



An independent agency of the Commonwealth of Pennsylvania

May 1, 2003

Dear Fellow Pennsylvanian:

As Chair of the Patient Safety Authority, I am pleased to submit to you a copy of the Authority's Annual Report, consistent with requirements of Act 13 of 2002.

This important legislation was signed into law on March 20, 2002. Among other things, the Act introduced innovative patient safety reforms for Pennsylvania consumers, especially the creation of the Patient Safety Authority under an 11 member Board of Directors. All of the Board members were appointed by the end of May 2003, and they have met frequently following their first meeting in July.

Pennsylvania is unique in establishing an independent agency like the Patient Safety Authority. No other state has established an error reporting system such as the one mandated by Act 13. For that reason, the Board has devoted considerable time, as a group and individually, to examining this very complex issue. Board members studied and evaluated error reporting systems already in place in Pennsylvania and elsewhere, and they met with information technology and health industry consultants from around the country. The Board also actively solicited input from Pennsylvania's healthcare and legal communities regarding the approach the Authority should take in implementing an effective medical error reporting system.

I am proud of the Board's accomplishments over the past several months. Board members have been tireless in their commitment to establish an effective, comprehensive and user-friendly mandatory error reporting system. They not only established a new agency within state government, but they are aggressively moving forward in initiating an innovative data collection and analysis system as mandated by Act 13.

With your help and support, I remain hopeful that Pennsylvania will continue to stand in the forefront of patient safety innovation in our country.

Sincerely,

Robert S. Muscalus, DO
Physician General and Chair



ANNUAL REPORT

May 1, 2003

INTRODUCTION:

The Patient Safety Authority was established under Act 13 of 2002, the Medical Care Availability and Reduction of Error (“Mcare”) Act, as an independent state agency (“a body corporate and politic”). It operates under an eleven member Board of Directors, six appointed by the Governor and four appointed by the Senate and House leadership. The chair is the Physician General who is also a member of the Board.

The Authority is charged with taking steps to reduce and eliminate medical errors by identifying problems and recommending solutions that promote patient safety in hospitals, ambulatory surgical facilities and birthing centers. Under Act 13, those three types of healthcare facilities must report all medical errors (called “serious events” in the Act) and near-misses (called “incidents” in the Act) to the Authority. In turn, the Authority can issue recommendations to medical facilities on a facility-specific or statewide basis regarding changes, trends and improvements in healthcare practices and procedures for the purpose of reducing the number and severity of serious events and incidents.

The Authority’s role is non-regulatory and non-punitive, distinguishing it from other state agencies involved in regulating and/or licensing health care facilities or individual providers.

The Authority is funded through the Patient Safety Trust Fund, moneys for which come from an annual surcharge on licensing fees charged to those medical facilities that are required to report to the Authority.

Act 13 requires the Authority to contract with an outside vendor to perform data collection and analysis activity related to medical errors. The Authority has issued a Request for Proposal (RFP) to identify that outside data collection and analysis vendor. The RFP calls for a multi-year contract; bids are due June 11, 2003. A copy of the RFP is available on the Authority’s website at www.psa.state.pa.us or through PA PowerPort, Keyword: Patient Safety. The Authority is requiring that a phase-in of the reporting system be implemented by the end of September 2003.

BOARD OF DIRECTORS:

Members of the Board of Directors are appointed by the Governor and the General Assembly, according to certain occupational or residence requirements. Current members include:

- The Physician General, who serves as Chair: Robert S. Muscalus, DO
Residence: Hummelstown (Dauphin County)
- Appointee of the President pro tempore of the Senate: Danae Powers, MD
Residence: State College (Centre County)
- Appointee of the Minority Leader of the Senate: Cliff Rieders, Esq.
Residence: Williamsport (Lycoming County)
- Appointee of the Speaker of the House: Hon. Mary Ann Dailey, RN
Residence: Pottstown (Montgomery County)
- Appointee of the Minority Leader of the House: Howard F. Messer, Esq.
Residence: Pittsburgh (Allegheny County)
- Physician appointed by the Governor: Nathan J. Zuckerman, MD
Residence: Langhorne (Bucks County)
- Nurse appointed by the Governor: Joan M. Garzarelli, RN, MSN
Residence: Breinigsville (Lehigh County)
- Pharmacist appointed by the Governor: Patricia Clancy Kienle, RPH
Residence: Laflin (Luzerne County)
- Hospital employee appointed by the Governor: Stanton N. Smullens, MD
Residence: Philadelphia (Philadelphia County)
- Health care worker appointed by the Governor: Anita Fuhrman, RN, BS.
Residence: Lebanon (Lebanon County)
- Non-health care worker appointed by the Governor: Lorina L. Marshall-Blake
Residence: Philadelphia (Philadelphia County)

MEETINGS TO-DATE:

The Board of Directors was appointed in May 2002. Since holding its first public meeting in July 2002, the Board has held numerous public and committee meetings, often weekly. Representatives of healthcare, consumer and other stakeholder groups, including the General Assembly, have attended and spoken at the public meetings. Following are the dates of all public meetings held by the Authority since its inception:

- | | |
|--------------------|-------------------|
| July 2, 2002 | December 9, 2002 |
| August 13, 2002 | January 13, 2003 |
| September 10, 2002 | February 10, 2003 |
| November 18, 2002 | April 14, 2003 |

Minutes of the public meetings are available on the Authority’s website at www.psa.state.pa.us or through PA PowerPort, Keyword: Patient Safety

SERIOUS EVENTS AND INCIDENTS:

As previously noted, the Authority has issued an RFP to develop a comprehensive electronic system to receive reports of serious events and incidents, to conduct analysis of those serious events and incidents, and to make recommendations to medical facilities about ways to reduce or prevent similar serious events and incidents from occurring in the future.

In addition to this new reporting and analysis system, which is scheduled for phase-in by September 2003, other complaint and error reporting systems are already in place in Pennsylvania and remain in effect. Through these systems, Pennsylvania citizens retain their right to file complaints against individual healthcare providers and facilities. More information about these complaint and error reporting systems are available on the Authority's website.

In response to Act 13 requirements that the Authority report certain information related to serious events and incidents over the past year, please note the following:

- The number of serious events and incidents reported by medical facilities on a geographical basis: N/A- The reporting system is scheduled for phase-in by September 2003
- The information derived from the data collected, including any recognized trends concerning patient safety: N/A- The reporting system is scheduled for phase-in by September 2003
- The number of anonymous reports filed and reviews conducted by the authority: N/A- The reporting system is scheduled for phase-in by September 2003
- The number of referrals to licensure boards for failure to report under this chapter: N/A- The reporting system is scheduled for phase-in by September 2003

RECOMMENDATIONS FOR REGULATORY CHANGE

Act 13 calls upon the Authority to suggest recommendations for statutory or regulatory changes that may help improve patient safety in the Commonwealth. Because the Authority is currently in the process of establishing a reporting system, no specific recommendations are suggested. However, as the system becomes operational, we will be better able to identify specific issues that may warrant recommendations for change. Of particular interest is the success of anonymous reporting as currently defined in addition to the adequacy of existing whistleblower protections.

ADDITIONAL INFORMATION:

Additional information about the Authority is available on the Authority's website at www.psa.state.pa.us or through PA PowerPort, Keyword: Patient Safety. In addition, you can contact the Authority directly at the following numbers or addresses:

Office Location:
539 Forum Building
Harrisburg, PA 17120

Mailing Address:
P. O. Box 8410
Harrisburg, PA 17105-8410

Phone: 717-346-0469

Fax: 717-346-1090

Email: patientsafetyauthority@state.pa.us