Wyoming Law Review

Volume 8 | Number 2 Article 1

2008

Error Reporting and Injury Compensation: Advancing Patient Safety Through a State Patient Safety Organization

Paul J. Barringer

Allen B. Kachalia

WYOMING LAW REVIEW

VOLUME 8 *2008* NUMBER 2

ERROR REPORTING AND INJURY COMPENSATION: ADVANCING PATIENT SAFETY THROUGH A STATE PATIENT SAFETY ORGANIZATION

*Paul J. Barringer, J.D., M.P.A.†**
and
*Allen B. Kachalia, M.D., J.D.***

ABSTRACT

For a number of years, reducing the incidence of medical errors has been a major driver of U.S. health policy. Some states have created voluntary reporting systems to facilitate identification and analysis of medical errors and to support development of patient safety initiatives. In addition, the federal government has passed laws to encourage the development of voluntary reporting initiatives at the state level that are protected and confidential. This article provides an outline of voluntary reporting initiatives undertaken to date at the state level, and summarizes the present status of the new federal law. It also describes how a structured compensation process tied to a state patient safety organization could offer a new opportunity to enhance reporting and leverage the liability system to improve safety.

† Correspondence and reprint requests to: Paul Barringer, Common Good, 1730 Rhode Island Avenue, NW, Suite 308, Washington, DC 20036. Phone 202-293-7450; Fax 202-293-7451; Email PBarringer@cgood.org. This work was supported by The Robert Wood Johnson Foundation. We thank Jack Glode and Fran Cadez for helpful comments, and Brynna Pietz and Andrew Wasicek for exceptionally able research assistance.

* Paul Barringer: General Counsel of Common Good, bipartisan legal and health care reform coalition of Washington D.C..

** Allen Kachalia: Assistant Professor, Harvard Medical School, and Associate Physician, Brigham and Women's Hospital.

INTRODUCTION

Over the past decade, patient safety has become an increasingly important driver of U.S. health policy. Particularly catalyzed by the Institute of Medicine's landmark 1999 report, *To Err is Human: Building a Safer Health System*, the prevalence and consequences of errors in health care treatment have generated substantial public attention and interest from political leaders.[1] In turn, policy makers at both the state and federal levels have considered a number of proposals through which they might use policy change to promote safer health care.[2]

A consistent goal of policy makers addressing patient safety is to promote collection of data on errors in a systematic way; under the theory that improved information and subsequent awareness of errors can help prevent errors from recurring.[3] Among the leading policy approaches in this regard has been the idea of creating an efficient process for reporting and analyzing information about medical errors. A number of states have established statewide patient safety centers that collect and aggregate reported information about errors, and use analyses of such data to inform safety improvement strategies.[4] Congress has also passed law to encourage enhanced reporting of information about error.[5]

Though patient safety advocates often stress the benefits of transparency and communication about errors, some health care providers may be cautious—in large measure because of the fear that such openness may generate greater malpractice exposure.[6] In fact, some health policy experts have identified the legal

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[1] *See, e.g.,* M. L. Millenson, *How the US News Media Made Patient Safety a Priority,* BRIT. MED. J. 324(7344): 1044 (2002); L. Leape, *Institute of Medicine Medical Error Figures Are Not Exaggerated*, J. OF THE AM. MED. ASS'N 284(1): 95-97 (2000); L. Leape & D. M. Berwick, *Five Years After To Err is Human*, J. OF THE AM. MED. ASS'N 293(19): 2384-2390 (2005).

[2] The Patient Safety and Quality Improvement Act of 2005, Pub. L. No. 109-41, 119 Stat. 424 (2005) (signed into law July 29, 2005); PA. PUBLIC LAW 154, No. 13; N.Y. PUB. HEALTH LAW Article 29-D, Title 2 (McKinney 2008), Section 2998; National Academy for State Health Policy, *Quality and Patient Safety: State adverse event reporting rules and regulations*, http://www.nashp.org/_docdisp_page.cfm?LID=2A789909-5310-11D6-BCF000A0CC558925 (last visited April 11, 2008).

[3] J. Rosenthal & M. Booth, *Maximizing the Use of State Adverse Event Data to Improve Patient Safety*, Portland, ME: National Academy for State Health Policy (2005).

[4] J. Rosenthal & M. Booth, *State Patient Safety Centers: A New Approach to Promote Patient Safety,* Portland, ME: National Academy for State Health Policy (2004).

[5] The Patient Safety and Quality Improvement Act of 2005, Pub. L. No. 109-41, 119 Stat. 424 (2005) (signed into law July 29, 2005).

[6] L.T. Kohn, J. M. Corrigan & M. S. Donaldson, *To Err is Human: Building a Safer Health System*, Washington, D.C.: National Academies Press (2000); Joint Commission on Accreditation of Healthcare Organizations, *Health Care at the Crossroads: Strategies for Improving the Medical Liability System and Preventing Patient Injury*, Oakbrook Terrace, IL: Joint Commission (2005), *available at* www.jointcommission.org/NR/rdonlyres/167DD821-A395-48FD-87F9-6AB12BCACB0F/0/Medical_Liability.pdf; D.M. Studdert & T.B. Brennan, *No-Fault Compensation for Medical Injuries: The Prospect for Error Prevention*, J. OF THE AM. MED. ASS'N 286(2): 217-223 (2001).

system as an impediment to improving health care quality—precisely because of the chilling effect it has on providers' willingness to disclose.[7] Various safety initiatives have been designed with this potential concern in mind. Despite such efforts, a number of observers continue to question the extent to which patient safety initiatives can succeed without some fundamental change in our current legal process or environment.[8]

To date, the possibility of incorporating a new process that integrates compensation and safety systems to resolve injury claims as part of a larger safety initiative remains a largely untapped opportunity. Many academics and advocates—among whom we count ourselves—have called for experimentation with alternative approaches to resolving medical liability disputes and compensating patient injuries, particularly as part of broader patient safety initiatives.[9] Some of the alternatives that have been proposed have generated stakeholder opposition to such an extent that their practical feasibility is likely limited.[10] However, a carefully constructed, alternative compensation system could satisfy the needs and objections of key stakeholders in the current system—patients and health care providers.

This article provides a framework for state policy makers who are considering the creation of a statewide patient safety organization, and possibly including a voluntary component for the resolution of injury claims. In particular, we discuss the experiences of a number of other states in establishing the mission, functioning, and funding of their patient safety organizations. We then describe the federal patient safety law passed in 2005, the Patient Safety and Quality Improvement Act, along with its newly released proposed regulations relating to the creation and operation of designated patient safety organizations. Based on this information, we set forth guiding principles for a new state patient safety

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[7] J.M. Corrigan, A. Greiner & S. M. Erickson, *Fostering Rapid Advances in Health Care: Learning from System Demonstrations*, Washington, DC: National Academies Press (2002); D.M. Studdert & T.B. Brennan, *No-Fault Compensation for Medical Injuries: The Prospect for Error Prevention*, J. OF THE AM. MED. ASS'N 286(2): 217-223 (2001).

[8] Joint Commission on Accreditation of Healthcare Organizations, *Health Care at the Crossroads: Strategies for Improving the Medical Liability System and Preventing Patient Injury*, Oakbrook Terrace, IL: Joint Commission (2005) *available at* www.jointcommission.org/NR/rdonlyres/167DD821-A395-48FD-87F9-6AB12BCACB0F/0/Medical_Liability.pdf.

[9] *See, e.g.,* M.M. Mello, D. M. Studdert, A. Kachalia & T. A. Brennan *"Health Courts" and Accountability for Patient Safety*, MILBANK QUARTERLY 84(3): 459-492 (2006); *see also* P. Barringer, *Windows of Opportunity: State-Based Ideas for Improving Medical Injury Compensation and Enhancing Patient Safety*, Washington, DC: Common Good (2006), *available at* www.commongood.org/assets/attachments/Windows_of_opportunity_web.pdf.

[10] *See, e.g.*, M.M. Mello, D. M. Studdert, P. Moran & E. A. Dauer, *Policy Experimentation with Administrative Compensation for Medical Injury: Issues Under State Constitutional Law*, HARV. J. ON LEGIS. 45: 59-106 (2008); *see also* P.J. Barringer, D. M. Studdert, A. B. Kachalia & M. M. Mello, *Administrative Compensation of Medical Injuries: A Hardy Perennial Blooms Again*, J. HEALTH POL. POL'Y & L. (2008) (forthcoming).

organization, or PSO. We also describe why and how this new organization might pursue establishment of an alternative dispute resolution process as a component of its statewide patient safety activities.

PATIENT SAFETY IN U.S. HEALTH POLICY

Historically, little was known about the prevalence of errors in American health care.[11] Errors tended to be addressed individually within particular institutions, and the public had little reason to believe that they were common. Public perception about error frequency shifted in a profound way, however, with the 1999 publication of the Institute of Medicine's (IOM) landmark report, *To Err is Human: Building a Safer Health System*.[12] Indeed, there may be no single event that more galvanized public interest in health care quality and patient safety than this report, which found that as many as 98,000 people were dying every year because of medical errors in American hospitals.[13] The report went on to discuss factors contributing to errors and concluded that most errors were caused by breakdowns in systems of care delivery.[14]

In this and in subsequent reports, the IOM suggested that error reporting programs be improved throughout the health care system. In particular, the reports stressed that more information about errors and near-misses (errors that do not result in any harm) needed to be collected in order to address and prevent medical errors.[15] Moreover, aggregating and analyzing such data would allow hospitals and providers to learn more about the patterns and frequencies of medical error and to correct the system-wide breakdowns that led to these failures.

As *To Err is Human* made clear, reporting can serve two main functions: (1) first and foremost, providing a base of information to help advance the safety of care and (2) holding providers accountable for performance. These functions are conceptually compatible, but in practice they can be difficult to achieve at the same time. *Mandatory* reporting systems can serve both functions, but are

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[11] K.E. Wood & D.B. Nash, *Mandatory State-Based Error-Reporting Systems: Current and Future Prospects*, AM. J. OF MED. QUALITY 20(6): 297-303 (2005).

[12] L.T. KOHN, J. M. CORRIGAN & M. S. DONALDSON, TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM, (Washington, DC: National Academies Press) (2000).

[13] M.L. Millenson, *How the US News Media Made Patient Safety a Priority*, BRIT. MED. J. 324(7344): 1044 (2002).

[14] L.T. KOHN, J. M. CORRIGAN, & M. S. DONALDSON, TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM, (Washington, DC: National Academies Press) (2000).

[15] INSTITUTE OF MEDICINE CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY (WASHINGTON, DC: National Academies Press) (2001); L.T. KOHN, J. M. CORRIGAN & M. S. DONALDSON, TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM (Washington, DC: National Academies Press) (2000); J.M. CORRIGAN, A. GREINER & S. M. ERICKSON, FOSTERING RAPID ADVANCES IN HEALTH CARE: LEARNING FROM SYSTEM DEMONSTRATIONS (Washington, DC: National Academies Press) (2002).

often seen as primarily promoting accountability. Mandatory systems typically require that reports be made to a state regulatory agency, often within the state Department of Health. States then generally have the authority to investigate individual instances of care and issue corrective directives or citations. These mandatory programs protect the public by making sure that serious events are reported, and that follow-up action occurs on serious adverse events. They also provide an incentive for health care providers to improve safety at the clinical level, since failure to do so can lead to penalties and/or undesirable exposure.

Yet, mandatory systems can have shortcomings, particularly in addressing the second core function of reporting systems: helping to improve safety. Mandatory systems requiring reports of serious injuries or death can only aggregate data about a small number of events—since these serious events are relatively uncommon. Some state mandatory systems have addressed this by also requiring reports of near misses, under the rationale that having more data reported would allow states to gain greater perspective on trends and weaknesses in safety systems.[16] Regardless of whether a mandatory reporting system collects data on near misses or only serious adverse events, however, fear of punitive sanctions or malpractice liability associated with reporting is likely to reduce compliance with reporting requirements—which in turn can lead to underreporting. (Note too that the related investigation, paperwork, and other duties associated with compliance can also lead to underreporting). To address the malpractice concern, some states have added confidentiality protections to provide increased incentives for reporting. Still, health care providers have expressed concern about the extent to which such information is truly protected.[17]

In contrast to mandatory serious adverse event reporting systems, *voluntary* reporting programs tend to be expressly oriented towards advancing safety in a systematic way. Typically, voluntary systems focus on errors and near misses that involve minimal or no harm, but can also include serious events; reports are made on a confidential basis and do not necessarily trigger external investigations, fines, or penalties. These reports are also generally afforded some kind of legal protections from discoverability. Since these systems are designed to capture a larger number of errors, they can be especially useful in identifying patterns of errors occurring across providers that relate to system problems affecting large numbers of health care institutions. This is particularly the case given that these types of errors may not occur frequently enough for individual institutions to identify a system failing based solely on its own data. The IOM emphasized that both mandatory and voluntary reporting systems have important functions, and that each should ideally be operated separately.

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[16] K. E. Wood & D. B. Nash, *Mandatory State-Based Error-Reporting Systems: Current and Future Prospects,* AM. J. OF MED. QUALITY 20(6): 297-303 (2005).

[17] J. Garbutt, A. D. Waterman, J. M. Kapp, W. C. Dunagan, W. Levinson, V. Fraser & T. H. Gallagher, *Lost Opportunities: How Physicians Communicate About Medical Errors*, HEALTH AFFAIRS 27(1): 246-255 (2008).

Recent years have seen the development and introduction of numerous legislative initiatives at the state and federal levels to address patient safety issues.[18] Many of these initiatives have been oriented towards enhanced reporting of information about errors in medical treatment. At the state level, particular interest has been focused on the establishment and refinement of mandatory state error reporting systems. More than half of all states now have some kind of mandatory adverse event reporting system in place.[19] However, there has also been interest at the state level in facilitating the development of voluntary reporting programs. In particular, statewide patient safety organizations have been established in a number of states to spearhead collaborative, learning-oriented approaches to improving safety of care—in some cases partly through voluntary reporting initiatives.

STATE PATIENT SAFETY ORGANIZATIONS

To date, state patient safety organizations have been established in Connecticut, Florida, Maryland, Massachusetts, New York, Oregon and Pennsylvania. Each of these organizations has been established by the state legislature. Most, but not all, of these entities have enacted some type of reporting system; the extent to which reporting to these systems is voluntary varies by state. To help inform the potential structure and activities of a new state patient safety organization, we outline in the following section the present structure and function of these existing organizations.

Connecticut

In 2004, the Connecticut General Assembly passed legislation that would allow the Department of Public Health (DPH) to designate qualified entities as patient safety organizations.[20] The 2004 law required hospitals and outpatient surgical facilities to contract with one or more patient safety organizations as they became available.[21] The legislation also specified that qualifying entities would have several specific characteristics: its primary function would be to improve patient safety; it would have a staff capable of reviewing patient safety work product; it would not be a component of a health insurer; and its mission would not

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[18] *See, e.g.,* The Patient Safety and Quality Improvement Act of 2005, Pub. L. No. 109-41, 119 Stat. 424 (2005) (signed into law July 29, 2005); PA. PUBLIC LAW, 154, No. 13; NEW YORK SB 8127;. Health Information and Quality Improvement Act of 2000; MD. CODE REGS. §10.07. 06.01 (2008); CONN. GEN. STAT. § 19a-127n (2004); National Academy for State Health Policy. Quality and Patient Safety: State adverse event reporting rules and regulations, http://www.nashp.org/_docdisp_page.cfm?LID=2A789909-5310-11D6-BCF000A0CC558925 (last visited April11, 2008).

[19] National Academy for State Health Policy, *Patient Safety Toolbox for States*, www.pstoolbox.org (last visited March 27, 2008).

[20] CONN. GEN. STAT. § 19a-127o (2004).

[21] CONN. GEN. STAT. § 19a-127o (2004).

create a conflict of interest with the health care providers with which it contracts. The legislation additionally states that any private or public organization or a component of any private or public organization may apply to the Department of Public Health to be designated as a patient safety organization (PSO).[22] Note that the state implemented a mandatory adverse event reporting system within the DPH in 2002 separately from the efforts undertaken by the designated PSOs.[23]

In turn, DPH designated Qualidigm, the state's Medicare Quality Improvement Organization, and the Connecticut Healthcare Research and Education Foundation (CHREF, an affiliate of the Connecticut Hospital Association) as patient safety organizations in 2004.[24] In addition, the Connecticut Ambulatory Surgery Center Association (ASC Association) formed the Ambulatory Surgery Center Patient Safety Organization (ASCPSO), which was added as a state patient safety organization in 2005.[25] Qualidigm is a non-profit research and consulting company that is governed by a board of directors composed of nurses, physicians, scientists and administrators. The other organizations are professional associations governed by their representative members; the ASCPSO contracts solely with ambulatory surgery centers while CHREF works primarily with its hospital members, but will accept contracts with any provider.[26] Qualidigm maintains a mix of contracts with providers, health care facilities and others.[27]

In their capacity as the state's patient safety organizations, Qualidigm, CHREF, and the ASCPSO assist health care providers in making quality enhancements and improving outcomes; they serve as learning organizations but have no regulatory or formal reporting function. In particular, they provide technical assistance with completing root cause analyses and improving quality standards. They also host workshops, issue alerts, and sponsor training on how providers can facilitate a culture of safety. Health care providers are not required to submit any error-

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[22] CONN. GEN. STAT. § 19a-127o (2004).

[23] CONN. GEN. STAT. § 19a-127n (2004). Hospitals and outpatient surgical facilities are required to report adverse events listed in the National Quality Forum's report, Serious Reportable Events in Healthcare. Additionally, DPH has been directed to implement strategies for reducing medical errors and making systems improvements. DPH collaborates with the Quality of Care Advisory Committee, within the General Assembly, to make specific recommendations about improving patient safety.

[24] Personal Communication with Nancy Safer (Patient Safety Organization Manager, Qualidigm) on April 11, 2008; Qualidigm, Patient Safety Organization, www.qualidigm.org/Professionals/Topic/PatientSafety/PSO.aspx (last visited accessed March 27, 2008).

[25] Ambulatory Surgery Association Patient Safety Organization, LLC, *About Us*, http://ctasc patientsafety.org/about.htm (last visited April 11, 2008).

[26] Personal Communication with Tricia Dinneen Priebe (Ambulatory Surgery Center Patient Safety Organization, Administrator) on April 11, 2008; Personal Communication with Julie Petrellis (Director of Clinical Data Support, Connecticut Hospital Association) on April 11, 2008.

[27] Personal Communication with Tricia Dinneen Priebe (Ambulatory Surgery Center Patient Safety Organization, Administrator) on April 11, 2008.

related data, but all information that the PSOs receive about errors and medical care is kept confidential. The designated PSOs are required to make occasional recommendations to the Quality of Care Advisory Committee within the state legislature, the DPH, health care providers, and others about patient safety best practices.

Florida

The Florida Patient Safety Corporation (FPSC) was established by the Florida Legislature in 2004 to serve as a learning organization that would assist health care providers in improving the quality and safety of clinical care in the state.[28] It was also created in part to address "skyrocketing liability insurance premiums."[29] The FPSC maintains a reporting system to which participants can report near misses; reporting is made on a voluntary and anonymous basis that is independent of mandatory systems used for regulatory purposes.[30] This system, run in partnership with the University of Miami/Jackson Memorial Hospital Center for Patient Safety and CS STARS (a software vendor that is a unit of Marsh, an insurance services firm), receives reports from approximately seventy (70) hospitals as well as several birthing centers and ambulatory surgical centers in the state. The FPSC also provides patient resources, convenes conferences, issues patient safety advisory reports, and provides reports to the legislature, among other activities.[31] Note that the FPSC is allowed to receive the adverse event information that is reported to the state's Agency for Healthcare Administration in order to analyze the data for trends and suggest best practice changes.

The FPSC is governed by a board of directors that includes physicians, nurses and other health care professionals with expertise in patient safety.[32] Designated committees provide input to the board, with specific issue focuses, including

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[28] FLA. STAT. § 381.0271 (2004); Florida Patient Safety Corporation *About Us,* www.floridapatientsafetycorp.com/AboutUs/tabid/4287/Default.aspx (last visited March 27, 2008).

[29] *See* Florida Patient Safety Corporation, *About Us,* www.floridapatientsafetycorp.com/AboutUs/tabid/4287/Default.aspx (last visited March 27, 2008); *see also* J. Rosenthal & M. Booth, *State Patient Safety Centers: A New Approach to Promote Patient Safety,* Portland, ME: National Academy for State Health Policy (2004).

[30] FLA. STAT. § 395.0197 (2007); FLA. STAT. § 458.351 (2000); FLA. STAT. § 459.026 (2000) all outline the mandatory reporting requirements for healthcare facilities in the state; Florida Patient Safety Corporation, *Near Miss Reporting System and Advisories*, www.floridapatientsafetycorp.com/NearMissReportingSystemsandAdvisors/tabid/4289/Default.aspx (last visited March 27, 2008).

[31] Florida Patient Safety Corporation, www.floridapatientsafetycorp.com (last visited March 27, 2008).

[32] Florida Patient Safety Corporation, *Board of Directors*, www.floridapatientsafetycorp.com/BoardofDirectors/tabid/4209/language/en-US/Default.aspx (last visited March 27, 2008).

scientific research, education, and litigation alternatives.[33] The operations of the FPSC are funded by the legislature, although the enabling legislation requires the organization to seek private sector funding and to apply for grants to accomplish its goals and duties.[34]

Maryland

The Maryland General Assembly passed a broad legislative package in 2001 that called on the Maryland Health Care Commission, an independent state agency, to address patient safety through a variety of approaches.[35] The Health Care Commission in turn produced a report with a series of recommendations for improving quality throughout the state, including the establishment of a patient safety center and the expansion of a mandatory error reporting system that would include root cause analyses.[36] In 2003, the state legislature passed legislation which enabled the Health Care Commission to establish the Maryland Patient Safety Center (MPSC) in an effort to develop and implement new approaches to improving the quality and safety of health care in Maryland.[37] The Commission selected the Delmarva Foundation (the local Medicare-designated Quality Improvement Organization) and the LogicQual Research Institute (a subsidiary of the Maryland Hospital Association) to run the MPSC.

The MPSC collects and analyzes data about adverse events in Maryland hospitals. Several hospitals use the MPSC's online event reporting tool; others use their own data collection tools but ultimately also send data to the MPSC.[38] The MPSC uses this data to promote collaboration and learning among hospitals, to provide feedback to hospitals, and to help identify patterns of errors across hospitals. The MPSC sponsors educational conferences and seminars, conference calls, and collaborative workshops, and its website provides a variety of patient safety resources and documents. The MPSC has had a particular emphasis on

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[33] Florida Patient Safety Corporation, *Advisory Committees*, www.floridapatientsafetycorp.com/AdvisoryCommittees/tabid/4212/language/en-US/Default.aspx (last visited March 27, 2008). Note the Litigation Alternatives Committee has considered different approaches to resolving injury claims, such as administrative compensation and disclosure programs.

[34] Personal Communication with Susan A. Moore (CEO, Florida Patient Safety Corporation) on March 26, 2008.

[35] MD. CODE ANN. HEALTH-GEN. § 19-139 (2001); Maryland Patient Safety Center, *About Us*, www.marylandpatientsafety.org/html/aboutUs.html (last visited March 27, 2008).

[36] Maryland Health Care Commission, *"Final Report on the Study of Patient Safety in Maryland"* (January 2003). Note that the mandatory reporting of serious adverse events is addressed in Code of Maryland Regulations §10.07.06 *et seq*.

[37] MD. CODE ANN. HEALTH-OCC. § 1-401 (West 2006).

[38] Maryland Patient Safety Center, *Home*, www.marylandpatientsafety.org (last visited March 27, 2008).

analyzing data collected in the contexts of emergency and perinatal care.[39] For example, the MPSC's Emergency Department Collaborative has promoted inter-institutional strategies to improve handoffs and transitions in emergency departments; in a similar fashion, the MPSC's Perinatal Collaborative has promoted strategies to enhance perinatal care by addressing standardization of fetal monitoring language, teamwork training, and documentation.

The operations of the MPSC are overseen by a board of directors, which includes a patient advocate, an insurance representative (currently the Senior Vice President and Chief Medical Officer of CareFirst BlueCross BlueShield), and members of the health care provider community and state legislature.[40] Funding for the operation of the MPSC has come from the Delmarva Foundation and the LogicQual Research Institute.[41]

Massachusetts

In 2002, the General Court of the Commonwealth of Massachusetts (the state legislature) created the Betsy Lehman Center for Patient Safety and Medical Error Reduction (Lehman Center) within the Department of Public Health (DPH).[42] The organization began operation in 2004.[43] Although housed within DPH, the Lehman Center functions separately from other DPH divisions, including the Division of Healthcare Quality (which investigates complaints against health care facilities) and the Board of Registration in Medicine (which investigates complaints and handles disciplinary proceedings involving health care providers). The state's mandatory adverse event reporting filters through these two other entities, while the Lehman Center coordinates efforts to recommend and implement system changes.[44]

The Lehman Center collects and analyzes information about errors that it receives from patients, families, and health care providers. The Lehman Center does not currently participate in any error reporting but may soon initiate a

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[39] Maryland Patient Safety Center, *ED Collaborative*, www.marylandpatientsafety.org/html/collaboratives/ed/index.html. (last visited March 27, 2008); Maryland Patient Safety Center, *Perinatal Collaborative*, www.marylandpatientsafety.org/html/collaboratives/perinatal/index.html (last visited March 27, 2008).

[40] Maryland Patient Safety Center, *Board of Directors*, www.marylandpatientsafety.org/html/board.html (last visited March 27, 2008).

[41] Maryland Patient Safety Center, *"Maryland Patient Safety Center is Established,"* June 18, 2004, *available at* www.marylandpatientsafety.org/html/news/061804.html.

[42] MASS. GEN. LAWS ch. 6, A Section 16E (2008).

[43] Betsy Lehman Center for Patient Safety and Medical Error Reduction, www.mass.gov/dph/betsylehman (last visited March 27, 2008).

[44] 105 MASS. CODE REGS. 130.331 (2008); Personal communication with Eileen McHale (Patient Safety Ombudsman, Betsy Lehman Center) on March 28, 2008.

voluntary and confidential reporting process.[45] It monitors this information to discern trends and patterns that may be emerging in errors across institutions, and it issues patient safety alerts based on this monitoring. The Lehman Center functions as a clearinghouse for developing, evaluating, and disseminating patient safety-related information. This includes sponsorship of educational and training programs as well as distribution of best practices for reducing medical errors. The Lehman Center also functions as an ombudsman for patients, families, and consumers on patient safety-related issues.

Within the Lehman Center there is a Patient Safety and Medical Errors Reduction Board, which includes the Secretary of Health and Human Services, the Director of Consumer Affairs and Business Relations, and the Attorney General.[46] The Board is responsible for appointing the Director of the Lehman Center and has general oversight of the center. The nonprofit Massachusetts Coalition for the Prevention of Medical Errors serves as the Advisory Committee for the Lehman Center. The Lehman Center was launched with $200,000 from the state's health care quality trust fund;[47] the organization now operates with state appropriations.[48]

New York

New York's Patient Safety Center (NYPSC) was established in 2000 as part of broad patient safety-oriented legislation, the Patient Health Information and Quality Improvement Act.[49] This Act called for the creation of a statewide information system within the Department of Health (DOH) to collect and make available to the public data on health plans and providers. This information is collected by the DOH and made available to the NYPSC in order to devise strategies and recommendations for improving patient safety, as well as to track the progress of providers statewide.[50] To carry out its mission of increasing public access to health care information, the NYPSC provides patient-friendly information about preventing medical errors and publishes a periodic newsletter on health care quality and safety issues. The Center also helps to formulate and/or

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[45] Personal communication with Eileen McHale (Patient Safety Ombudsman, Betsy Lehman Center) on March 28, 2008.

[46] MASS. GEN. LAWS ch. 6, A Section 16E (2008).

[47] Alice Dembner, *Push For Patient Safety Honors Writer*, BOSTON GLOBE, January 14, 2004, at B3.

[48] Personal communication with Eileen McHale (Patient Safety Ombudsman, Betsy Lehman Center) on March 28, 2008.

[49] N.Y. PUB. HEALTH LAW Article 29-D, Title 2, § 2998 (McKinney 2008); Patient Safety Center, *About the Patient Health Information and Quality Improvement Act of 2000*, www.health.state.ny.us/nysdoh/healthinfo/about.htm (last visited March 27, 2008).

[50] Personal Communication with Debbie Klein, (Executive Assistant, New York Patient Safety Center) on March 27, 2008.

improve clinical guidelines and standards for a variety of topics. The NYPSC was also tasked with developing (and has created) a voluntary and collaborative error reporting system to improve quality and reduce medical errors. [51] Separate from the state's mandatory reporting system, and consistent with the IOM's recommendations, this approach encourages greater reporting and facilitates learning. The NYPSC is directed by the DOH, which appoints an acting director. In turn, the NYPSC director appoints various advisory groups and subcommittees to assist with its activities.[52]

The NYPSC is housed within the state Department of Health, which also has several other patient safety initiatives. First, the New York Patient Occurrence and Tracking System (NYPORTS) is a mandatory reporting system for adverse events that occur in hospitals.[53] Serious adverse events, for example, patient deaths or serious impairments other than those related to the natural course of disease or where treatment was improper, are investigated individually. Hospitals are required to conduct a root cause analysis of these events.[54] In addition, the DOH administers the Patient Safety and Patient/Resident Safety Award Program, which recognizes excellence in quality improvement among providers and provides grant support to awardee institutions to share their insights with other health care providers.[55]

Oregon

Oregon's Patient Safety Commission (OPSC) was created by the state legislature in 2003 as a semi-independent state agency.[56] Like other state patient safety centers, the OPSC's mission is to improve patient safety by encouraging a patient safety culture and reducing the risk of serious adverse events. The Commission provides reports about patient safety issues to the legislature, makes available de-identified case studies, issues other reports, and convenes working groups in the state.[57] It also maintains a voluntary and confidential adverse event reporting system for participating hospitals, nursing homes, pharmacies, and

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[51] N.Y. PUB. HEALTH LAW Article 29-D, Title 2, § 2998 (McKinney 2008).

[52] Personal Communication with Debbie Klein (Executive Assistant New York Patient Safety Center) on March 27, 2008.

[53] State of New York Department of Health, *New York Patient Occurrence and Tracking System Report* (2002-2004), *available at* www.health.state.ny.us/nysdoh/hospital/nyports.

[54] N.Y. COMP. CODES R. & REGS. Tit. 10, § 405.8 (2008).

[55] State of New York Department of Health, *DOH Initiatives*, www.health.state.ny.us/nysdoh/healthinfo/pscdohi.htm (last visited March 27, 2008).

[56] OR. REV. STAT. § 442.820 (2003).

[57] Oregon Patient Safety Commission, www.oregon.gov/DHS/ph/pscommission/index.shtml (last visited March 27, 2008).

ambulatory surgery centers.[58] Of the twenty-six states with error reporting laws in place, Oregon is the only state that has established only a voluntary reporting system.[59]

The OPSC is governed by a seventeen-member Board of Directors, which includes the Public Health Officer as well as physicians, insurance representatives, labor representatives, academics, consumers, pharmacists, nurses, and administrators, to be appointed by the Governor to four year terms and confirmed by the Senate. The Board's duties include appointing a Director and establishing various groups and subcommittees. The legislation requires the OPSC to maintain a consumer advisory group and technical advisory group.[60] The OPSC is funded by fees assessed upon all health care facilities of the type for which there is a reporting program in place, including hospitals, nursing homes, pharmacies, and ambulatory surgery centers.[61] These organizations are required to pay the fees to support the OPSC, but they are not required to participate in the reporting program.

Pennsylvania

Pennsylvania's Patient Safety Authority (PSA) was established by legislation in 2002 as an independent state agency.[62] The PSA was created as part of a broader legislative initiative addressing patient safety and liability issues, the Medical Care Availability and Reduction of Error (MCARE) Act.[63] The most significant program administered by the PSA is the Pennsylvania Patient Safety Reporting System (PA-PSRS), which receives and analyzes reports of "serious events" (actual occurrences) and "incidents" (near misses). More than 400 institutions are subject to mandatory reporting requirements under the PA-PSRS. The PSA also provides consumer-friendly information about patient safety, convenes public meetings, studies various patient safety topics, and issues extensive quarterly patient safety advisories based on these studies.

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[58] OR. REV. STAT. § 442.820 (2003); Personal communication with Linda Goertz (Executive Assistant, Oregon Patient Safety Commission) on February 25, 2008.

[59] There are twenty-six states, and the District of Columbia, which have some type of error reporting law in place. Of those twenty-six states, Oregon is the sole state to maintain *only* a voluntary reporting system—the other twenty-five maintain mandatory systems, and some have additional voluntary reporting programs in place. National Academy for State Health Policy, *Quality and Patient Safety: State Adverse Event Reporting Rules and Regulations,* www.nashp.org/_docdisp_page.cfm?LID=2A789909-5310-11D6-BCF000A0CC558925 (last visited March 27, 2008).

[60] OR. REV. STAT. § 442.820 (2003).

[61] Personal communication with Linda Goertz (Executive Assistant, Oregon Patient Safety Commission) on February 25, 2008.

[62] PA. PUBLIC LAW 154, No. 13; Patient Safety Authority, www.psa.state.pa.us/psa/site/default.asp (last visited March 27, 2008).

[63] PA. PUBLIC LAW 154, No. 13.

The PSA is headed by an eleven-member Board of Directors which includes the Physician General, several political appointees, consumers, physicians, nurses, pharmacists, and administrators.[64] Financial support for the PSA comes from the state's Patient Safety Trust Fund, which in turn is funded by licensing fees assessed on health care providers that are required to report to the PSA. Note that the total annual assessment on health care providers to fund the Authority is limited by law to $5 million for the PSA's first year, plus an additional amount indexed to the Consumer Price Index.[65]

FEDERAL PATIENT SAFETY LEGISLATION

Public attention to patient safety has also generated interest at the federal level. In Congress, several years of discussion and debate led to the development of a proposal to encourage voluntary reporting, which took legislative form in the Patient Safety and Quality Improvement Act of 2005 (PSQIA).[66] Signed into law on July 29, 2005, the PSQIA is aimed directly at improving patient safety through creating confidentiality protections designed to encourage voluntary reporting of medical adverse events. In particular, the PSQIA empowers the Secretary of the U.S. Department of Health and Human Services (HHS) to designate qualifying organizations as "Patient Safety Organizations" (PSO) to collect and analyze information reported by health care providers.[67]

In the broadest perspective, the PSQIA represents an attempt on the part of federal policy makers to improve the quality of care by encouraging the development of voluntary, provider-driven approaches to improving patient safety. Significantly, organizations qualifying as a "PSO" under the PSQIA are neither to be funded nor controlled by the federal government, nor does the law mandate that specific reporting must occur. Rather, PSOs are intended to collect and analyze information about adverse events occurring in health care treatment on a voluntary basis, independent of health insurers or other state or federal regulatory bodies.

A primary goal of the PSQIA is to ameliorate health care providers' fears that information they report about errors may be used against them in disciplinary proceedings or medical malpractice litigation. As discussed above, many health policy and patient safety experts have noted that this fear can hamper patient safety

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[64] Pennsylvania Patient Safety Authority, *Board of Directors*, www.health.state.ny.us/nysdoh/healthinfo/pscdohi.htm (last visited March 27, 2008).

[65] PA. PUBLIC LAW 154, No. 13.

[66] The Patient Safety and Quality Improvement Act of 2005, Pub. L. No. 109-41, 119 Stat. 424 (2005) (signed into law July 29, 2005).

[67] Department of Health and Human Services, Patient Safety and Quality Improvement; Proposed Rule, 73 Fed. Reg. 8112-8183 (February 12 2008) (to be codified at 42 C.F.R. pt. 3); Proposed § 3.104—Secretarial Actions.

efforts by chilling providers' willingness to report information about errors (which in turn reduces the amount of data available for patient safety analyses). The PSQIA aims to address providers' concerns about reporting by providing uniform statutes under which specified patient safety information is protected. Organizations that gain PSO certification will be able to offer to providers the benefits of review and analysis of patient safety work product that is shielded by strong federal protections. In particular, the law provides legal privilege and confidentiality protection for information that is reported by health care providers to a qualified PSO. The law also protects "patient safety work product"—information developed by a PSO for the purpose of patient safety related activities—by significantly limiting use of such information in civil, criminal, and administrative proceedings.[68]

The PSQIA also is aimed at encouraging greater aggregation of data about medical errors. To help meet this goal, the law provides for the establishment of a Network of Patient Safety Databases (NPSD), with common reporting formats, interoperable reporting systems, and other standardized elements that can be used as a resource by providers and PSOs to analyze national and regional patient safety trends and patterns.

The PSQIA does provide some detail about the designation and functioning of PSOs. For example, it specifies that PSOs must work with more than one health care provider; it also provides eligibility criteria for organizations that would like to be designated as PSOs. However, much of the detail about the functioning of PSOs under the PSQIA is left to regulation. Proposed regulations for the implementation of the PSQIA, much anticipated, were released by HHS in February 2008.[69] As this article was being written, HHS was soliciting comments about the proposed regulations; the final rule may differ from the current proposal.[70] As proposed, the regulations describe how clinicians can report information on a confidential basis, the ways in which such information can be analyzed for patient safety purposes, and how such data can be shared with providers to give feedback on improving safety without jeopardizing the law's confidentiality protections. They also outline how an organization can become designated as a PSO.

The proposed rules make clear that a number of different kinds of organizations can become PSOs, including private, public, for-profit and not-for-profit entities. However, health insurance issuers (or components of health insurance issuers) may not become PSOs. A process for certifying and listing PSOs will be implemented by the Agency for Healthcare Research and Quality (AHRQ). AHRQ's review

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[68] The proposed rule gives total privilege and confidentiality protections, but there are limited exceptions and permissions under which work product can be disclosed to authorities or other parties.

[69] Department of Health and Human Services, Patient Safety and Quality Improvement; Proposed Rule, 73 Fed. Reg. 8112-8183 (February 12 2008) (to be codified at 42 C.F.R. pt. 3).

[70] Comments were to be submitted on the proposed rule by April 14, 2008.

process for listing as a PSO is intended to be simple and straightforward, which is expected to encourage a number of organizations to pursue the listing. Entities seeking to become a PSO will submit an application to AHRQ; certification will rely primarily on attestations of entities seeking listing rather than submission and review of documentation by AHRQ. The proposed rule suggests that little time will be required to submit these forms; an average burden of 30 minutes annually for each entity.

Pursuant to the proposed regulation in its current form, requirements that applicant organizations must meet to gain PSO certification include the following:

— The organization must undertake efforts to improve safety and quality, and the mission and primary activities of the organization must be patient safety-oriented.

— The organization must collect and analyze patient safety work product in a standardized manner, and use this to provide direct feedback to providers about encouraging a culture of safety and reducing patient risk.

— The organization must develop and disseminate information relating to patient safety improvements.

— The organization must employ qualified staff.

— The confidentiality and security of patient safety work product must be maintained.

— Disclosure statements submitted to the Secretary must meet certain requirements.

PSOs will be able to offer expertise to providers about preventing adverse events; they can also provide feedback and recommendations about information they have collected and analyzed. Health care providers in a wide variety of settings will be able to report information to a PSO. To promote data aggregation across providers (and, implicitly, to facilitate identification of system failures and learning about errors), the rule requires PSOs to have at least two contracts with providers for the receipt and review of patient safety work product. These contracts must be for a "reasonable period of time." Subject to certain constraints, PSOs may aggregate patient safety work product gained from multiple clients, as well as other PSOs. Note that the PSQIA called on HHS to implement a network of patient safety databases. However, the proposed regulations do not address this issue except in passing and to note that the other provisions of the law will be implemented independent of the proposed rule.

To ensure that providers are willing to report information, the regulation provides that patient safety work product gains strong privilege and confidentiality protections. Breach of these provisions can lead to substantial civil money penalties, to be enforced by the Office of Civil Rights within HHS. The proposed rules do not in any way obviate existing requirements under federal privacy and confidentiality laws, including the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Instead, the rules specify that providers reporting information to a PSO must continue to satisfy obligations under HIPAA; where providers are covered entities under HIPAA, they must execute business associate contracts with PSOs. By contrast, providers need not have a contract with a PSO to receive PSQIA protection.

In sum, the federal government has taken major steps through the PSQIA and its proposed regulation to promote voluntary reporting and analysis of information about errors. Although no federal funds are available to support such reporting, the confidentiality and privilege protections have substantial potential to spur private entities to work in concert with health care providers to collect, aggregate, and analyze error-related information. In turn, the private sector has taken notice. Indeed, AHRQ estimates that between 50 and 100 entities will seek to become listed as a PSO in the first 3 years after publication of the final rule.

ELEMENTS OF A STATEWIDE PATIENT SAFETY ORGANIZATION

The experience from the state patient safety centers described above, and the directives embedded in evolving federal patient safety law and regulation, provide helpful guidance to policy makers in other states interested in creating a patient safety organization to advance a multi-pronged patient safety agenda in their states. To the extent that such an entity is to be legislatively created, it would be reasonable for the legislature to direct the new organization to have, as has been the case in other states, a mission that is broad and generally oriented around improving the safety and quality of health care provided to its residents. Of course, these initiatives could also be launched without legislative involvement, for example, by a nonprofit organization created by health care providers or other stakeholders. In either case, the functions of the new organization ought to include serving as a resource to patients and health care providers by convening educational conferences and training sessions, by publishing and disseminating resources targeted to both patient and provider audiences, and by establishing a voluntary reporting system for information about errors and near misses. As described above, the legal system has been identified by a number of observers as tending to impede efforts to enhance quality of care.[71] To begin to address this

[71] Joint Commission on Accreditation of Healthcare Organizations, *Health Care at the Crossroads: Strategies for Improving the Medical Liability System and Preventing Patient Injury*, Oakbrook Terrace, IL: Joint Commission (2005), *available at* www.jointcommission.org/NR/rdonlyres/167DD821-A395-48FD-87F9-6AB12BCACB0F/0/Medical_Liability.pdf.

issue, and generally to integrate liability and patient safety to a greater extent, the new organization might also include initiation of an injury compensation pilot project that would be voluntary for both claimants and defendants.

Development and dissemination of information resources of value to health care providers and consumers ought to be a major function of the patient safety center. Oriented toward providers, this might include maintaining and disseminating information about patient safety best practices through various channels.[72] Particularly to the extent that the voluntary error reporting system discussed below identifies patterns or trends across institutions, this outreach ought to be informed by such data analysis, with preventive strategies targeted towards those problem areas that analysis of errors has identified. Given adequate resources, it would make sense for the organization's staff to conduct regional training sessions for providers on a periodic basis and to convene a statewide patient safety conference or event annually or biannually.

For patients, the organization's website could offer tips for individuals about getting safe and effective health care services, as well as links to outside organizations that offer guidance about quality, health, wellness and related topics (*e.g.*, AHRQ, MedlinePlus.gov, and MerckSource.com). If adequate resources are available, organization staff might author periodic consumer-focused columns about patient safety and health quality issues for newspapers around the state. It might also serve as a place through which patients could report adverse experiences in treatment, or provide a statewide patient ombudsman.

Dissemination of educational resources will be helpful, but the real potential of a patient safety center lies in its ability to aggregate information about errors, and employ analyses of this data to drive prevention strategies. Consequently, the establishment of a reporting database within the patient safety center will be highly desirable. Twenty-five states and the District of Columbia already require that serious adverse events be reported.[73] But a voluntary reporting system housed within a patient safety center, like several of the states described above, could capture substantially more data than the existing mandatory systems.

Ideally, therefore, the patient safety center will establish a database with standardized protocols for reporting; this database will receive confidential reports of actual errors, serious and minor, as well as near misses. Reports will be made on a voluntary basis from institutions across the state; the patient safety center will aggregate and analyze this data, particularly for broad patterns of errors occurring

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[72] This might include publication of information on the internet, distribution of such information through email updates, and publication of periodic newsletters.

[73] National Academy for State Health Policy, *Quality and Patient Safety: State Adverse Event Reporting Rules and Regulations*, www.nashp.org/_docdisp_page.cfm?LID=2A789909-5310-11D6-BCF000A0CC558925 (last visited March 27, 2008).

across institutions. Results of these analyses will be shared with institutions via the reports, newsletters, conferences, and training sessions described above. The Board of Medicine may also want to use this information, on a de-identified basis, to develop statewide alerts about problems occurring at the clinical level.

To minimize providers fears associated with the potential adverse consequences of error reporting, information reported to the center ought to be confidential and non-discoverable. The best way to accomplish this will be for the center to gain certification by AHRQ as a patient safety organization (PSO) under federal law (i.e., the PSQIA). Given the current status of the PSQIA's proposed regulations, it is not possible at this time to identify all the requirements that gaining such certification will entail. However, based on the proposed regulations in their current form, it appears likely that the administrative burden associated with making the application to AHRQ will be minimal. And assuming a new patient safety center meets the specific criteria set by HHS (likely to include, for example, having a safety-oriented mission, qualified staff, multiple provider contracts, and so on) gaining PSO certification should be relatively straightforward.

Once the organization gains PSO certification, reporting by providers will gain protections pursuant to federal law and regulation. In turn, the PSO can use the information it collects to promote a culture of safety within health care institutions and to facilitate collaborative learning environments that are focused on continuously improving patient safety. The parameters described in federal law and regulation should provide a helpful roadmap to the PSO as it undertakes these initiatives.

Finally, the PSO has a golden opportunity to gain further information about medical errors, and generally to integrate liability and patient safety issues, by developing an injury compensation pilot project that would be completely voluntary for patients and providers. We next describe how this initiative could be structured.

ESTABLISHING A VOLUNTARY INJURY COMPENSATION PILOT

Through the years, considerable attention has been devoted to the ways in which the legal system functions in resolving medical liability disputes and in compensating patient injuries. A number of observers have noted that the current system is inefficient, highly adversarial, time consuming, and does little to facilitate enhancements in patient safety.[74] In addition, a number of academics, advocates, and policy makers have suggested that these system failings could best

[74] M.M. Mello, D. M. Studdert, A. Kachalia & T. A. Brennan, *"Health Courts" and Accountability for Patient Safety*, MILBANK QUARTERLY 84(3): 459-492 (2006); D.M. Studdert & T. A. Brennan, *No-Fault Compensation for Medical Injuries: The Prospect for Error Prevention*, J. OF THE AM. MED. ASS'N 286(2): 217-223 (2001).

be addressed by removing medical liability claims from the tort system altogether, and instead processing them through an administrative system with specialized judges and court-appointed expert witnesses.[75] Today's administrative proposals tend to contemplate strong linkages with patient safety initiatives and structures, with the goal of creating feedback loops whereby health care providers can learn from mistakes and hopefully take steps to prevent them from reoccurring.

Although conceptually elegant, a number of past administrative compensation proposals have failed to engender a positive response from health care providers (due to concern about potentially increased liability), attorneys (due to concern about erosion of individual rights and vested interests in the functioning of the current system), and patients (due to concern about potential limitations of compensation awards).[76] These responses are generally quite consistent across both broad administrative compensation proposals as well as more limited variants, such as the removal of certain kinds of cases (*e.g.,* obstetrics claims) from the tort system.[77]

In contexts where stakeholder concerns have made enacting an administrative compensation system through legislation unlikely, some observers have suggested that a compensation process much like the administrative compensation proposal could be created on a purely contractual basis, without legislation.[78] In particular, patients could opt into the jurisdiction of a non-tort alternative as part of the subscriber agreement between an individual and his or her health plan, or as part of the admission documents executed between an individual and a hospital or other health care provider at the initiation of a treatment episode.

Although this approach dodges the near-certain constitutional challenges that would likely ensue from any legislatively enacted program, it still faces barriers. Health plans are generally unenthusiastic about this approach, even where there

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[75] M.M. Mello, D. M. Studdert, A. Kachalia & T. A. Brennan, *"Health Courts" and Accountability for Patient Safety*, MILBANK QUARTERLY 84(3): 459-492 (2006); D.M. Studdert & T. A. Brennan, *No-Fault Compensation for Medical Injuries: The Prospect for Error Prevention*, J. OF THE AM. MED. ASS'N 286(2): 217-223 (2001); P. Barringer, *Windows of Opportunity: State-Based Ideas for Improving Medical Injury Compensation and Enhancing Patient Safety,* Washington, D.C.: Common Good (2006), *available at* www.commongood.org/assets/attachments/Windows_of_opportunity_web.pdf.

[76] P.J. Barringer, D. M. Studdert, A. B. Kachalia & M. M. Mello, *Administrative Compensation of Medical Injuries: A Hardy Perennial Blooms Again*, J. HEALTH POL. POL'Y & L. (2008) (forthcoming).

[77] *Id.*

[78] M.M. Mello, D. M. Studdert, P. Moran & E. A. Dauer, *Policy Experimentation with Administrative Compensation for Medical Injury: Issues Under State Constitutional Law*, 45 HARV. J. ON LEGIS. 59, 106 (2008).

is favorable state law.[79] Hospitals worry about the effect of asking patients to waive rights in the event of injury (before treatment has even begun), as well as the staff time required to execute such agreements en masse. And attorneys are generally very critical of opt-in agreements that bind patients before an injury has occurred.[80]

An alternative approach—the approach we advocate in this paper—will likely face substantially fewer barriers to implementation. In particular, a PSO might make available to patients and providers a process for resolving medical injury claims that involves certain elements of the administrative compensation proposal—but that is completely voluntary for patients and health care providers. The PSO would prescribe criteria by which this process would be made available to patients and providers; this ought to occur after efforts have been made through formal and informal programs at the provider level to disclose the circumstances of injury, offer an apology where warranted, and pay mutually agreeable compensation for the injury.[81] To the extent that these steps have occurred and the matter remains unresolved, the claimant and defendant could mutually agree to have their case heard and resolved by the PSO's structured voluntary compensation process. The proposed approach essentially would amount to voluntary arbitration with some added structure.[82] Naturally, liability carriers would need to participate in this initiative, along with providers and patients. It would also be vitally important for patients to be provided adequate, meaningful notice of the system and its limitations, to ensure that patient agreements to participate were made on a knowing, willing, and voluntary basis.

This process would need to be administered separately from the PSO's other functions, including reporting and provider training. Failure to do so could chill providers' willingness voluntarily to report information about errors. To maintain

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[79] For example, New York passed a law in the early 1990s to allow health plans to bind their members to arbitration for medical injury claims. *See* N.Y. PUB. HEALTH LAW § 4406-a (McKinney 2008); *see also* P.D. Jacobson, *Legal Challenges to Managed Care Cost Containment Programs: An Initial Assessment,* HEALTH AFFAIRS 18(4): 69 (1999). However, few if any plans in New York have done so pursuant to this law. By contrast, Kaiser Permanente (KP) requires that its California members arbitrate medical injury claims. Note that California has considerable pro-arbitration statutory and case law; in addition, the arbitration approach makes particular sense in this context given KP's integrated structure.

[80] Vesna Jacksic, *Patient Arbitration Acts are Alarming Attorneys*, NAT'L L. J., March 28, 2008.

[81] Programs currently operating in a number of states around the country (especially the COPIC Insurance Company's "3-R" program) provide excellent examples for how such activities can be put in place. Note too that many states have apology laws in place to encourage adoption of such disclosure initiatives, although the effect of these state laws varies.

[82] For background information on the use of arbitration in medical injury litigation, *see* U.S. General Accounting Office, *Medical Malpractice: Alternatives to Litigation,* Washington D.C.: GAO/HRD-92-28 (1992). For information on a recently enacted law that contemplates use of post-injury arbitration agreements with some structured elements, *see* A.L. Sorrel, *Physicians See North Carolina Tort Reform as First Step*, AMNEWS, October 8, 2007.

appropriate separation, the compensation process should be administered by an outside vendor pursuant to a methodology and particular standards established by the PSO. In particular, the process would entail the use of arbitrator neutrals who had completed a certain prescribed number of hours of medico-legal training.[83] Rather than each party retaining its own expert witness, the neutral in each case would retain between one and three expert witnesses, selected from a pre-approved panel of experts who met certain credentialing standards. Consulting with these experts, the neutral would determine the liability in the matter, including the standard of care and other relevant issues.To the extent that compensation was to be paid, a specific methodology or schedule would be used to determine non-economic damages; this would be based on patient circumstances and severity of injury, would be completely transparent, and would involve specific values being paid depending on these factors up to a cap. Significantly, information generated through this process would be used by the PSO, on a de-identified basis, for patient safety purposes. Again, however, the compensation process would be operated separately from the PSO's reporting or training functions, and on a completely voluntary basis for the parties.

To the extent that the agreement to participate in the alternative is made after an injury occurs, it is likely to generate selection issues—but far less likely to engender opposition from the bar, or concerns from health care providers about enforceability. Moreover, the structured compensation process has the potential, particularly in light of its link to the PSO, to answer to the needs and wishes of patients who have suffered medical injuries. Evidence suggests that patients who have been injured due to medical care want to have an explanation, an apology, and an assurance that what has happened will not reoccur.[84] The structured compensation process can meet these needs by promoting utilization of disclosure and apology initiatives at the provider level; that is, by requiring that such steps be taken before the parties can opt into the structured compensation process. Of course, the PSO can also promote disclosure and apology programs through its educational and outreach initiatives. In addition, the tie to the PSO helps to ensure that claimants' injury experiences will be used for learning and prevention purposes. Finally, many past plaintiffs and consumers have decried the adversarialism of the existing legal system;[85] the PSO's structured compensation

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[83] Training programs for judges in various specialty courts should offer guidance as to the crafting of this curriculum. As one example, consider the training curriculum prescribed by the "ASTAR" (Advanced Science and Technology Adjudication Resource) program for its "Fellows," or specially trained judges, http://einshac.org/platformB.htm (last visited March 31, 2008).

[84] T. Delbanco & S.K. Bell, *Guilty, Afraid and Alone—Struggling with Medical Error*, NEW ENG. J. MED. 357(17): 1682-1683 (2007); R.R. Bovbjerg & B. Raymond, *Patient Safety, Just Compensation and Medical Liability Reform*, Oakland, CA: Kaiser Permanente Institute for Health Policy (2003).

[85] *See, e.g.,* S.S Sheridan & M. J. Hatlie, *We're Not Your Enemy: An Appeal from a Consumer to Re-imagine Tort Reform*, PATIENT SAFETY AND QUALITY HEALTHCARE, July/August: 22-26, 2007.

process may offer a way to substantially reduce the adversarial nature of the process by which the claim is resolved.

Establishing a new PSO, and structured compensation process, will take resources. Following the lead of other states, financing for the patient safety organization might come from a variety of sources, including legislative appropriations, contributions from providers, and grant support. A strong argument can be made for general support from the legislature, given the potential for a PSO to advance shared public policy objectives: the reduction of health care errors and the provision of safer health care services to state residents. Moreover, the creation of a PSO may well have substantial returns on investment. In particular, AHRQ has estimated that total benefits from PSOs will save the nation almost $300 million annually by 2012 (with net benefits—total benefits minus total costs—reaching over $100 million).[86] As noted above, a number of states have imposed assessments on participating providers to fund the operation of state patient safety organizations. Foundation support may be available to support this initiative, particularly for establishing the voluntary compensation pilot.

CONCLUSION

Improving patient safety is almost certain to continue to be a major driver of health policy at the federal and state levels. Creating a voluntary state reporting system offers great potential to facilitate identification and analysis of medical errors—and development of proactive patient safety initiatives. The 2005 federal patient safety law—the Patient Safety and Quality Improvement Act—provides an excellent opportunity for state patient safety organizations to collect voluntarily reported information about errors in a way that is protected and confidential. And a structured compensation process tied to the state organization could offer a new opportunity to enhance reporting and leveraging the liability system to improve safety. With leadership from state policy makers and leaders in the fields of law and medicine, this promising reform may become a reality.

[86] Department of Health and Human Services, Patient Safety and Quality Improvement; Proposed Rule, 73 Fed. Reg. 8112-8183 (February 12, 2008) (to be codified at 42 C.F.R. pt. 3).