

## PENNSYLVANIA'S APPROACH TO REDUCING MEDICAL ERROR: THE STORY OF THE PATIENT SAFETY AUTHORITY

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Over the last decade, national headlines on prominent medical errors such as the blood transfusion mix-up at Duke University Medical Center<sup>1</sup> and the release of the Institute of Medicine ("IOM") report, *To Err is Human* in 1999<sup>2</sup> have ignited the patient safety movement in the United States. New partnerships, such as the National Patient Safety Foundation,<sup>3</sup> have been created to understand and reduce medical error. Increased research dollars are now being spent to investigate the role of teamwork and error reporting in improving patient safety, and numerous books have been published on the subject. This intensified focus on patient safety could not occur at a more critical time as the United States confronts another malpractice crisis that is forcing many doctors to either relocate or stop performing certain procedures, and in some cases, forcing physicians into early retirement.<sup>4</sup>

Traditionally, attempts to reduce error have been addressed primarily through malpractice litigation. The goals of medical malpractice litigation are "to deter unsafe practices, to compensate persons injured through negligence, and to exact corrective justice."<sup>5</sup> However, this punitive approach encourages providers to keep their mistakes hidden for fear of professional liability. As a result, many errors continue to remain underreported and lapses in the system persist.

New and innovative solutions will be necessary if we are to learn from our mistakes and truly improve the safety of our healthcare system. The purpose of

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1. Avery Comarow, *Jessica's Story: One Mistake Didn't Kill Her - The Organ Donor System Was Fatally Flawed*, U.S. NEWS & WORLD REP., July 28, 2003, at 51.

2. IOM, *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* (Linda T. Kohn et al. eds., 2000).

3. National Patient Safety Foundation, <http://www.npsf.org/> (last visited Dec. 22, 2005) (It is the National Patient Safety Foundation's mission to "[I]mprove the Safety of Patients through our efforts to: Identify and create a core body of knowledge; Identify pathways to apply the knowledge; Develop and enhance the culture of receptivity to patient safety; Raise public awareness and foster communications about patient safety; and Improve the status of the Foundation and its ability to meet its goals.").

4. Stephen C. Schoenbaum & Randall R. Bovbjerg, *Malpractice Reform Must Include Steps to Prevent Medical Injury*, 140 ANNALS OF INTERNAL MED. 51, 51 (2004).

5. David M. Studdert et al., *Medical Malpractice*, 350 NEW ENG. J. MED. 283, 283 (2004).

this paper is to explore what Pennsylvania is doing to improve patient safety and reduce medical error.

#### I. MAKING THE CONNECTION BETWEEN MEDICAL LIABILITY AND PATIENT SAFETY

Both medical malpractice litigation and the patient safety movement aim to reduce medical error. However, the philosophies behind each movement are conflicting. The medical malpractice movement relies on a punitive, blame-the-individual approach to reducing medical error.<sup>6</sup> It is thought that penalizing providers for their mistakes will prevent them from making similar mistakes in the future.<sup>7</sup>

The patient safety movement is a relatively new movement focused on identifying errors pro-actively by fostering an atmosphere that is open to discussing errors.<sup>8</sup> Providers are encouraged to be open and honest with their patients, especially if they commit a medical error, and to share their errors with colleagues to prevent others from making the same mistake.<sup>9</sup> To encourage this culture of openness, leaders of the patient safety movement emphasize a systems based approach to thinking about reducing medical errors.<sup>10</sup> That is, errors should be thought of as the result of lapses in the system, and not the result of incompetent clinicians.<sup>11</sup>

Currently, the conflict between these two movements is making it much more difficult to improve the quality of the healthcare system. The threat of malpractice litigation and the difficulty with obtaining malpractice insurance have negatively impacted physicians' desires to discuss their errors openly.<sup>12</sup> As a result, errors remain underreported and patients are often uninformed when an error occurs.<sup>13</sup> Therefore, though the malpractice system is allegedly designed to improve patient safety, it actually hinders improvements because of the threat of litigation.<sup>14</sup> While significant legal change seems unlikely given the present political atmosphere, much can be done in the present setting to improve patient

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6. Studdert et al., *supra* note 5, at 287.

7. *Id.*

8. *Id.* ("Transparency has become the leitmotif of the patient-safety movement: to learn from errors, we must first identify them; to identify them, we must foster an atmosphere that is conducive to openness about mistakes.")

9. *Id.*

10. *Id.*

11. Studdert et al., *supra* note 5, at 287.

12. *Id.* ("The reluctance of physicians to engage in [patient safety activities] stems from the belief that they are being asked to be open about errors with little or no assurance of legal protection at a time when litigation is on the rise. . .").

13. *Id.*

14. *Id.*

safety.<sup>15</sup> Understanding and applying the principles of the patient safety movement represents a significant opportunity to reduce the number of medical errors in the healthcare system.

## II. HISTORY OF THE PATIENT SAFETY MOVEMENT

The IOM's 1999 Report, *To Err is Human*, catapulted the problem of medical errors to the forefront of national attention and ignited the patient safety movement.<sup>16</sup> However, the existence of medical errors within the United States healthcare system was documented several decades prior to the release of this report. In 1964, Elihu M. Schimmel found that over an eight-month period twenty percent of admissions to a university hospital had one or more iatrogenic injuries, of which approximately twenty percent were fatal.<sup>17</sup> In 1981, Steel et al. wrote that thirty-six percent of patients admitted to a medical service in a university teaching hospital incurred iatrogenic illnesses, one-quarter of which were either life threatening or led to significant disability.<sup>18</sup>

Two prominent studies published in the early 1990s further confirmed the problem of medical errors in the U.S. healthcare system. In 1991, a study was released indicating that 3.7 % of hospitalizations in New York resulted in adverse events, of which 13.6 % led to death.<sup>19</sup> In 1992, a study in Colorado and Utah found the incidence of adverse events to be 2.9 % of hospitalizations, of which 6.6 % led to death.<sup>20</sup> Taken together, these two studies served as the basis for the 1999 IOM report stating that 44,000-98,000 preventable deaths occur each year as a result of preventable adverse events.<sup>21</sup> This is greater than the number of deaths each year from motor vehicle accidents, breast cancer, or AIDS.<sup>22</sup>

As the longitudinal nature of the research suggests, this problem has persisted for decades. However, greater efforts need to be made to identify errors, learn from them, and prevent their recurrence, for we can no longer ignore this problem. One proposed solution is using error-reporting systems. These will be discussed in the remainder of this paper.

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15. See Schoenbaum & Bovbjerg, *supra* note 4.

16. IOM, *supra* note 2.

17. See Elihu M. Schimmel, *The Hazards of Hospitalization*, 60 ANNALS OF INTERNAL MED. 100, 101 (1964).

18. See Knight Steel et al., *Iatrogenic Illness on a General Medical Service at a University Hospital*, 304 NEW ENG. J. MED. 638, 639 (1981).

19. Troyen A. Brennan et al., *Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study I*, 324 NEW ENG. J. MED. 370, 371 (1991).

20. Eric J. Thomas et al., *Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado*, 38 MED. CARE 261, 261 (2000).

21. IOM, *supra* note 2, at 1 (“[T]he results of the study in Colorado and Utah imply that at least 44,000 Americans die each year as a result of medical errors. The results of the New York Study suggest the number may be as high as 98,000.”).

22. *Id.*

## III. PLACE OF ERROR REPORTING IN THE PATIENT SAFETY MOVEMENT

As part of its recommendations for improving patient safety and reducing medical errors, the IOM advocated the four following specific approaches:<sup>23</sup>

- Creation of a national forum for leadership and knowledge on patient safety
- Reporting systems to identify and learn from error
- Creating safety performance standards for healthcare providers
- Adoption of patient safety programs within healthcare organizations

Within this framework, the IOM called for the creation of a nationwide system of error reporting with both mandatory and voluntary aspects.<sup>24</sup> The mandatory reporting system would collect standardized information from state governments about adverse events which resulted in serious injuries or deaths.<sup>25</sup> This system would be available to the public and would be linked to systems of accountability.<sup>26</sup> A specific national voluntary reporting system was not agreed upon at this time because insufficient data existed on how to best integrate a voluntary system with a mandatory one.<sup>27</sup>

In its discussion of reporting systems, the IOM made specific reference to the success of the Aviation Safety Reporting System ("ASRS").<sup>28</sup> Charles Billings, M.D., the retired Chief Scientist of the National Aeronautics and Space Administration ("NASA") who designed, started, and managed ASRS for over twenty years, commented on the elements necessary for success. He felt the first element was a "tangible, widely agreed upon need for more and better information."<sup>29</sup> The second requirement was "for a respected body, one independent of the influences of other stakeholders, to conduct the collection and analysis of data."<sup>30</sup> He specifically referenced demands by the aviation community that ASRS be placed under the auspices of NASA, a respected and

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23. IOM, *supra* note 2, at 86-106.

24. *Id.*

25. *Id.* at 87.

26. *Id.* at 88.

27. Report of the Quality Interagency Coordination Task Force to the President, *Doing What Counts for Patient Safety: Federal Actions to Reduce Medical Errors and Their Impact*, (2004), <http://www.quic.gov/Report/toc.htm> ("The IOM recommends that more research be conducted to determine the best way to develop voluntary reporting systems that complement proposed mandatory reporting systems and can identify potential precursors to errors, thus preventing patient harm."). *See also* Executive Summary and Actions, <http://www.quic.gov/Report/mederr2.htm>.

28. IOM, *supra* note 2, at 72-73, and 95-97.

29. Charles Billings, *Incident Reporting Systems in Medicine and Experience with the Aviation Safety Reporting System*, in *A TALE OF TWO STORIES: CONTRASTING VIEWS OF PATIENT SAFETY* App. B (1998), available at <http://www.npsf.org/exec/billings.html>.

30. Billings, *supra*, note 29, at 1-2.

independent third party, rather than the regulating agency, the Federal Aeronautics Administration (“FAA”), when the FAA wanted to establish the reporting system.<sup>31</sup> This approach allowed aviation experts to review the incidents and develop new knowledge to try to prevent them.<sup>32</sup>

In order to decrease the overall number of errors in the healthcare system, information must be easily understood and easy to act on. This is important for two reasons. One, the public expects, and has a right to know, that they are receiving the safest healthcare possible. Second, information about errors can be analyzed to help us explain why they occurred, and it can also help us take the necessary steps to prevent them from happening again. Therefore, establishing error-reporting systems in all fifty states, with both voluntary and mandatory components, would facilitate both learning and accountability. Thus, these systems would hold institutions accountable for delivering high-quality healthcare, and it would empower individuals with more information to improve patient safety.

#### IV. ISSUES WITH ERROR-REPORTING SYSTEMS

Errors in healthcare tend to be underreported because of the lack of anonymity, fear of lawsuits, amount of time required to complete a report, and a feeling that healthcare organizations will not make adequate use of the reports to effect a change.<sup>33</sup> This is primarily because past efforts to report errors in some healthcare organizations have relied on paper-based systems.<sup>34</sup> These systems are time-consuming, costly, and do not readily lend themselves to statistical analyses to ascertain causes of error.<sup>35</sup>

Therefore, a web-based system for reporting errors has been proposed to overcome these limitations.<sup>36</sup> Advantages such as being user-friendly, providing anonymity, requiring less time to report an event, and enabling individuals to report errors from computer terminals anywhere in the system enables larger amounts of information on errors to be collected and analyzed.<sup>37</sup> The collection of information in one central source also facilitates quicker generation of reports

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31. *Id.* at 3-4. (“The NASA Aviation Safety Reporting System was established in response to the cries of virtually everybody in the community, directly at the order of the FAA Administrator working through the Administrator of the National Aeronautics and Space Administration. NASA was chosen because we represented a respected and presumably objective third party.”).

32. *Id.* at 5. (“But like descriptive epidemiology anywhere else, incident reports can provide only descriptions of phenomena. Analytic studies and other research remain critical to a full understanding of the phenomena”).

33. Hagop S. Mekhjian et al., *Development of a Web-Based Event Reporting System in an Academic Environment*, 11 J. AM. MED. INFORMATICS ASS’N. 11, 11 (2004).

34. *Id.*

35. *Id.* at 11-12, 17.

36. Mekhjian et al., *supra* note 33, at 12.

37. Mekhjian et al., *supra* note 33, at 18.

and can enable organizations to more readily take steps to prevent errors from happening in the future.<sup>38</sup>

But even with the instillation of a web-based error reporting system, underreporting represents a significant problem.<sup>39</sup> This begs the question: should the system be mandatory or voluntary? The characteristics of the two systems are illustrated below.<sup>40</sup>

	<b>Mandatory</b>	<b>Voluntary</b>
Purpose	Accountability	Safety Improvement
Scope of Report	Errors Resulting in serious harm or death	Near misses
Reports submitted by	Organizations	Organizations or Providers
Level of Disclosure	Publicly Available	Confidential

Mandatory reporting systems are characterized by their emphasis on accountability, often requiring an institution to disclose when a patient has been severely injured.<sup>41</sup> Such reporting makes providers reluctant to admit and disclose errors because there is potential for the information to be used in court in a punitive manner.<sup>42</sup> On the other hand, voluntary reporting systems enable information on near misses to be captured, and they provide more information for learning about the root causes of error.<sup>43</sup>

While providers might prefer a voluntary reporting system, given their reluctance to admit blame, mandatory error reporting can create further institutional policies to monitor and reduce error. Holding healthcare organizations publicly accountable for reducing errors will necessitate increased attention and action from the leadership within these institutions.<sup>44</sup> This is especially important at a time when healthcare consumers are facing escalating costs, while simultaneously demanding evidence of high quality from providers.

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38. *See id.*

39. *See id.* at 12.

40. Table I was made by Author Adam S. Evans using information available in IOM, *supra* note 2.

41. IOM, *supra* note 2, at 87-88, 102-04.

42. *Id.* at 109-131.

43. *Id.* at 87.

44. Barry R. Furrow, *Medical Mistakes: Tiptoeing Toward Safety*, 3 HOUS. J. HEALTH L. & POL'Y 181, 205-06 (2003) (Discussing that mandatory reporting will reshape leadership within health care institutions because "[t]he connection between disclosure of errors and their correction is primarily fostered by the leadership climate.").

State governments, by their regulatory nature, can play a significant role in this regard.

#### V. ISSUES WITH CURRENT STATE REPORTING SYSTEMS

Twenty-one states currently have mandatory error reporting systems.<sup>45</sup> Since the focus of mandatory reporting systems are to hold providers accountable and inform the public about the safety of the healthcare system, disclosure remains a central part of designing an error reporting system.<sup>46</sup> However, providers fear that too much disclosure could lead to an increase in the number of lawsuits.<sup>47</sup> Therefore, what information and how much to disclose are decisions with which states frequently grapple.<sup>48</sup> States can choose to release information on specific incidents or aggregate information that may or may not identify facilities.<sup>49</sup> No evidence currently exists as to the most appropriate amount of disclosure to ensure improved patient safety.<sup>50</sup>

All state systems are plagued by underreporting, for reasons ranging from a hospital culture that is against reporting, fears of liability, fears of poor publicity, and lack of a system to identify errors.<sup>51</sup> As a result, states are now choosing to establish mandatory reporting systems in statutes, release aggregate reports, and assure greater protection of data received.<sup>52</sup>

#### VI. WHAT IS PENNSYLVANIA DOING TO IMPROVE PATIENT SAFETY?

Pennsylvania is currently facing a malpractice crisis and dealing with reports citing problems in patient safety in many of its hospitals. Over the last six years, physicians' malpractice costs have risen eighty-seven percent in Pennsylvania.<sup>53</sup> At the same time, there remains room for improvement in the quality of care delivered. In 2000, Pennsylvania ranked eighteenth among all states regarding the quality of care delivered to its Medicare beneficiaries.<sup>54</sup> A report released in 2001 by the Pennsylvania Department of Health and the Pennsylvania Health Care

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45. Mimi Marchev et al., *How States Report Medical Errors to the Public: Issues and Barriers*, NAT'L ACAD. FOR STATE HEALTH POL'Y 1, 2 (2003), available at [http://www.nashp.org/files/GNL52\\_medical\\_errors\\_reporting\\_for\\_the\\_web.pdf](http://www.nashp.org/files/GNL52_medical_errors_reporting_for_the_web.pdf)

46. *Id.* at 1.

47. *Id.* at 2.

48. *Id.* at 11.

49. *Id.*

50. Marchev et al., *supra* note 45, at 31.

51. *Id.*

52. *Id.*

53. OFFICE OF HEALTH CARE REFORM, GOVERNOR'S PLAN FOR MEDICAL MALPRACTICE LIABILITY REFORM 1, 25 (2004), <http://www.ohcr.state.pa.us/pdf/govsplan.pdf>.

54. Stephen F. Jencks et al., *Quality of Medical Care Delivered to Medicare Beneficiaries*, 284 JAMA 1670, 1674 (2000).

Cost Containment Council found that 5,294 individuals hospitalized in Pennsylvania during the year had suffered an adverse event.<sup>55</sup>

As a result of the ongoing malpractice crisis and heightened public awareness regarding the presence of medical errors, the State of Pennsylvania in late 2001 and early 2002 recognized that swift action needed to be taken. As directed by then Governor Mark Schweiker, an intense period of negotiations ensued between the Pennsylvania Medical Society (“PMS”), the Hospital Alliance of Pennsylvania (“HAP”), the Pennsylvania Trial Lawyer’s Association, the insurance industry, and the state legislature.<sup>56</sup> Act 13, the Medical Care Availability and Reduction of Error Act (“MCARE”) was the result of these negotiations and was signed into law on May 20, 2002.<sup>57</sup> The act has three significant portions: Chapter 3 addresses Patient Safety, Chapter 5 deals with Medical Professional Liability, and Chapter 7 addresses Liability Insurance Reform, including the CAT Fund (Medical Professional Liability Catastrophic Lost Fund).<sup>58</sup> In its conceptual framework, MCARE combines medical liability reform with patient safety.

The Act has many specific patient safety requirements: it requires medical facilities, including acute care hospitals, ambulatory surgical facilities, and birthing centers (approximately 400 across the Commonwealth) to implement patient safety plans, appoint patient safety officers, and establish patient safety committees.<sup>59</sup> It requires mandatory reporting of serious events, incidents, and infrastructure failures in these facilities.<sup>60</sup> The Act does have protections in place to ensure confidentiality of information.<sup>61</sup> In addition, the Act specifically calls for the creation of the Patient Safety Authority (“PSA”) in the State of Pennsylvania.<sup>62</sup>

## VII. THE PATIENT SAFETY AUTHORITY

The patient safety provisions (Chapter 3) of the MCARE Law (Act 13 of 2002) incorporate many of the recommendations of the IOM Report and others from the patient safety literature. The PSA is unique compared to all other states with error reporting systems. Pennsylvania is the first and only state to require the

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55. OFFICE OF HEALTH CARE REFORM, *supra* note 53, at 11, 13.

56. Ovetta Wiggins & Josh Goldstein, *Pennsylvania Legislators Approve Malpractice Law Overhaul*, PHILA. INQUIRER, Mar. 2002, available at [http://www.path.org/Content/NavigationMenu/Consumers/PaTLA\\_in\\_the\\_News/Pa\\_legislators\\_approve\\_malpractice-law\\_overhaul\\_\(March\\_2002\).htm](http://www.path.org/Content/NavigationMenu/Consumers/PaTLA_in_the_News/Pa_legislators_approve_malpractice-law_overhaul_(March_2002).htm).

57. Medical Care Availability and Reduction of Error Act (“MCARE”), PA. STAT. ANN. tit. 40, § 1303 (West 2005).

58. § 1303

59. Robert Muscalus, Presentation at Jefferson HealthSystem Risk Management Retreat: Act 13 of 2002. (Apr. 6, 2004).

60. *Id.*

61. *Id.*

62. *Id.*

reporting of both serious events and near misses and to require full written disclosure to patients.<sup>63</sup> It is also unique in that it is a mandatory system which protects institutions that report errors and fines hospitals that do not report, serving to keep the incentives to report aligned with one another.<sup>64</sup>

As stated previously, Act 13 establishes the PSA as an independent, non-regulatory state agency whose primary responsibilities are to “[r]educe and eliminate medical errors by identifying problems and implementing solutions that promote patient safety.”<sup>65</sup> The PSA’s job is to function in a learning role rather than an accountability role.<sup>66</sup> Accountability remains with the Pennsylvania Department of Health (“PA DOH”), where mandatory reporting of serious events was governed by Chapter 51 of Pennsylvania’s Health Care Facility Act.<sup>67</sup>

The PSA is comprised of eleven members appointed by the Governor and General Assembly.<sup>68</sup> The Physician General of Pennsylvania serves as the chairperson, and the other members of the board include a physician, a pharmacist, a hospital employee, a healthcare worker, a nurse, a non-healthcare worker, and four state residents.<sup>69</sup>

The PSA has the following responsibilities:<sup>70</sup>

1. Receive reports of serious events and incidents from medical facilities within twenty-four hours of confirmation
2. Contract with an entity(s) to collect, analyze, and evaluate reports of serious events and incidents
3. Evaluate contractor recommendations re: changes, trends, and improvements in health care practices
4. Issue recommendations to facilities after consultation and approval by DOH (facility-specific or statewide)
5. Report annually to the DOH and General Assembly

Act 13 defines a serious event as “[a]n 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.”<sup>71</sup> An incident (near miss) is “[a]n 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

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63. Furrow, *supra* note 44, at 216.

64. *Id.* at 214.

65. Muscalus, *supra* note 59.

66. *Id.*

67. 51 PA. CODE § 51.3 (1979) available at [http://www.pacode.com/Secure/data/025/chapter51/025\\_0051.pdf](http://www.pacode.com/Secure/data/025/chapter51/025_0051.pdf).

68. 40 PA. CONS. STAT. ANN. § 1303.303(b) (West 2005) amended by 2005 Pa. Legis. Serv. (West).

69. § 1303.303(b)(1)-(7).

70. Muscalus, *supra* note 59.

71. 40 PA. STAT. ANN. § 1303.303 (West 2005).

an unanticipated injury or require the delivery of additional health care services to the patient.”<sup>72</sup> The act also calls for infrastructure failures to be reported which it defines as “[a]n undesirable or unintended event, occurrence or situation involving the infrastructure of a medical facility or the discontinuation or significant disruption of a service which could seriously compromise patient safety.”<sup>73</sup>

The act has whistleblower protections to allow serious events to be anonymously reported.<sup>74</sup> In the occurrence of a serious event, a provider must notify the patient in writing within seven days after discovery of the event<sup>75</sup> and the healthcare facility must report it to the DOH and PSA within twenty-four hours after discovery.<sup>76</sup> Infrastructure failures also have to be reported to the DOH within twenty-four hours.<sup>77</sup> There is no required time period to report incidents.

Hospitals that do not report incidents can be fined up to \$1,000 a day.<sup>78</sup> Health care providers failing to report can be referred to the state licensing board.<sup>79</sup> The Act also made certain that the Act is adequately funded. It established the Patient Safety Trust Fund of \$5.0 M/year derived from the reporting facilities to fund the activities of the PSA and the reporting system.<sup>80</sup> This amounts to approximately \$100 per licensed bed.

#### VIII. ESTABLISHING THE REPORTING SYSTEM IN PENNSYLVANIA

The PSA held its first meeting in Harrisburg on July 20, 2002. After several months of hiring staff, being sworn in as Pennsylvania Commission Members, and reviewing different models of reporting systems - including the Veterans Administration Patient Safety Reporting System, the contracting process began. Much of the initial contracting work involved the research, negotiation, and writing of the Request for Proposal (“RFP”) necessary to carry out its mandate to contract with an entity or entities for the purpose of collecting, analyzing, and evaluating data regarding reports of serious events and incidents.<sup>81</sup> The RFP was written by a subcommittee of the PSA with the aid of Computer Aid, Inc.<sup>82</sup> and

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72. § 1303.302.

73. § 1303.302.

74. 40 PA. STAT. ANN. § 1303.304(b) (West 2002).

75. 40 PA. STAT. ANN. § 1303.308(b) (West 2002).

76. 40 PA. STAT. ANN. § 1303.313(a) (West 2004).

77. § 1303.313(c).

78. § 1303.313(f).

79. § 1303.313(e).

80. 40 PA. STAT. ANN. § 1303.305 (West 2002).

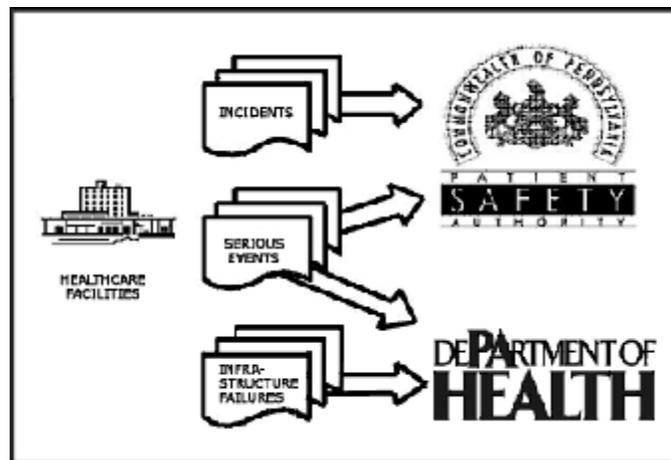
81. 40 PA. STAT. ANN. § 1303.304(a)(5) (West 2002).

82. Meetings of Patient Safety Authority, Final Minutes 5 (Feb. 10, 2003).

was released on April 23, 2003.<sup>83</sup> Following Pennsylvania's detailed and precise open-bid process, the contract was awarded to the Emergency Care Research Institute ("ECRI") in partnership with the Institute for Safe Medical Practices ("ISMP") and the Electronic Data Systems Corporation ("EDS").<sup>84</sup> The contract was signed on September 19, 2003.<sup>85</sup> ECRI and ISMP are both Pennsylvania based non-profit health services research organizations, and EDS is a large, international information technology firm.<sup>86</sup>

In response to the requirements of the RFP, ECRI, and ISMP developed the Pennsylvania Patient Reporting System, known as PA-PSRS (pronounced PAY-sirs), which is a secure web-based system that allows health care facilities to electronically submit reports of serious events and incidents.<sup>87</sup> It also allows reporting of serious events and infrastructure failures to the PA DOH.<sup>88</sup> The reporting requirements of the Act are depicted in Figure 1.<sup>89</sup>

Figure 1.



83. Meetings of Patient Safety Authority, Final Minutes 3-4 (May 7, 2003).

84. PATIENT SAFETY AUTHORITY ANNUAL REPORT 2-3 (2004).

85. *Id.* at 3.

86. *Id.*

87. *Id.*

88. *Id.*

89. Muscalus, *supra* note 59.

## IX. THE PA-PSRS SYSTEM AND ITS IMPLEMENTATION

The foundation of the PA-PSRS system is the “Patient Safety Net,” a web based reporting system developed by the University Health Consortium (“UHC”), licensed by ECRI, and fully owned by the PSA.<sup>90</sup> The system is secure and allows a health care facility to query its own reports to monitor trends and areas of concern within its institution.<sup>91</sup> It also allows benchmarking<sup>92</sup> with other facilities on a regional, but protected basis.<sup>93</sup> As Billings states that “[c]ounting incidents is a waste of time”<sup>94</sup> and that “[i]ncidents reports, properly interpreted, provide new knowledge[.]”<sup>95</sup> an extremely important part of the system is the ability of the facilities to include root cause analyses.<sup>96</sup> In addition, oversight and analysis of the reports to detect trends and to alert the PSA and healthcare facilities in urgent patient safety situations is provided in real time by medical and patient safety experts from ECRI and ISMP.<sup>97</sup>

Implementation of PA-PSRS began in November 2003 with testing of the system by twenty-two health care facilities that volunteered to participate in the program.<sup>98</sup> Phase II of the testing started in March 2004 when data was first sent by PA-PSRS to the DOH.<sup>99</sup> In late April 2004, the first of nineteen separate training sessions commenced.<sup>100</sup> Mandatory use of PA-PSRS began

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90. PATIENT SAFETY AUTHORITY ANNUAL REPORT, *supra* note 84, at 3.

91. *Id.*

92. “Benchmarking is the process of identifying, understanding, and adapting outstanding practices from organizations anywhere in the world to help your organization improve its performance.” The Benchmark Exchange, <http://www.benchnet.com/wib.htm> (last visited Dec. 23, 2005).

93. Patient Safety Authority, PA-PSRS (Pennsylvania Patient Safety Reporting System), <http://www.psa.state.pa.us/psa/cwp/view.asp?a=1165&q=441808&psaNav=> (last visited Dec. 23, 2005) (“[T]he PA-PSRS program will provide individual facilities with detailed reports analyzing data related to their specific facilities or to certain geographic regions and the state as a whole. . . . Because Act 13 contains strong confidentiality and whistleblower protections, all information submitted through PA-PSRS is confidential, and no information about individual facilities or providers will be made public.”).

94. Billings, *supra* note 29.

95. *Id.* at 5.

96. *Id.*

97. PATIENT SAFETY AUTHORITY ANNUAL REPORT, *supra* note 84, at 9-10.

98. *Id.* at 4.

99. Press Release, Patient Safety Authority Marks Patient Safety Awareness Week (Mar. 9, 2004), [http://www.psa.state.pa.us/psa/lib/psa/press\\_releases/press\\_release\\_pt\\_safety\\_week\\_3-09-04.pdf](http://www.psa.state.pa.us/psa/lib/psa/press_releases/press_release_pt_safety_week_3-09-04.pdf).

100. Press Release, Statewide Mandatory Reporting System in Place, Patient Safety Authority (June 28, 2004), [http://www.psa.state.pa.us/psa/lib/psa/press\\_releases/press\\_release-\\_mandatory](http://www.psa.state.pa.us/psa/lib/psa/press_releases/press_release-_mandatory)

on June 7, 2004 and was completed by June 28, 2004 when the approximately 400 health care facilities were all using the system.<sup>101</sup> Separate Chapter 51 reporting to PA DOH ceased. During the testing period, approximately ninety-five percent of the reports were of incidents and five percent were of serious events (actual harm).<sup>102</sup>

#### X. WHAT IS THE IMPACT OF REPORTING?

The State of Pennsylvania, along with many other states, has contributed significant resources toward creating statewide error reporting systems. However, how do we know that publicly reporting medical errors will actually meet their intended goals, which is decreasing the amount of overall errors while improving patient safety? How do we know that reporting incidents and serious events, analyzing them, and giving feedback to health care facilities will also improve patient safety? As noted earlier, error reporting has proven useful in other industries, most notably aviation. Since 1975, the 500,000 reports provided to the ASRS have enabled greater improvements in aviation safety in areas such as pilot training, and airport and aircraft design.<sup>103</sup>

In the healthcare field, publicly reporting on provider performance has been shown to lead to improved health outcomes for certain populations of patients. The New York State Department of Health has been publishing data on patients undergoing coronary artery bypass surgery since 1989 and has observed a decrease in mortality from this procedure.<sup>104</sup> In 1993, the Missouri Department of Public Health published an obstetrics consumer report of all Missouri Hospitals offering obstetrical services.<sup>105</sup> One year later, all hospitals had improved clinical outcomes.<sup>106</sup>

While various types of error reporting systems exist in both medical and non-medical fields, few documented findings of the utility of such information in reducing the occurrence of medical errors actually exists. The National Nosocomial Infection Survey, administered by the Centers for Disease Control

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101. *Id.*

102. PATIENT SAFETY AUTHORITY ANNUAL REPORT, *supra* note 84, at 8.

103. Paul Barach & Stephen D. Small, *Reporting and Preventing Medical Mishaps: Lessons From Non-Medical Near Miss Reporting Systems*, 320 *BMJ* 759, 762 (2000).

104. Edward L. Hannan et al., *Improving the Outcomes of Coronary Artery Bypass Surgery in New York State*, 271 *JAMA* 761, 763 (1994).

105. Daniel R. Longo et al., *Consumer Reports in Health Care: Do they Make a Difference in Patient Care?*, 278 *JAMA* 1579 (1997).

106. *Id.* at 1581-1582.

and Prevention, is the only program where error reporting has been demonstrated to improve safety.<sup>107</sup>

Results like this are encouraging and, though the error reporting movement in medicine is in its infancy, the expectation is that increased public reporting of medical errors will reduce their occurrence, will lead to decreased numbers of lawsuits, and will help change the culture of medicine from one of blame to one of learning and prevention.

#### XI. CONCLUSION

Given the malpractice crisis facing the United States and the near epidemic of medical errors reported in the media, improving patient safety is a subject sure to gain attention from policymakers and the public. Creative solutions to combat this problem are vital to improving the quality of care delivered in this country. Pennsylvania's approach to reducing medical error is one model that bears closer attention as policymakers search for the best way to deal with this issue.

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107. Lucian L. Leape, *Reporting of Adverse Events*, 347 NEW ENG. J. MED. 1633, 1634 (2002) ("The only program whose effect on safety has been demonstrated by a controlled trial is the National Nosocomial Infection Survey. Nosocomial Infection rates in hospitals that implemented the full program were 32 percent lower than in hospitals without the program.").