or disapproval.¹⁵ “After consultation and approval by the department,” the Authority shall “issue 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.”¹⁶ In making recommendations, the Authority must consider improved quality care, implementation feasibility, practices and costs to patients, payors and medical facilities.¹⁷

While Act 13 provides for anonymous reports, it only permits anonymous reports to the Patient Safety Authority after internal reports to the affected medical facility have been made pursuant to the procedures outlined in that medical facility's patient safety plan, developed pursuant to this Act.¹⁸ 40 P.S. §1303.304(b). Act 13 then requires the Patient Safety Authority to notify the affected facility of the report and conduct an independent investigation where the affected facility has not already done so, or where the Authority is dissatisfied with the facility's investigation. The Authority may also report the facility to the Department for failure to report pursuant to 313(e) (requiring reporting of serious events to

¹⁴ 40 P.S. §1303.303.

¹⁵ 40 P.S. §1303.304.

¹⁶ 40 P.S. §1303.304.

¹⁷ 40 P.S. §1303.304.

¹⁸ 40 P.S. §1303.304(b).

¹¹ 98 Philadelphia Medicine 5 (May 2002)

¹² 40 P.S. §1303.301.

¹³ 40 P.S. §1303.102.

the appropriate licensing board) or (f) (requiring reports to the Authority of serious events, infrastructure failures, to notify patients of serious events or incidents failure to develop or comply with patient safety plans.)¹⁹

Act 13 requires the Authority to perform other duties, such as preparing annual reports, administering a trust fund, working with the Department of Health to evaluate data, and make recommendations.²⁰

Act 13 requires medical facilities to develop, implement, and comply with an internal patient safety plan, approved by the Department of Health, which designates a patient safety officer and committee, establishes a reporting system, notifies patients of serious incidents and prohibits retaliatory action with protections of Pennsylvania's Whistleblower Law. 40 P.S. §1303.307

Section 308 of Act 13 sets forth the reporting and notification requirements of the Act. "A health care worker who reasonably believes that a serious event or incident has occurred shall report the serious event or incident according to the patient safety plan of the medical facility unless the health care worker knows that a report has already been made." The report shall be made immediately or as soon thereafter as reasonably practicable, but in not later than 24 hours. 40 P.S. §1303.308(a).

The Act 13 defines "Incident" as an event, occurrence or situation involving the clinical care of a patient in a medical facility which could have injured the patient but did not either cause an unanticipated injury or require the delivery of additional health care services to the patient. The term does not include a serious event. The act defines "Serious event" as an event, occurrence or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional health care services to the patient. The term does not include an incident."²¹

Section 308 also requires the medical facility to notify an affected patient, or the patient's designee or adult member of the family when a patient is unable to give consent to family notification, in writing of the serious event within seven days of the occurrence or discovery of a serious event. Such notification shall not constitute an acknowledgment or admission of liability. 40 P.S. §1303.308(b). Act 13 further provides the protections and remedies

set forth in the act of December 12, 1986 (P.L. 1559, No. 169), known as the Whistleblower Law, without limiting appropriate disciplinary action for failure to meet defined performance expectations, unprofessional conduct, false reports or failure to report serious events. 40 P.S. §1303.308.

Act 13 outlines the requirements and responsibilities of the internal patient safety officer and patient safety committee of the medical facilities. 40 P.S. §1303.309, 310.

Act 13 provides for confidentiality of documents, materials or information solely prepared or created for purposes of the patient safety committee complying with its responsibilities set forth in section 310 (b) of Act 13 and documents received by the authority or the Department, and prevents the discoverability of those documents in any civil or administrative action or proceeding, except in limited circumstances such as licensure or corrective action by the Department. The Act further prohibits individuals from testifying about information gained by the person's involvement with meetings of the patient safety committee or governing board of a medical facility, patient safety authority, Department of health, Department of State, but, does not protect or apply to matters gained outside of the person's responsibilities or participation with the patient safety committee or governing board of a medical facility. Where original documents are destroyed, a Court may order the release of some documents. 40 P.S. §1303.311.

Act 13 exempts any documents made confidential by section 311(a) (solely prepared or created for purposes of the patient safety committee complying with its responsibilities set forth in section 310 (b)) from the Right-to-Know Law, 65 P.S. §66.1 *et seq.* 40 P.S. §1303.311 (j).

Act 13 also protects individuals who report information or who provide services to the Authority from criminal or civil liability, unless the person with malice toward those affected provides false information with knowledge or reason to believe that the information was false. 40 P.S. §1303.311 (i).

Act 13 authorizes the Authority to recommend a medical facility for certification based upon a reduction of serious events at that facility, and Act 13 requires a discount rate to be determined and provided by insurance provider for certified programs. 40 P.S. §1303.312.

Act 13 requires medical facilities to report serious events within 24 hours of confirmation of the serious event and to report incidents (commonly thought of as near misses), and to report an infrastructure failure within 24

¹⁹ 40 P.S. §1303.304(b).

²⁰ 40 P.S. §1303.304, 306.

²¹ 40 P.S. §1303.302.

hours. Reporting under this act satisfies other reporting requirements. Failure to report or to develop and comply with the patient safety plan, or failure to notify a patient of a serious event can result in notification to licensing boards, and/or an administrative penalty of \$1,000 per day, and constitutes a violation of Pennsylvania's other reporting statute the Health Care Facilities Act, (July 19, 1979 (P.L. 130, No. 48), subjecting facilities to those penalties as well. 40 P.S. §1303.313.

Act 13 abrogates 28 Pa. Code §51.3(f) and (g) (relating to notifications) for a medical facility upon the reporting of a serious event, incident or infrastructure failure pursuant to Act 13. 40 P.S. §1303.314.

HISTORY OF THE PATIENT SAFETY AUTHORITY: SLOW TO START, PROMISE FOR THE FUTURE

The Patient Safety Authority came into existence in the Spring of 2002, and one of its first missions was to hire a contractor as provided for under the statute. The process of hiring a contractor was long and arduous. The Patient Safety Authority established a committee, in order to receive bids, evaluate them, and make a recommendation based upon points assigned to each contractor. This process was confidential, but the choice of the contractor was accompanied by the great expectation that medical errors could be reduced, thus reducing medical malpractice insurance premiums for doctors and the hospital community.

On August 9, 2002, the Authority learned that medical facilities ignored the Chapter 51 reporting requirements previously in effect and which the Authority was required to expand. Chapter 51 reporting by the Department of Health between 1997 and 1999 indicated that facilities reported only a few incidents. In light of the *1999 Report: To Err is Human*, the lack of reports to the Department of Health evidences a failure to report and/or a failure to enforce reporting requirements.²² Therefore, the Patient Safety Authority faced formidable obstacles to implementing its mandate.

Apprehensions about the Patient Safety Authority surfaced due to its slow start. Reports of the slow start appeared in J. Robinet, "Slow start for Patient Safety Authority," *Physician's News Digest, Inc.*

(April 2003) as well as an article in the Philadelphia Daily News raising questions of the wisdom of the Patient Safety Authority. Robinet quotes Democratic State Legislative leaders expressing concerns. These concerns also appear in questioning of Board Member Dr. Danae Powers, M.D.²³ There was great frustration that standards and definitions among participating facilities varied and the medical staff appeared uninformed about their internal patient safety officers.²⁴ An example evidenced the lack of uniformity and the reluctance to report errors. In the example, a participating hospital's internal patient safety officer instructed a physician not to report a situation where a healthy obstetrics patient sustained congestive heart failure because of fluid overload from an IV. The rationale for not reporting the situation was that it is not unanticipated that too much fluid will cause such failure, obviously ignoring the fact that too much fluid was the actual trigger for reporting.²⁵

Dr. Danae Powers, M.D., compellingly testified about the silence which occurs within the medical community, which perpetuates, hides and sometimes even rewards medical errors. By highlighting specific examples, Dr. Powers testimony opens the door to potential change. First, she discussed a CBS Sixty Minutes report where physicians talked patients into unnecessary heart surgeries, resulting not only in the initial medical error of surgery itself, but also medical errors and deaths from surgery. Despite the fact that people in the system complained to the facility, the facility claimed it was unaware of any problem until the FBI raided its files. Second, Dr. Powers discussed an internationally recognized transplant surgeon, aggressively recruited by a medical facility.²⁶ At the facility, the surgeon became aware of internal procedures jeopardizing patients and causing deaths. The surgeon, together with colleagues, pursued internal processes to correct the problems, including informing the

²² *Senate Judiciary Committee Medical Malpractice Insurance* (Monday, September 15, 2003), Stewart J. Greenleaf, Chairman, Majority, Jay Costa, Chairman, Minority, Testimony By: Clifford Alan Rieders, Esquire, Member, Pennsylvania Patient Safety Authority, p. 16.

²³ *Senate Judiciary Committee Medical Malpractice Insurance* (Monday, September 15, 2003), Stewart J. Greenleaf, Chairman, Majority, Jay Costa, Chairman, Minority, Testimony By: Clifford Alan Rieders, Esquire, Member, Pennsylvania Patient Safety Authority, Exhibit 4, Testimony of Dr. Powers, p. 41-46.

²⁴ *Id.* at 46.

²⁵ *Id.* at 47.

²⁶ *Senate Judiciary Committee Medical Malpractice Insurance* (Monday, September 15, 2003), Stewart J. Greenleaf, Chairman, Majority, Jay Costa, Chairman, Minority, Testimony By: Clifford Alan Rieders, Esquire, Member, Pennsylvania Patient Safety Authority, Exhibit 4, Testimony of Dr. Powers, p. 27-29.

board and administration. Ultimately, the physician lost privileges at the hospital and suffered blacklisting in the physician data bank as disruptive.²⁷ Third, Dr. Powers testified about the firing of a very qualified ob/gyn for expressing concerns about maternal deaths. While that doctor had not been involved in maternal deaths, those that terminated her had been.²⁸

Thus, Dr. Powers' testimony identified a strong need for strengthening whistleblower protection. She expressed hope that the state attorney general would be empowered to enforce the whistleblower protections, to avoid such significant out of pocket legal expenses on those reporting medical errors.²⁹

Dr. Powers also expressed concerns about whether the Patient Safety Authority, of which she is a member, will provide the relief intended by providing an environment open to dialogue about mistakes and near misses, and systemic approaches to correct them, or whether instead it will simply add another layer of bureaucratic reporting on an already overburdened system.³⁰ Dr. Powers emphasized the need for a non-punitive approach, highlighting that if you thank people for bringing things to light, instead of punishing them, you are likely to get more people to report.³¹

Subsequently, the Patient Safety Authority together in close connection with its vendor, developed the Patient Safety Reporting System, PA-PSRS. The reporting system has a series of categories of care followed by the types of errors which may have occurred. It is similar but more comprehensive than the list of serious reportable events identified by the National Quality Forum. A user manual and extensive trainings were offered throughout the summer of 2004, including nineteen training sessions at eleven locations. A phase in of mandatory reporting was scheduled.

On March 23, 2004, the Patient Safety Authority, through its Chair, issued a letter notice to facilities about the time-line for mandatory reporting as required by the Act. The Patient Safety Authority issued four patient safety advisories: one for Patient Safety Week,

and one in June 2004, in September 2004, and a supplementary advisory on October 28, 2004. The Authority has prepared two annual reports, one dated May 1, 2003 and the other April 30, 2004. The Authority issued five press releases. After a vendor was selected, initial voluntary and partial reporting started on November 17, 2003. Mandatory reporting began June 28, 2004. On August 2, 2004, the Authority adopted a Right to Know Policy, which requires to submit requests for documents in writing with specifications as to what documents are being requested and that they are being requested pursuant to Pennsylvania's Right to Know Act.

The first advisory indicated that 22 participating facilities made approximately 2,500 reports. The reporting of near misses revealed a potential problem with the abbreviation of surgical procedures of left total hip replacement (LTHR) and left total knee replacement (LTKR) which both the physician and patient detected. The advisory also discussed patient falls and preventing MRI's for those with pacemakers. The advisory showed that reporting of near misses can be a very positive step toward preventing patient harm.

CONCERNS OF THE MINORITY

From the onset, the Hospital Association of Pennsylvania has been involved with the Patient Safety Authority. HAP has attended every public meeting through its representatives and lobbyists, and has had continuous contact with the Chairman and certain members of the Patient Safety Authority with respect to appropriate protocols to identify serious events. Without consulting the Patient Safety Authority, HAP published a Guide to compliance with Act 13, which was not approved by the Authority, and which was relied upon by the hospitals to create their patient safety plan.³²

While the cooperation of the Hospital Association was welcome, this member, among others, expressed some concern about the cozy relationship between HAP and the government agencies involved, the Department of Health and the Patient Safety Authority. The Authority also established bilaws which expanded the confidentiality require-

²⁷ *Id.* at 29.

²⁸ *Id.* at 29-31.

²⁹ *Senate Judiciary Committee Medical Malpractice Insurance* (Monday, September 15, 2003), Stewart J. Greenleaf, Chairman, Majority, Jay Costa, Chairman, Minority, Testimony By: Clifford Alan Rieders, Esquire, Member, Pennsylvania Patient Safety Authority, Exhibit 4, Testimony of Dr. Powers, p. 73.

³⁰ *Id.*, p. 56-57.

³¹ *Id.* p. 63.

³² *Senate Judiciary Committee Medical Malpractice Insurance* (Monday, September 15, 2003), Stewart J. Greenleaf, Chairman, Majority, Jay Costa, Chairman, Minority, Testimony By: Clifford Alan Rieders, Esquire, Member, Pennsylvania Patient Safety Authority p. 16.

ments beyond what was required by Act. 13.³³

For more than a year, discussion and debate focused upon the definition of “serious event.” Many different models were looked at, including those from the Veterans Administration, which has attempted to tackle the problem of medical errors.

However, Chapter 3 of the statute defines “serious event and it was decided repeatedly by members of the Patient Safety Authority that this definition could not and should not be watered down. Members of the Patient Safety Authority were deeply involved in the establishment of the computer model, which constitutes the means by which serious events will be reported to the Patient Safety Authority, and ultimately the Department of Health. During the test phase of the Patient Safety Net (PS Net), it was found that reporting by the hospitals was often anemic. However, it was believed that when the full reporting system went online and training was completed, there would be greater opportunity to assure that Pennsylvania’s patient safety reporting system would become fully functional as originally anticipated.

Every hospital in the state is required to have a patient safety plan and a patient safety officer. The Department of Health indicates that they have received assurances that the statute has been complied with in this respect, although to the chagrin of some Patient Safety Authority members, there does not appear to be any ongoing supervision concerning the continuity of the patient safety plans, the updating thereof, or the efficacy of the Patient Safety Officers who have been appointed by the hospitals in question.

The Patient Safety Authority has worked on a very close basis with its contractor to create the Pennsylvania patient safety reporting system. That computer-based system was approved in several different sessions, as recently as March of ’04. At the meeting held in March of ’04, there was some suggestion that hospitals should be able to re-define “serious events” in such a way that they would not have to answer all of the questions necessary to enable the Patient Safety Authority or the Department of Health to do its work of acting upon serious events and taking remedial action. The Patient Safety Authority rejected adulterating the definition of serious event or the reporting requirements.

Thereafter, however, the definition of serious event with its reporting requirements were changed. When the agenda for the April 5,

2004, board meeting was circulated, it was stated that this would be an “important meeting” because it “will continue the issues dealt with at the last meeting.” The agenda indicated that it would deal with several issues related to the statewide rollout of the PA-PSRS program, including but not limited to “final modifications to the report submission questionnaire, particularly issues related to the Department of Health’s requirement that all questions be answered.”

This author and others did not know any more about the agenda or the meaning of that particular statement until the meeting took place. At the meeting on April 5, 2004, a motion was made by one of the physician members that not all serious events be subject to the full reporting requirements of the Pennsylvania patient safety reporting system previously approved.

Question #10 contains a harm score. Subsections (E), (F), (G) and (H) are entitled “Event, Harm,” and read, in their entirety, as follows:

- E. An event occurred that contributed to or resulted in temporary harm and required treatment or intervention.
- F. An event occurred that contributed to or resulted in temporary harm and required initial or prolonged hospitalization.
- G. An event occurred that contributed to or resulted in permanent harm.
- H. An event occurred that resulted in a near-death event (e.g., required ICU care or other intervention necessary to?).

The motion promulgated was that if a hospital checked (E) or (F), the system would default and the other questions would not have to be answered, although they could be answered.

Under questioning by some Patient Safety Authority board members, it was revealed that it would therefore be up to a hospital as to whether they desire to answer all of the questions simply by their ability to choose (E) or (F). The statute, of course, makes no distinction between serious events. The harm score (E) through (H) are all serious events.

Discussion and debate took place on the subject, and a motion to table was defeated.

By a split vote, the Patient Safety Authority voted to change the reporting system previously adopted, and to permit hospitals to avoid answering the full panoply of questions when they checked (E) or (F) under the “Event, Harm” score.

It was revealed during the meeting that there had been discussions between the Hospital Association of Pennsylvania and the Department of Health, which apparently led to the

³³ *Id.*

motion that was made and passed at the meeting.

This minority dissenter is concerned by the following:

1. The Board as a whole was not consulted concerning the proposed motion or change to the serious event reporting system previously agreed upon.
2. There were obviously off-the-record discussions, conceivably violating the Sunshine Act and other state laws, by and between the Hospital Association of Pennsylvania, the Department of Health, and perhaps administrative staff of the Patient Safety Authority.
3. The ability of the hospitals to choose a harm event that would negate the full reporting requirement of the Act is in contradistinction to the purposes of the Act, and will totally undermine the concept of patient safety.
4. It is already known that there has been underreporting by hospitals under the trial program, and as a result of the motion adopted by the Board, there will be an ability of the hospitals to report even less thoroughly.
5. The purposes of the Patient Safety Authority are to have full non-punitive confidential reporting. The consequence of essentially rewriting the reporting requirements concerning "serious event" disembowels the salutary purposes of the Act without any corresponding benefit.
6. The complaint by the Hospital Association of Pennsylvania that answering all of the questions designed under the system would be too time consuming was not borne out by any evidence or any other reasonable information conveyed to the Board.
7. It was acknowledged by John Combs, the representative for the Hospital Association of Pennsylvania, that a person could receive the medication and be hospitalized for a year, and yet a hospital could check (E) or (F) and therefore not have to answer all of the full reporting requirements of the computer program.

It is believed and therefore averred that the Patient Safety Authority, by adopting the motion to limit reporting of serious events, may have violated the law and certainly the spirit of the legislature in enacting Act 13.

The dissenters saw this as a major departure from the concept of patient safety, which has been promised to the citizens of Pennsylvania by the legislature.

The dissenters further requested that their opposition be noted in the mandatory report

to the legislature that must be made by the Patient Safety Authority.

Verbatim transcripts are available from both the March and April meetings, as well as Minutes.

Agreed to by Clifford A. Rieders and Representative Mary Ann Dailey.

Danae Powers, M.D. has given her permission to reiterate that she voted against the Motion to permit hospitals to select harm scores that would result in less than complete reporting.

IMPLICATIONS FOR THE FUTURE: A MODEL FOR OTHER STATES

Pennsylvania took leadership nationally in establishing the first Patient Safety Authority in the country. In its first advisory, dated March 8, 2003, the Authority reported that its reporting system was "... the first system of its kind in the country[.]" The advisory quoted Jill Rosenthal, project manager with the National Academy for State Health Policy, as identifying the system as innovative in reporting "... both adverse events and near misses[.]" Information from the National Academy for State Health Policy³⁴ identifies six states including Pennsylvania, Massachusetts, Florida, Oregon, New York and Maryland, without a center, but through a peer review process, who have initiatives for reporting and examining medical errors in an effort to reduce them. The NASHP has issued a paper on this subject which it expects will be available Monday November 1, 2004. While no federal center is in place, information from NASHP provides that both the House of Representative and the Senate have different versions of bills to promote reporting of adverse events which can be funneled up through existing state entities to the federal level to the Department of Health and Human Services. The executive summary should become available at www.nashp.org.

THE PATIENT SAFETY AUTHORITY WEBSITE

Pennsylvania's Patient Safety Authority created an informative website at www.psa.state.pa.us. Applicable medical facilities are required to report incidents and serious events through this secured website, which is not available to the public. This website reporting system includes reporting of information to the Department of Health, such as infrastructure failures, which are not within the purview of the Patient Safety Authority. As noted by the Board Chair and Physician General, Dr. Robert S. Muscalus, D.O. in a press release and in other documents, the Patient Safety Author-

ity's reporting system creates one place for reporting this type of information by including reports that only go to the Department of Health within its own system. Having only one place to report this information will likely be seen positively by those having to report, and thus facilitate more reporting. In addition, the website provides public access to the patient advisories issued by the Authority, as well as the Patient Safety Authority's press releases, bi-laws, and other public documents, currently consisting of the RFP, and testimony before the Senate Banking and Insurance Committee and the House Insurance Committee. While the website provides extensive information about the Patient Safety Authority, documents created by and for the Authority, without any information about facilities or providers, the raw data collected by the Authority is conspicuously absent from public access, including information about the total number of reports, even in a form which protects the identity of the source of the reports, unless this information is included in the annual reports to the legislature which are required. No reports to the legislature have been due since the mandatory reporting has been fully in effect. To date, therefore, the public only has access to reporting information which can be gleaned from the patient safety advisories, and the annual reports already submitted prior to the start of full mandatory reporting.

LEGISLATIVE PROPOSAL TO EXPAND THE POWERS OF THE PATIENT SAFETY AUTHORITY, INCLUDING STRENGTHENING THE WHISTLEBLOWER PROTECTION

On February 12, 2004, Patient Safety Authority Board Member and Honorable Member of the Pennsylvania House of Representatives, Honorable Mary Ann Dailey,

introduced House Bill 2371 into the House. House Bill 2371, along with HB 2192, expand the Whistleblower protection by declaring the policy of such protection, providing for no retaliation against health care workers reporting near misses, provides for damages against facilities for such retaliation, including pain and suffering, cost of litigation and attorney fees. Furthermore, the Act authorizes civil penalties of up to \$5,000 for acts or omissions which impair patient safety or quality of patient care. The Acts further expand the power of the Patient Safety Authority, including defining powers to investigate, make recommendations both for safety and for discipline, and maintain confidential toll free reporting. It would appear that the act was introduced to address the concerns about the current widespread retaliation and deprivileging of physicians who try to correct systems with patient errors and that only independently wealthy physicians could utilize the litigation to enforce the whistleblower protections provided by the Mcare Act. H.B. 2371 passed the house. The last action on H.B. 2371 occurred on June 29, 2004, having been submitted to the Senate Committee on public health and welfare. The bill failed to pass by November 30, 2004. It therefore became null and void. Since Hon. Rep. Dailey left the legislature, the bill would then need to be taken up by another representative and reintroduced. Key portions of the Whistleblower law have been resubmitted as House Bill 96, Session of 2005 sponsored by Representative "Bud" George and others.

CONCLUSION

The establishment of the Patient Safety Authority and the Pennsylvania Reporting System are major steps in a long path toward reducing medical errors. The transition from a non-reporting climate to one where reports are made continues through this process.