


Announcing Remedies for Medical Injury: A Proposal for Medical Liability Reform Based on the Patient Protection and Affordable Care Act

Steven E. Raper

Follow this and additional works at: <http://digitalcommons.law.umaryland.edu/jhclp>

 Part of the [Health Law Commons](#), [Law and Society Commons](#), and the [State and Local Government Law Commons](#)

Recommended Citation

Steven E. Raper, *Announcing Remedies for Medical Injury: A Proposal for Medical Liability Reform Based on the Patient Protection and Affordable Care Act*, 16 J. Health Care L. & Pol'y 309 (2013).

Available at: <http://digitalcommons.law.umaryland.edu/jhclp/vol16/iss2/3>

This Article is brought to you for free and open access by DigitalCommons@UM Carey Law. It has been accepted for inclusion in Journal of Health Care Law and Policy by an authorized administrator of DigitalCommons@UM Carey Law. For more information, please contact smccarty@law.umaryland.edu.

ANNOUNCING REMEDIES FOR MEDICAL INJURY: A PROPOSAL FOR MEDICAL LIABILITY REFORM BASED ON THE PATIENT PROTECTION AND AFFORDABLE CARE ACT

STEVEN E. RAPER, MD, JD*

I. INTRODUCTION

From a patient's standpoint, change is needed in the current medical liability system of compensation for medical injury.¹ Liability reform is embedded in the DNA of the Obama Presidency, as initially shown by the President's two attempts at reform. The first attempt was the creation of an Executive branch program for liability reform prior to specific Congressional approval.² Second, a Legislative branch provision in the landmark Patient Protection and Affordable Care Act (PPACA) also acknowledges the need for liability reform.³ With regard to the first attempt, on September 9, 2009, President Obama directed the Secretary of Health and Human Services (HHS) to establish a grants initiative to help states and health care systems tie patient safety to medical liability reform, thus reducing preventable injuries, enhancing communication between doctors and their patients, ensuring

Copyright © 2013 by Steven E. Raper.

* Associate Professor of Surgery, University of Pennsylvania Perelman School of Medicine. I thank Professor Tom Baker for his comments on an earlier draft of this article.

1. See Randall R. Bovbjerg, *Reform of Medical Liability and Patient Safety: Are Health Courts and Medicare the Keys to Effective Change?*, 9 J. HEALTH CARE L. & POL'Y 252, 257 (2006) (discussing the deficiencies in different areas of malpractice policy); Donald J. Palmisano, *Health Care in Crisis: The Need for Medical Liability Reform*, 5 YALE J. HEALTH POL'Y L. & ETHICS 371, 371 (2005) (stating that a health care crisis exists in the United States and that the need for medical liability reform is great).

2. See Press Release, President Barack Obama, Demonstration Grants for the Development, Implementation, and Evaluation of Alternatives to the Current Medical Liability System (Sept. 17, 2009), available at <http://www.whitehouse.gov/the-press-office/presidential-memorandum-concerning-medical-liability-reform>; see also Benjamin Grossberg, *Uniformity, Federalism, And Tort Reform: The Erie Implications of Medical Malpractice Certificate of Merit Statutes*, 159 U. PA. L. REV. 217, 220 (2010) (discussing a 2009 bill amendment that would have provided states with incentives to implement medical liability reform).

3. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6801, 124 Stat. 119, 804 (2010) (“[H]ealth care reform presents an opportunity to address issues related to medical malpractice and medical liability insurance . . .”).

patients with medical injuries are compensated in a fair and timely manner, reducing the incidence of frivolous lawsuits, and reducing liability premiums.⁴

To implement this directive, in June 2010, the Agency for Healthcare Research and Quality (AHRQ, a Sub-Agency of the Department of Health and Human Services) announced \$23.2 million in funding for seven demonstration grants to operate through June 2013 and thirteen one-year planning grants.⁵ AHRQ terminated funding opportunities for both the demonstration grants and planning grants as of March 6, 2012.⁶ The funding opportunity was terminated because the Agency has no further appropriated funds to support these grants.⁷ In its place, medical liability reform was addressed in a small but conceptually important part of the recently affirmed PPACA as discussed below.⁸

Why do both the Executive and Legislative branches of government feel compelled to champion medical liability reform? Viewed from the perspective of the patient, there are three major deficiencies in the way medical injury is currently compensated. First, the current medical malpractice regime leads to degradation of the physician-patient relationship. Second, it is the patient that is directly affected by the practice of *defensive medicine*, or tests, procedures, and subspecialty consults done to avoid lawsuits. Lastly, inefficiencies in the prevailing medical

4. President Barack Obama, Remarks by the President to a Joint Session of Congress on Health Care (Sept. 9, 2009) *available at* http://www.whitehouse.gov/the_press_office/Remarks-by-the-President-to-a-Joint-Session-of-Congress-on-Health-Care; *see also* AGENCY FOR HEALTHCARE RESEARCH & QUALITY, MEDICAL LIABILITY REFORM AND PATIENT SAFETY INITIATIVE PROGRESS REPORT 1 (2009), *available at* <http://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/liability/mediabrep.pdf> (summarizing the goals of the grants initiative).

5. *See* AGENCY FOR HEALTHCARE RESEARCH & QUALITY, *supra* note 4, at 1. The demonstration projects can be placed in three categories. *Id.* at 3. The first category, “Preventing Harm Through Best Practices,” seeks to improve care in clinical areas that frequently are the subject of a large number of medical malpractice claims, testing whether implementing new ways to prevent medical injury can simultaneously improve patient safety and reduce the number of malpractice lawsuits. *Id.* at 3–4. A second category, “Improving Communication With Patients,” seeks to test whether better communication can lead to fewer lawsuits, fairer and faster compensation, and improved patient safety. *Id.* at 3, 4–6. Lastly, one project, “Alternative Methods of Dispute Resolution,” is trying to improve dispute resolution after a malpractice claim has been filed; through the use of an expanded and enhanced “judge-directed negotiation” program in New York courts, coupled with a new hospital early disclosure and settlement model. *Id.* at 3, 6–7.

6. *Termination Notice for Two AHRQ FOA’s: PAR-11-023, Patient Safety and Medical Liability Reform Planning Projects (R21) and PAR-11-025, Patient Safety and Medical Liability Reform Demonstration Projects (R18)*, AGENCY FOR HEALTHCARE RESEARCH & QUALITY (Mar. 6, 2012), <http://grants.nih.gov/grants/guide/notice-files/NOT-HS-12-008.html>.

7. E-mail from Karen J. Migdail, Senior Policy Advisor, Agency For Healthcare Research & Quality, to Steven E. Raper, Assoc. Professor of Surgery, University of Pa. Perelman Sch. of Med. (Sept. 13, 2012, 14:31 EST) (on file with the author).

8. *See* 42 U.S.C. § 280g-15 (2011) (authorizing the HHS Secretary to award grants to individual states to develop, implement, and evaluate changes to their existing medical liability systems); *see also infra* Part II.

malpractice regime lead to underclaiming and undercompensation for the medically injured as well as long delays between injury and case resolution.⁹

Liability reform and the problems borne by patients can be ameliorated by a Patient's Compensation program as discussed in this article. The Patient's Compensation program proposed here is different than any of the proposals funded under the original Obama initiative. There are two main features of the proposed Patient's Compensation program. First is scheduling a defined set of injuries for which there is consensus that medical care is the cause of the injury. Given the generally accepted notion that faulty systems of care and not individual negligence cause medical injury, it is not necessary for a patient to prove negligence, only that the injury is one of those on the schedule. Further, the schedule of injuries is stratified by severity, so that only meaningful injuries are compensated. The conceptual model for the medical injury compensation schedule is the Federal Sentencing Guidelines. Second, to enhance patient safety and access to the information patients need to know, the schedule of remedies for medical injury will be announced.

Announcing remedies—*ex ante* determination and declaration of the precise remedy—for injuries sustained as a result of medical care holds the promise of three important patient benefits.¹⁰ First, there is greater equality; an injured patient's right to compensation is not constrained by factors such as race, socioeconomic status, or what a plaintiff's attorney would consider to be a "valuable" case. Second, announcing remedies for medical injury holds the promise of greater compliance with rules, such as those designed to enhance patient safety, as well as decrease positive and negative defensive medicine behaviors. Lastly, announcing such remedies decreases the costs of recovering from medical injury, or hedonic adaptation.¹¹ Hedonic adaptation, or regaining the enjoyment of life, is an important process for helping patients recover from injury. Plaintiffs' attorneys arguing for hedonic damages frame disability as inherently and tragically limiting the ability to enjoy life, impairing such recovery.

There are two basic approaches to improving the method by which patients injured by medical care are compensated. The first approach is to apply various reforms to tort-based medical malpractice, such as caps on pain and suffering, and the second approach is to abandon negligence in favor of an administrative model.

9. See Catherine T. Struve, *Doctors, the Adversary System, and Procedural Reform in Medical Liability Litigation*, 72 *FORDHAM L. REV.* 943, 944 (2004) (stating that the medical liability system in the United States is flawed and results in both undercompensation and underclaiming).

10. See Samuel L. Bray, *Announcing Remedies*, 97 *CORNELL L. REV.* 753, 764–774 (2012) (describing the three benefits of announcing remedies as "more equality . . . , more compliance . . . , and lower costs of telling").

11. See Samuel R. Bagenstos & Margo Schlanger, *Hedonic Damages, Hedonic Adaptation, and Disability*, 60 *VAND. L. REV.* 745, 748 (2007) (stating that hedonic damages go beyond pain and suffering damages in compensating for limitations on quality of life).

Although commentators have put forth many arguments both supporting and opposing various forms of medical liability reform, they have proposed relatively few models for its revision. This article will discuss an administrative approach to liability reform different than any funded to date. Part II will explain the Affordable Care Act's guidance in the development of State Demonstration Programs. Part III will summarize the negative impact of the current medical liability regime of patients who suffer medical injury. Part IV will address how a Patient's Compensation program would ameliorate many of the problems with the current approach to medical liability. Although modest in scope and ambition, such a novel alternative to compensating medical injury is a viable and much needed option to traditional tort reform.

II. PPACA PROVISIONS AND ALTERNATIVES TO CURRENT MEDICAL TORT LITIGATION

Congress clearly senses that the current medical malpractice system needs improvement, as noted in the Affordable Care Act's *Sense of the Senate Regarding Medical Malpractice*.¹² The United States Senate noted that the existing civil litigation system could be improved with regard to patient safety, reduction of medical errors, more efficient resolution of disputes, increased availability of prompt, fair resolution of disputes, and access to liability insurance.¹³ In enacting the Affordable Care Act, Congress appears content to stay out of a leadership role in creating meaningful reform, instead working through the States.¹⁴

The Public Health Service Act, 42 U.S.C 280g et seq., was amended by adding § 399V-4, *State Demonstration Programs to Evaluate Alternatives to Current Medical Tort Litigation*.¹⁵ Selected provisions are worth noting in the context of their strong adherence to a states-based emphasis on tort reform. The amended section authorized the Secretary of HHS to award demonstration grants, not to exceed a five-year period, to states for the development, implementation, and evaluation of alternatives to current tort litigation for resolving disputes over injuries allegedly caused by health care providers or health care organizations.¹⁶ For purposes of funding such grants, Congress authorized \$50 million dollars.¹⁷ However, the funds have not been appropriated at the time of publication.¹⁸ To be

12. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6801, 124 Stat. 119, 804 (2010) (stating that there is a need for medical liability reform).

13. *Id.* (stating that states should be incentivized to make changes to the current civil litigation system in order to improve the medical liability system).

14. *See id.* (stating that the states should develop, implement, and evaluate changes to the medical liability system).

15. 42 U.S.C. § 280g-15(a) (2011).

16. § 280g-15(a).

17. § 280g-15(k).

18. *See* E-mail from Karen J. Migdail, *supra* note 7.

eligible for a demonstration program, states must show that an alternative to tort litigation resolves disputes over medical injuries and reduces the rate of such injuries by mining and analysis of data relevant to patient safety.¹⁹ The alternative should, additionally, improve liability insurance access; provide information differentiating between the alternative and the existing liability system; ensure that patients can leave the alternative procedure at any time; not conflict with State law; and lastly, preserve the legal rights of the patient, including their access to the State's legal system and ability to file a medical malpractice claim.²⁰

Each state proposing a demonstration project is required to identify sources from which claims would be compensated.²¹ The scope of the demonstration project could be determined geographically, encompassing the entire state, or a limited region, or could be based on an area defined by medical practice, providers or health care organizations.²² Jurisdiction, however, could not be based on a specific patient population or payer.²³ States would also need to determine how patients would get notification that their medical care qualifies for the alternative, and how patients could opt out of or quit participation.²⁴

States granted demonstration projects must report, annually, on the efficacy of the demonstration project, the impact on patient safety, and the availability and cost of malpractice insurance.²⁵ HHS is also directed to submit to Congress a report documenting, among other data, the effect of such demonstration projects on the quality of care, the number and types of medical injuries, the time taken to resolve disputes, and the availability and cost of malpractice insurance.²⁶ Further, an evaluation of each state demonstration program is required, to include a number of specific measures.²⁷ Congress authorized the appropriation of \$50,000,000 to carry

19. § 280g-15(c)(1)(A)–(B).

20. § 280g-15(c)(2).

21. § 280g-15(c)(3) (specifying that funding sources may be public, private, or a combination of the two and encourages funding methods to provide financial incentives for activities that improve patient safety, as well as compensation for plaintiffs).

22. § 280g-15(c)(4)(A).

23. *Id.*

24. § 280g-15(c)(4)(B) (stipulating that a patient's decision to participate in that alternative program may be made at any time and may not be limited).

25. § 280g-15(e)(1).

26. § 280g-15(e)(2).

27. § 280g-15(g)(3). Measures include an analysis and comparisons on the basis of “(a) the nature and number of disputes over injuries allegedly caused by health care providers or health care organizations; (b) the nature and number of claims in which tort litigation was pursued despite the existence of an alternative; (c) the disposition of disputes and claims, including the length of time and estimated costs to all parties; (d) the medical liability environment; (e) health care quality; (f) patient safety in terms of detecting, analyzing, and helping to reduce medical errors and adverse events; (g) patient and health care provider and organization satisfaction with the alternative and with the medical liability environment; and (h) impact on utilization of medical services, appropriately adjusted for risk.” *Id.*

out the State demonstration programs beginning in 2011 and continuing for five fiscal years.²⁸ Section 10608 also dealt briefly with medical malpractice by noting that for purposes of the section, an “individual, or an officer, governing board member, employee, or contractor of a free clinic” who volunteers his or her services at a free clinic will be deemed “an employee of the Public Health Service for a calendar year.”²⁹

III. PATIENTS ARE NOT WELL-SERVED BY THE PREVAILING MEDICAL MALPRACTICE REGIME

Viewed from the perspective of the patient, there are three major problems with the current medical malpractice regime: A) a degradation of the physician-patient relationship, B) the practice of *defensive medicine* to avoid lawsuits, and C) inefficiencies in the malpractice process leading to underclaiming and undercompensation for the medically injured.³⁰ Each of these problems can be ameliorated by a Patient’s Compensation program.

A. Degradation of the Physician-Patient Relationship

Physicians’ fears of malpractice are disrupting a most venerated relationship, that of physician and patient. One well-respected commentator likened medical malpractice, through the eyes of physicians, to Melville’s *Moby Dick* “. . . evil, ubiquitous, and seemingly immortal.”³¹ Malpractice lawsuits attempt to hold physicians and other health care providers individually or collectively responsible for some medical injuries.³² The belief that “[o]nce an injury happens, someone bears the responsibility” is widely held.³³ In a Pew Charitable Trust study of Pennsylvania, liability concerns replaced doctors’ “previously ‘warm, fuzzy relationship with patients’ with hard-nosed scrutiny of the patient’s litigiousness”³⁴ Eighty-one percent of physicians in high-risk geographical areas, and seventy-five percent of physicians in low-risk areas, surveyed during the last Pennsylvania malpractice crisis responded that because of concerns about malpractice liability, every patient was viewed as a malpractice suit waiting to

28. § 280g-15(k).

29. 42 U.S.C. § 233(o)(1) (2011).

30. See Theodore Eisenberg, *The Empirical Effects of Tort Reform*, in RESEARCH HANDBOOK ON THE ECONOMICS OF TORTS (Jennifer Arlen ed., forthcoming Nov. 2013) (manuscript at 9–26), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2032740 (discussing problems with the current medical malpractice regime).

31. George J. Annas, *Doctors, Patients, and Lawyers — Two Centuries of Health Law*, 367 NEW ENG. J. MED. 445, 445 (2012).

32. See TOM BAKER, THE MEDICAL MALPRACTICE MYTH 113 (2005).

33. *Id.*

34. Michelle M. Mello et al., *Caring for Patients in a Malpractice Crisis: Physician Satisfaction and Quality of Care*, 23 HEALTH AFFS. 42, 49 (2004).

happen.³⁵ Further, ninety-one percent of medical specialists believed that the current medical malpractice system limits provision of the highest-quality medical care.³⁶ To maintain revenue, seventy-six percent of specialist physicians stated that they were likely to increase patient volume.³⁷ The relationship between volume and quality suggests that practices with a full patient load may have difficulty caring for more patients without compromising quality.³⁸

Fears of being sued cause physicians to view the current system of medical malpractice as damaging personally and professionally.³⁹ A nationwide survey of physicians found high levels of concern about the “dread risk” of malpractice litigation in a variety of geographic areas, practice settings, and specialties.⁴⁰ Physicians’ fear of the litigation process has led to the emergence of a medical malpractice stress syndrome.⁴¹ Regardless of outcome, malpractice litigation has personal consequences for physicians that include burnout and suicidal ideation.⁴² Closed claims review of surgical malpractice claims has shown that most technical and judgment errors occur during care provided by competent physicians, which means that all physicians are at risk of being sued.⁴³ Physicians’ fear of being sued for malpractice is worsened by a lack of knowledge about the actual risk of being named in a lawsuit; physicians responding to a survey estimated that one in five of their colleagues will be sued in a given year, an estimate three times higher than the actual closed claims rate in New York state.⁴⁴

Physician mistrust and resistance of the malpractice paradigm is due in large part to contemporary concepts of patient safety and error reduction approaches to

35. *Id.* at 48 tbl.3.

36. *Id.* at 49.

37. *Id.* at 50 tbl.3.

38. *Id.* at 50.

39. See Ian S. Metzler & John G. Meara, *Medical Liability Reform: Evidence for Legislative and Alternative Approaches*, 97 BULL. AM. C. SURGEONS 6, 6 (2012).

40. See Emily R. Carrier et al. *Physicians’ Fears of Malpractice Lawsuits Are Not Assuaged by Tort Reforms*, 29 HEALTH AFFS. 1585, 1591 (2010) (defining dread risk as the fear of an unlikely, uncontrollable, and unpredictable event that triggers an irrational level of risk aversion).

41. See Jeffrey J. Segal & Michael Sacopulos, *A Modified No-fault Malpractice System Can Resolve Multiple Healthcare Deficiencies*, 467 CLINICAL ORTHOPAEDICS & RELATED RES. 420, 421 (2008) (stating that frequency and length of litigation all contribute to whether a physician experiences medical malpractice syndrome).

42. See Charles M. Balch et al., *Personal Consequences of Malpractice Lawsuits on American Surgeons*, 213 J. AM. C. SURGEONS 657, 665 (2011); see also Susan Kreimer, *Lawsuits Are Stressing Docs*, HOSPS. & HEALTH NETWORKS (Am. Hosp. Ass’n, Washington, D.C.), Feb. 2012, at 17 (suggesting that hospitals not prejudice physicians who are sued for malpractice due to the added stress that it brings).

43. See F. Dean Griffen & Richard H. Turnage, *Reviews of Liability Claims Against Surgeons: What Have They Revealed?*, 43 ADVANCES SURGERY 199, 208 (2009).

44. Ann G. Lawthers et al., *Physicians’ Perceptions of the Risk of Being Sued*, 17 J. HEALTH POL. POL’Y & L. 463, 468–69 (1992).

the problem of medical injury that focus on “fixing the system, not fixing blame.”⁴⁵ These adversarial and very personal claims against physicians occur despite accumulating evidence that most errors are multifactorial, or “systems” errors.⁴⁶ The conceptual leap made in the Institute of Medicine’s landmark report *To Err is Human* was the need to understand medical injuries as systems errors rather than the negligent acts of individuals.⁴⁷ Based largely on precepts gleaned from *To Err*, intensive efforts on the part of health care organizations have decreased medical injuries. One such effort was the national Five Million Lives Campaign.⁴⁸ A recent Commonwealth Fund report provided ten case studies felt to hold promise for further improving patient safety.⁴⁹ Critics note that annual surveys have documented improvements in medical care and decreases in patient morbidity and mortality, but such improvements have not been uniformly successful.⁵⁰ A decade after *To Err* was released, much has been accomplished in making patients safer, leading one eminent patient safety scholar to upgrade systemic efforts from a “C+”

45. COMM. ON QUALITY OF HEALTH CARE IN AM., INST. OF MED., *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* 179 (Linda T. Kohn et al. eds., 2000).

46. See Selwyn O. Rogers et al., *Analysis of Surgical Errors in Closed Malpractice Claims at 4 Liability Insurers*, 140 *SURGERY* 25, 30 (2006) (finding that surgical errors often result from multiple layers of failures rather than from individual physician error).

47. COMM. ON QUALITY OF HEALTH CARE IN AM., INST. OF MED., *supra* note 45, at 179 (addressing that one of the major issues in detecting and handling errors is the lack of collaboration among health professionals in problem solving).

48. *Protecting Five Million Lives From Harm*, INST. FOR HEALTHCARE IMPROVEMENT, <http://www.ihl.org/offerings/Initiatives/PastStrategicInitiatives/5MillionLivesCampaign/Pages/default.aspx> (last visited Apr. 23, 2013). The 5 Million Lives Campaign, which had enrolled more than 2,000 hospitals, adapted each of the campaign’s twelve interventions aimed at reducing infection, surgical complication, medication errors, and other forms of unreliable care. *Id.* Eight states registered all of their hospitals in the campaign, and eighteen states had over ninety percent of their hospitals participate. *Id.* The campaign documented, among other signs of progress, that sixty-five hospitals in the program avoided ventilator-associated pneumonia for a year or more, and thirty-five hospitals avoided central line-associated bloodstream infection in at least one of their ICUs. *Id.* Enrolled Rhode Island hospitals had a forty-two percent decrease in central-line associated bloodstream infections from 2006–2007, and enrolled New Jersey hospitals reported a seventy percent reduction in pressure ulcers. *Id.*

49. DOUGLAS MCCARTHY & DAVID BLUMENTHAL, COMMONWEALTH FUND, *COMMITTED TO SAFETY: TEN CASE STUDIES ON REDUCING HARM TO PATIENTS* (2006), available at http://www.commonwealthfund.org/~media/Files/Publications/Fund%20Report/2006/Apr/Committed%20to%20Safety%20Ten%20Case%20Studies%20on%20Reducing%20Harm%20to%20Patients/923_McCarthy_committed_to_safety_10_case_studies%20pdf.pdf.

50. See, e.g., HEALTH GRADES, *FIFTH ANNUAL PATIENT SAFETY IN AMERICAN HOSPITALS STUDY 5* (2008), available at <http://hg-article-center.s3-website-us-east-1.amazonaws.com/a9/9a/3b64b168487c86c30dc0986dc344/PatientSafetyInAmericanHospitalsStudy2008.pdf> (finding that substantial progress continues to be made; for example, 249 Distinguished Hospitals for Patient Safety achieved, on average, forty-three percent less patient harm, and noting that while all hospitals do not achieve this level, an additional 220,000 incidents and 37,000 deaths among hospitalized Medicare patients from 2004 to 2006 could potentially have been prevented).

to a “B-.”⁵¹ Medical injuries continue to occur despite a decade of improvements in patient safety; morbidity and mortality occur due to the ever more complex nature of medical treatment.⁵²

Balancing a systems-based approach resisting the natural tendency to blame individuals for errors against accountability for blameworthy behavior is a recent development. The mental model for patient safety in the first five years was “no blame and shame”; a mantra that helped engage reluctant providers and undoubtedly generated substantial progress towards improving patient safety.⁵³ Currently, it has become clear that consequences for failure to adhere to safety rules need to be enhanced.⁵⁴ One model for differentiating injuries due to systems errors which should be managed with systems re-engineering from willful, blameworthy acts is that of the *just culture* advocated by David Marx.⁵⁵ Physicians have not yet embraced sanctions against such acts even for willful violations of reasonable safety standards such as hand hygiene.⁵⁶

51. See Robert M. Wachter, *Patient Safety at Ten: Unmistakable Progress, Troubling Gaps*, 29 HEALTH AFFS. 165, 172 (2010) (noting a stronger business case for focusing on patient safety due to enhanced accreditation standards and error reporting requirements).

52. See KRISTIN REED & RICK MAY, HEALTH GRADES, EIGHTH ANNUAL PATIENT SAFETY IN AMERICAN HOSPITALS STUDY 1–2 (2011), available at <https://www.cpmhealthgrades.com/CPM/assets/File/HealthGradesPatientSafetyInAmericanHospitalsStudy2011.pdf> (reporting that from 2007 through 2009, 667,828 Medicare beneficiaries experienced 708,642 patient safety events and that such events were associated with \$7.3 billion of excess cost, and that Medicare patients sustaining at least one patient safety event post-operatively had approximately a one-in-ten chance of dying as a result of the event, with 79,670 in-hospital deaths occurring among patients who experienced patient safety events).

53. See ROBERT M. WACHTER, UNDERSTANDING PATIENT SAFETY 21 (2d ed. 2007) (noting that the modern approach to the patient safety movement is more successful because it acknowledges that humans err and allows for the creation of systems to prevent and catch such errors).

54. See Lucian L. Leape, *New World of Patient Safety*, 144 ARCHIVES SURGERY 394, 397 (2009) (asserting that while individual unintended safety violations should not be punished, willfully failing to use safe practices cannot continued to be tolerated); Donald Goldmann, *System Failure Versus Personal Accountability—The Case for Clean Hands*, 355 NEW ENG. J. MED. 121, 123 (2006) (explaining that specific safety practice violations should have consequences especially in cases where the hospital has perfected a new system for patient safety).

55. DAVID MARX, COLUMBIA UNIVERSITY, PATIENT SAFETY AND THE “JUST CULTURE”: A PRIMER FOR HEALTH CARE EXECUTIVES 5 (2001), available at <http://www.safer.healthcare.ucla.edu/safer/archive/ahrq/FinalPrimerDoc.pdf> (discussing individual accountability and four behavioral categories—human error, negligence, intentional rule violations, and reckless conduct—in describing blameworthy conduct and the need for authorities to take disciplinary action to deter such conduct); see also Allan S. Frankel et al., *Fair and Just Culture, Team Behavior, and Leadership Engagement: The Tools to Achieve High Reliability*, 41 HEALTH RES. & EDUC. TRUST 1690, 1692–93 (2006) (defining a *just culture* as one in which each individual is accountable for their own actions, but is not blamed for work environment faults beyond their control).

56. See Robert M. Wachter & Peter J. Pronovost, *Balancing “No Blame” and Accountability in Patient Safety*, 361 NEW ENG. J. MED. 1401, 1402 (2009) (commenting that physicians view themselves as entrepreneurs rather than employees and that such notions result in weak enforcement of safety standards or sanctions by peers in hospital settings).

A Patient's Compensation model holds promise for improving the physician-patient relationship by restoring trust, improving quality of care, and compensating patients without regard to negligence. There is some empiric data to support this contention. In the Swedish no-fault system, physicians participate personally in the filing of sixty percent of claims.⁵⁷ Physicians are committed to improving the safety and well-being of patients. By placing the responsibility for eliminating medical injury in the hands of the providers who care for patients, acceptance of an administrative compensation regime would engender less animosity.⁵⁸ Less physician defensiveness is noted in systems that do not require the patient to prove negligent care.⁵⁹ In the Virginia Neurological Birth-Related Neurological Injury Compensation program, over sixty physicians were able to avoid lawsuits and the costs, both professional and personal, generally associated with legal proceedings.⁶⁰ Because the Virginia compensation program is no-fault, physicians are also able to avoid being placed into a national database that monitors malpractice settlements, the NPDB.⁶¹ Being reported to the NPDB is uniformly considered as a major concern for practicing physicians; yet the American Medical Association believes that such medical liability claims data is a poor indicator of quality.⁶²

In Florida, Birth-Related Neurological Injury Compensation Association (NICA) payments help to fund benefits for children while prohibiting malpractice litigation on covered claims; the substantial benefits of increased protection from costly litigation and a resulting freedom to focus on patient care make full participation in the NICA Plan a positive for many obstetricians.⁶³ Because NICA covers the "truly catastrophic claims" of obstetricians and gynecologists, all Florida physicians, regardless of specialty, enjoy lower malpractice premiums than they otherwise would.⁶⁴

57. See David M. Studdert & Troyen A. Brennan, *Toward a Workable Model of "No-Fault" Compensation for Medical Injury in the United States*, 27 AM. J.L. & MED. 225, 230 (2001).

58. See Allen B. Kachalia et al., *Beyond Negligence: Avoidability and Medical Injury Compensation*, 66 SOC. SCI. & MED. 387, 388 (2008) (noting that the administrative compensation regime is based on injury avoidability rather than on practitioner negligence).

59. See MICHELLE M. MELLO ET AL., SYNTHESIS PROJECT, MEDICAL MALPRACTICE—UPDATE 1, 4 (2011), available at <http://www.rwjf.org/content/dam/farm/reports/reports/2011/rwjf70017>.

60. JOINT LEGISLATIVE AUDIT & REVIEW COMM'N, VA. GEN. ASSEMBLY, REVIEW OF THE VIRGINIA BIRTH-RELATED NEUROLOGICAL INJURY COMPENSATION PROGRAM 33 (2003), available at <http://jlarc.virginia.gov/reports/Rpt284.pdf>.

61. *Id.*

62. See *National Practitioner Data Bank*, AM. MED. ASS'N, <http://www.ama-assn.org/ama/pub/physician-resources/legal-topics/business-management-topics/national-practitioner-data-bank.page> (last visited Apr. 23, 2013).

63. *Non-Participating OBGYN'S*, FLA. BIRTH-RELATED NEUROLOGICAL INJURY COMP. ASSOC., http://www.nica.com/nonprt_obgyns/index.html (last visited Apr. 23, 2013).

64. *Other Physicians*, FLA. BIRTH-RELATED NEUROLOGICAL INJURY COMP. ASSOC., http://www.nica.com/other_physicians/index.html (last visited Apr. 23, 2013).

B. Patients Bear the Brunt of Positive and Negative Defensive Medicine

From the patient's point of view, medical tests, procedures, or specialty consultations performed in attempts to decrease the risk of malpractice claims are undesirable; such physician behavior is known as defensive medicine.⁶⁵ Defensive medicine is thought to become more prevalent when physicians perceive heightened malpractice risk.⁶⁶ There are two different types of physician behaviors which are considered defensive medicine; both types have the potential to negatively impact the patient. *Negative defensive medicine* includes behaviors in which physicians refuse to perform high risk procedures, enter high risk specialties, or care for high risk patients.⁶⁷ *Positive defensive medicine* occurs when physicians perform procedures and order tests or other services to reduce adverse outcomes, deter patients from filing medical malpractice claims, or enhance documented evidence that the physician is practicing standard of care, so that if, in the future, legal action is initiated, liability can be pre-empted.⁶⁸ None benefit the patient, some may lead to harm, and all are attempts by individual physicians to decrease the risk of being sued for malpractice.

1. Negative Defensive Behaviors

Specialized physicians' fear of lawsuits leads many to restrict the scope of their practices to exclude high-risk services such as obstetrics and spine surgery, and a smaller number of specialists are even discontinuing patient care or relocating to states with lower malpractice costs.⁶⁹ There is data to support the assertion that physicians engage in a number of types of negative defensive behavior; one well-studied example of avoiding a high risk procedure is the decline in rates of vaginal

65. See David M. Studdert et al., *Defensive Medicine Among High-Risk Specialist Physicians in a Volatile Malpractice Environment*, 293 JAMA 2609, 2609 (2005) ("Defensive medicine is a deviation from sound medical practice that is induced primarily by a threat of liability."); OFFICE OF TECH. ASSESSMENT, U.S. CONGRESS, PUB. NO. OTA-H-602, DEFENSIVE MEDICINE AND MEDICAL MALPRACTICE 13 (1994) (defining defensive medicine as "when doctors order tests, procedures, or visits, or avoid high-risk patients or procedures, primarily (but not necessarily solely) to reduce their exposure to malpractice liability").

66. See Studdert et al., *supra* note 65, at 2616.

67. See Daniel P. Kessler, *Evaluating the Medical Malpractice System and Options for Reform*, 25 J. ECON. PERSP. 93, 95 (2011) (noting that negative defensive medicine occurs when a physician refuses to offer care to a patient despite a potential benefit).

68. See *id.* (noting that positive defensive medicine creates incentives for doctors to take too many precautions); see also JACKSON HEALTHCARE, A COSTLY DEFENSE: PHYSICIANS SOUND OFF ON THE HIGH PRICE OF DEFENSIVE MEDICINE IN THE U.S. 20 (2011), available at http://www.Jacksonhealthcare.Com/Media/8968/Defensivemedicine_Ebook_Final.pdf (citing a 2009 survey quantifying the costs and impact of defensive medicine).

69. See Mello et al., *supra* note 34, at 44 (explaining that high liability risks and costs affect a physician's relationship with his or her patient).

birth after cesarean section (VBAC).⁷⁰ Since the 1990s, nationwide rates of VBAC have decreased sharply and rates of cesarean section have increased sharply; both trends are consistent with clinical behavior aimed at reducing obstetricians' exposure to malpractice litigation.⁷¹ Neurosurgery represents another discipline in which spinal surgery procedures—perceived by neurosurgeons as one of a series of “high-risk” procedures—are correlated with higher rates of litigation.⁷² Lastly, the decision by Centers for Medicare and Medicaid Services (CMS) to deny payment for services treating complications that could be “reasonably prevented” has led to concerns that hospitals may choose not to provide high-risk service lines or procedures.⁷³

In addition to the VBAC example noted above, other data exist to show that physicians might perform cesarean sections out of fear of litigation regardless of geographic area or liability climate.⁷⁴ Two well-designed studies have found that greater malpractice risk—measured by premiums or claims frequency in the area—was associated with a statistically significant increase in the incidence of cesarean sections.⁷⁵ Other studies have had mixed results, with some providing corroborating evidence⁷⁶ but others finding no difference in cesarean rates.⁷⁷ One study even

70. See Richard N. Waldman, *Together We Can Do Something Wonderful*, 115 *OBSTETRICS & GYNECOLOGY* 1116, 1118 (2010) (“Each one of us enters the labor and delivery room shouldering our concern for our two patients and weighed down by the yoke of liability.”); see also Carrier et al. *supra* note 40, at 1587 (finding that physician malpractice concerns are “pervasive” and “vary across specialties”).

71. See Y. Tony Yang et al., *Does Tort Law Improve the Health of Newborns, or Miscarry? A Longitudinal Analysis of the Effect of Liability Pressure on Birth Outcomes*, 9 *J. EMPIRICAL LEGAL STUD.* 217, 218 (2012) (estimating that a \$10,000 decrease in malpractice premiums would correspond to approximately 6,000 fewer total cesarean sections and 1,600 more VBACs).

72. See Richard L. Rovit et al., *Neurosurgical Experience with Malpractice Litigation: An Analysis of Closed Claims Against Neurosurgeons in New York State, 1999 Through 2003*, 106 *J. NEUROSURGERY* 1108, 1109 (2007) (studying 280 New York state closed claims against insured neurosurgeons and finding that spinal surgery cases had higher rates of litigation).

73. See Rocco Ricciardi et al., *Surgeon Involvement in the Care of Patients Deemed to have “Preventable” Conditions*, 209 *J. AM. COLL. SURGEONS* 707, 710 (2009).

74. See MICHELLE M. MELLO, SYNTHESIS PROJECT, *MEDICAL MALPRACTICE: IMPACT OF THE CRISIS AND EFFECT OF STATE TORT REFORMS* 5 (2006), available at https://folio.iupui.edu/bitstream/handle/10244/526/no10_researchreport.pdf (reporting that three different studies have found that greater malpractice risk was associated with slight increases in cesarean section incidence rates).

75. Lisa Dubay et al., *The Impact of Malpractice Fears on Cesarean Section Rates*, 18 *J. HEALTH ECON.* 491, 509 (1999) (finding that physicians perform more cesarean deliveries for mothers of lower socioeconomic status in response to greater malpractice claims risk); A. Russell Localio et al., *Relationship Between Malpractice Claims and Cesarean Delivery*, 269 *JAMA* 366, 371 (1993) (demonstrating a positive connection between the odds of cesarean delivery and malpractice risk).

76. See, e.g., Darren Grant & Melayne McInnes, *Malpractice Experience and the Incidence of Cesarean Delivery: A Physician-Level Longitudinal Analysis*, 41 *INQUIRY* 170, 184 (2004) (finding that malpractice claims are associated with influencing practice behavior by physicians performing cesarean deliveries); Steven M. Rock, *Malpractice Premiums and Primary Cesarean Section Rates in New York and Illinois*, 103 *PUB. HEALTH REPS.* 459, 463 (1988) (finding that a difference in number of cesarean deliveries may exist only if the difference in premiums are substantial).

showed that non-economic damage caps (a marker of decreased malpractice pressure) increased utilization of cesarean sections.⁷⁸

Although difficult to comprehensively analyze, there is also data to suggest that physicians avoid practicing in states with high malpractice premiums.⁷⁹ In a survey of resident physicians in rural Florida, 411 of 981 physicians decreased or eliminated health care services due to liability costs.⁸⁰ The problem of rural flight was also noted in a study correlating high malpractice rates with a per capita decrease in rural doctors.⁸¹ Physicians also choose to avoid on-call duties due to fears of being sued for malpractice; the American College of Surgeons and the American Association of Neurologic Surgeons have reported that one-third of survey respondents had been sued by emergency room patients.⁸² One survey of neurosurgeons showed that thirty-eight percent of respondents limit provision of trauma services due to, *inter alia*, liability concerns.⁸³

77. See, e.g., Michael Frakes, *Defensive Medicine and Obstetric Practices*, 9 J. EMPIRICAL LEGAL STUD. 457, 480 (2012) (documenting no change in the rate of cesarean deliveries, but finding a reduction in use of episiotomy with adoption of non-economic damage caps); Roger A. Rosenblatt et al., *Tort Reform and the Obstetric Access Crisis: The Case of the WAMI States*, 154 W.J. MED. 693, 699 (1991) (suggesting that declining obstetric care availability may be linked to the institution of significant tort reforms), but see Laura-Mae Baldwin et al., *Defensive Medicine and Obstetrics*, 274 J. AM. MED. ASS'N 1606, 1609 (1995) (finding no association between malpractice experience and the use of prenatal resources or cesarean deliveries by physicians).

78. Janet Currie & W. Bentley MacLeod, *First Do No Harm? Tort Reform and Birth Outcomes*, 123 Q.J. ECON. 795, 825 (2008).

79. See, e.g., Scott E. Maizel, *Maryland's Surgical Workforce—2007: An In-Depth Analysis and Implications for the Future*, 208 J. AM. COLL. SURGEONS 454, 458 (2009) (explaining how physicians are fleeing Maryland due to rising malpractice premiums); see also MASS. MED. SOC'Y, PHYSICIAN WORKFORCE STUDY 59 (2011) (reporting that approximately half of specialists and primary care physicians and approximately one-third of pediatricians have altered patient care as a result of their perceived risk of litigation); Erin P. Fraher, *Location, Location, Location: North Carolina Faces a Shortage of Primary Care and Specialty Practitioners in Rural and Underserved Counties*, 68 N.C. MED. J. 196, 197 (2007) (reasoning that significant anecdotal evidence shows that fewer physicians in North Carolina are delivering babies due to rising malpractice rates); KY. INST. OF MED., TASK FORCE REPORT: COMPREHENSIVE STATEWIDE PHYSICIAN WORKFORCE STUDY 21 (2007), available at <http://www.kyiom.org/pdf/KMAWorkforceReport9-24-07.pdf> (noting that while there is little research to support the claim, malpractice claims are believed to be an important factor in motivating physicians to retire early).

80. Robert G. Brooks et al., *Impact of the Medical Professional Liability Insurance Crisis on Access to Care in Florida*, 164 ARCHIVES INTERNAL MED. 2217, 2218–19 (2004) (documenting elimination of services as greatest among general surgeons (78.6%) and surgical specialists (73.6%)).

81. See Katherine Baicker & Amitabh Chandra, *The Effect of Malpractice Liability on the Delivery of Health Care*, 8 F. HEALTH ECON. & POL'Y 1, 19 (2005) (documenting a one percent decrease in per capita rural physicians and a two percent decrease in older rural physicians for every ten percent increase in malpractice premiums).

82. DIV. OF ADVOCACY & HEALTH POLICY, AM. COLL. OF SURGEONS, A GROWING CRISIS IN PATIENT ACCESS TO EMERGENCY SURGICAL CARE 1, 7 (2006), available at <http://www.facs.org/ahp/emergcarecrisis.pdf>.

83. Thomas R. Russell, *The Surgical Workforce: Averting a Patient Access Crisis*, 87 SURGICAL CLINICS N. AM. 797, 802 (2007).

2. Positive Defensive Behaviors

The conventional behavior described as defensive medicine has also been called *positive defensive* behavior.⁸⁴ Teasing out the effect of malpractice risk on physician behavior can be difficult because physicians may have more than one rationale for ordering a test, referral, or procedure; the desire to avoid malpractice claims as well as the intention to see that the patient receives an accurate diagnosis and correct treatment regardless of cost.⁸⁵ The Office of Technology Assessment's comprehensive study on *Defensive Medicine and Medical Malpractice* stated the problem bluntly: "accurate measurement of the extent of this phenomenon is virtually impossible."⁸⁶ As a result, it has been hard to determine the pervasiveness, cost, and consequences of defensive assurance behavior, and yet, a number of commentators have made such estimates.

A 2003 survey of high-risk specialists in Pennsylvania found that ninety-three percent reported that they sometimes or often engaged in at least one of six positive defensive behaviors.⁸⁷ Using data on Medicare spending for Part A and Part B services and hospitals' total expenditures, reductions in the cost of medical liability were found to lower health care expenditures.⁸⁸ Several types of medical liability reform lowered health plan costs offered by self-insured employers due in part to decreases in malpractice premiums.⁸⁹

States enacting tort reforms such as caps on medical malpractice damages experienced slower growth in expenditures for elderly patients admitted with heart disease.⁹⁰ Kessler and McClellan, in a much discussed early study, studied the relationship of medical liability and health care expenditures for acute myocardial

84. See Studdert et al., *supra* note 65, at 2616.

85. See OFFICE OF TECH. ASSESSMENT, U.S. CONGRESS, *supra* note 65, at 13.

86. *Id.* at 4.

87. Studdert et al., *supra* note 65, at 2612. Assurance behaviors studied included: ordering more diagnostic tests than were medically indicated; unnecessary referrals to specialists; prescribing more medications than were medically indicated; and suggesting unnecessary invasive procedures such as biopsies to confirm diagnoses. *Id.* at 2612–13. Physicians who were not confident about the adequacy of their liability coverage and physicians who perceived their insurance premiums to be very burdensome were significantly more likely to report these behaviors. *Id.*

88. See Katherine Baicker et al., *Malpractice Liability Costs and the Practice of Medicine in the Medicare Program*, 26 HEALTH AFFS. 841, 850 (2007) (reporting that states in the bottom quartile of malpractice payments per physician had lower payments from Medicare when compared to states in the top quartile).

89. See Ronen Avraham et al., *The Impact of Tort Reform on Employer-Sponsored Health Insurance Premiums* 16–17 (Nat'l Bureau of Econ. Research, Working Paper No. 15371, 2009), available at <http://www.nber.org/papers/w15371> (studying different medical liability reforms and finding that three out of four types of studied reforms resulted in a statistically significant decrease in health plan costs).

90. Daniel Kessler & Mark McClellan, *Do Doctors Practice Defensive Medicine?* 111 Q.J. ECON. 353, 373 (1996).

infarction and ischemic heart disease in a Medicare population.⁹¹ The analysis showed that direct liability reforms—those with caps on damage awards, punitive damages, mandatory prejudgment interest, or collateral source rule—reduced hospital expenditures by between five and nine percent.⁹²

The Kessler/McClellan study used Medicare claims data to examine whether patients in states without tort reforms received more health care services than patients with the same diagnoses in states that had such reforms; hypothesizing that the difference would approximate defensive medicine behaviors.⁹³ This study has been somewhat controversial because the authors attempted to extrapolate national defensive-medicine costs from these two diagnoses.⁹⁴ The study's findings are probably not generalizable to all conditions or all patients, but its estimates for the two diseases for which data were analyzed appear statistically accurate. It has been suggested on reanalysis of the Kessler/McClellan data that medical management does a better job of reducing overuse of costly and invasive medical technology.⁹⁵

Similar evidence of positive defensive behaviors have been documented in order rates for imaging studies, such as mammograms for breast cancer screening and computed tomograms for neurologic injury. Rates of screening mammography were shown to increase significantly in the setting of increased malpractice awards.⁹⁶ Compared to states without medical liability reform laws, states with laws that limited monetary damages, “mandated periodic award payments . . . or specified collateral source offset rules” had an approximately forty percent lower likelihood of imaging to assess neurologic injury.⁹⁷ A survey performed by the Massachusetts Medical Society showed that physicians' liability concerns directly impacted patients, and defensive testing and referrals cost in excess of \$280 million per year.⁹⁸ Further, professional liability concerns had a substantial effect on the scope of physicians' practices with thirty-eight percent of physicians reducing the

91. *Id.* at 354.

92. *Id.* at 378–79.

93. *Id.* at 354–55.

94. See CTR. FOR JUSTICE & DEMOCRACY, CRITIQUE OF OCTOBER 9, 2009, CBO LETTER TO SENATOR HATCH ON MEDICAL MALPRACTICE ISSUES 6 (2009) (referring to it as “the Long-Disputed Kessler McClellan Study” and pointing out that the General Accountability Office criticized the study because its findings were too narrow to be extrapolated to the general practice of medical practice).

95. See BAKER, *supra* note 32, at 131–32 (arguing that the study underestimated the effectiveness of medical management techniques in reducing expenses).

96. Baicker & Chandra, *supra* note 81, at 20–21 (documenting a four percent increase in mammography for every ten percent increase in the average malpractice award).

97. Rebecca Smith-Bindman et al., *Diagnostic Imaging Rates for Head Injury in the ED And 4 States' Medical Malpractice Tort Reforms*, 29 AM. J. EMERGENCY MED. 656, 660 (2011).

98. MASS. MED. SOC'Y, INVESTIGATION OF DEFENSIVE MEDICINE IN MASSACHUSETTS 1, 6–7 (2008).

number of high risk services and twenty-eight percent of physicians reducing the number of high-risk patients they saw.⁹⁹

In summary, although methodological challenges make it unlikely that there will ever be a completely accurate picture of the extent of defensive medicine, the studies cited above find that defensive behaviors exist.¹⁰⁰ The Congressional Budget Office recently concluded that “the weight of the empirical evidence now demonstrates a link between tort reform and the use of health care services.”¹⁰¹ But arguments about whether or not malpractice reforms decrease defensive behaviors miss the point; from a patient’s perspective, defensive medicine occurs, and it is the patient who must endure it.

The debate about defensive medicine has generally centered on whether malpractice liability reform will decrease health care costs. Most defensive-medicine studies have failed to demonstrate any real evidence on defensive medical practices arising from higher malpractice premiums.¹⁰² This debate, however, misses the fact that patients are the ones sustaining the burden of defensive medicines, tests, procedures, and care. A Patient’s Compensation Program, scheduling, and announcing the remedies for medical injury would decrease defensive medicine behaviors. Defensive medicine, as an attempt to avoid being sued for malpractice, creates overdeterrence instead of truly curbing subpar care.¹⁰³

Another advantage of a Patient’s Compensation approach would be to encourage greater integration of physicians into health care organizations as employees. Traditionally, physicians are licensed, independent practitioners who are credentialed and privileged by health care facilities but subject to limited authority.¹⁰⁴ Hammer and Sage note the fact that physicians are independent

99. *Id.* at 15 (averaging the percentage of reductions as to high-risk services and patients across the studied practice areas: anesthesiology, emergency medicine, family medicine, general surgery, internal medicine, neurosurgical surgery, obstetrics and gynecology, and orthopedic surgery).

100. See Letter from Douglas W. Elmendorf, Dir., Congressional Budget Office, to Sen. Orrin G. Hatch (Oct. 9, 2009), available at http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/106xx/doc10641/10-09-tort_reform.pdf (commenting that tort reform could reduce the practice of defensive medicine).

101. Letter from Douglas W. Elmendorf, Dir., Congressional Budget Office, to Sen. John D. Rockefeller, IV (Dec. 12, 2009), available at http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/108xx/doc10802/12-10-medical_malpractice.pdf.

102. See Eisenberg, *supra* note 30, at 19–21 (describing the “mixed results” found in various studies performed over the last four decades on how malpractice premiums influence defensive medical practices); Randall R. Bovbjerg et al., *Defensive Medicine and Tort Reform: New Evidence in an Old Bottle*, 21 J. HEALTH POL. POL’Y & L. 267, 268 (1996) (noting that, despite consensus as to the existence of defensive medical practices, researchers have been unsuccessful in providing objective evidence “to quantify the effects of defensiveness”).

103. Michelle M. Mello & Troyen A. Brennan, *Deterrence of Medical Errors: Theory and Evidence for Malpractice Reform*, 80 TEX. L. REV. 1595, 1606 (2001).

104. See BARRY R. FURROW ET AL., HEALTH LAW: CASES, MATERIALS, AND PROBLEMS 441 (6th ed. 2008).

practitioners and the formal relationship between physicians and hospitals has been cast as one in which “corporate ownership of hospitals’ physical assets [are] strictly separated from control over physicians’ specialized human capital.”¹⁰⁵

The advantages of physicians as employees are obvious. If the hospital employs its physician staff, then the *Copperweld* doctrine holds that component parts cannot create a conspiracy.¹⁰⁶ Most physicians, however, are not typically employees nor investor-owners of hospital facilities; they organize as medical staff, who are generally responsible for quality of care.¹⁰⁷ Because physicians were the ones purchasing from insurers, and were largely unrestrained in their spending, hospital medical staff became the true customers.¹⁰⁸ A Patient’s Compensation model holds promise for improving physician trust and decreasing resistance by improving quality of care, and compensating patients without regard to negligence. There is some empiric data to support this contention; in the Swedish system, physicians assist their injured patients in the filing of over half of all claims.¹⁰⁹

C. Inefficiency of the Medical Malpractice System

If the medical system has not traditionally done its best for patients, neither has the legal profession. A low rate of malpractice claims means many injured patients do not receive compensation. In a Utah/Colorado study of the behavior of malpractice claiming, ninety-seven percent of patients with negligent medical injuries did not file claims, with a conversely high rate of claims filed for injuries in the absence of negligence.¹¹⁰ In *The Common Law*, Holmes writes that in tort, individuals should be held morally accountable for their injurious acts.¹¹¹ Negligent medical error has likewise been deemed morally blameworthy.¹¹² For every injury caused by medical error that does not result in a claim and compensation, arguably the system has failed to right a moral wrong.¹¹³ The inescapable conclusion is that

105. Peter J. Hammer & William M. Sage, *Critical Issues in Hospital Antitrust Law*, 22 HEALTH AFFS. 88, 92 (2003).

106. *Id.* at 92–93. In *Copperweld Corp. v. Independence Tube Corp.*, the Supreme Court eliminated the intra-enterprise conspiracy doctrine between corporations and their wholly owned subsidiaries and held that Copperweld and a wholly owned subsidiary were incapable of conspiring with each other for purposes of §1 of the Sherman Act. 467 U.S. 752, 777 (1984).

107. See Hammer & Sage, *supra* note 105, at 92.

108. *Id.*

109. See Studdert & Brennan, *supra* note 57, at 230.

110. David M. Studdert et al., *Negligent Care and Malpractice Claiming Behavior in Utah and Colorado*, 38 MED. CARE 250, 256 (2000).

111. OLIVER W. HOLMES, JR., *THE COMMON LAW* 79 (1881).

112. EDMUND D. PELLEGRINO, *Prevention of Medical Error: Where Professional and Organizational Ethics Meet* 90, in ACCOUNTABILITY: PATIENT SAFETY AND POLICY REFORM (Virginia Sharpe ed., 2004) (explaining the importance of doctor accountability to victims of medical malpractice and their loved ones).

113. PAUL C. WEILER ET AL., *A MEASURE OF MALPRACTICE: MEDICAL INJURY, MALPRACTICE LITIGATION, AND PATIENT COMPENSATION* 78 (1993).

unless an appropriate level of claiming for negligent injuries occur, health care providers cannot accept the correct level of moral accountability.

The current medical malpractice system is inefficient, as judged by review of medical records and closed claims review. Three studies formed the basis for the Institute of Medicine's 2000 report *To Err is Human*.¹¹⁴ The California Medical Association study in a review of 20,864 medical charts showed that 4.65% of patients sustained a "potentially compensable event."¹¹⁵ Of these events, only 0.79% were considered as having had legal fault.¹¹⁶ In other words, only seventeen percent of patients sustaining medical injury would be eligible for compensation. The Harvard Medical Practice Study (HMPS) reviewed 30,121 medical charts and noted 1,278 injuries (3.7%).¹¹⁷ Of the injuries sustained by patients, 306 (27.6%) were adjudged due to negligence.¹¹⁸ The HMPS did show that thirty-eight percent of patients who sustained serious disabilities had negligent adverse events, compared to twenty percent if injuries were deemed non-negligent.¹¹⁹ Lastly, by matching a random sample of 31,429 medical charts with statewide data on medical malpractice claims, the study identified a statewide ratio of negligence to malpractice claims of 7.6:1.¹²⁰ A similar medical chart review was carried out in Utah and Colorado to validate the HMPS and showed the rate of adverse events to be 2.9% in both states.¹²¹ In Utah and Colorado, the rates of negligence contributing to adverse events were 32.6% and 27.5% respectively.¹²² The negligent adverse event to claims ratio was 5.1:1 and 6.7:1 in Utah and Colorado respectively.¹²³

114. COMM. ON QUALITY OF HEALTH CARE IN AM., INST. OF MED., *supra* note 45, at 1. The first study, the Harvard Medical Practice Study (HMPS), analyzed injuries sustained by a group of patients hospitalized in New York and the second study, using the HMPS as a model, analyzed incidents of adverse events and negligent adverse events in Utah and Colorado. *Id.*

115. Don Harper Mills, *Medical Insurance Feasibility Study—A Technical Summary*, 128 W.J. MED. 360, 361–62 (1978) (defining a "potentially compensable event" as a "disability caused by health care management").

116. *Id.* at 363.

117. 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).

118. *Id.*

119. Lucian L. Leape et al., *The Nature of Adverse Events in Hospitalized Patients—Results of the Harvard Medical Practice Study II*, 324 NEW ENG. J. MED. 377, 380 (1991).

120. A. Russell Localio et al., *Relation Between Malpractice Claims and Adverse Events Due to Negligence—Results of the Harvard Medical Practice Study III*, 325 NEW ENG. J. MED. 245, 248 (1991).

121. Eric J. Thomas et al., *Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado*, 38 MED. CARE 261, 265 (2000); *see also* Atul A. Gawande et al., *The Incidence and Nature of Surgical Adverse Events in Colorado and Utah in 1992*, 126 SURGERY 66, 71 (1999) (noting that the incidence of adverse events is the same in surgical and non-surgical care).

122. Thomas et al., *supra* note 121, at 265.

123. Studdert et al., *supra* note 110, at 254.

Closed claims reviews have also been used to study the efficacy of malpractice claims since studies begun in 1984 by the American Society of Anesthesiologists.¹²⁴ The medical specialties of anesthesia, obstetrics, emergency medicine, family medicine, and surgery have been the richest source of closed claims data.¹²⁵ Although relatively small in number, the surgery closed claims data are instructive; a follow-up to the Utah and Colorado study showed that sixty-six percent of all adverse events were surgical.¹²⁶ Closed claims data analysis has several advantages over medical chart reviews: physician fears of frank disclosure leading to sanction or litigation were already addressed; most of the compensated claims in these reports involve serious to catastrophic injuries; claims files contain richer information about the medical injury—in addition to the medical record, evidence, deposition transcripts, interrogatories and answers, claims manager reviews, and complaints and answers by opposing attorneys.¹²⁷

Two groups of researchers have each published a series of recent studies analyzing surgical closed claims data. One group consisted of members of Harvard-affiliated Departments of Surgery and the School of Public Health.¹²⁸ The other group consisted of the American College of Surgeons' (ACS) Committee on Patient Safety and Professional Liability.¹²⁹ The two groups analyzed closed malpractice claims from different vantage points. The ACS group sought to determine whether or not injuries were preventable by individual surgeons.¹³⁰ The

124. See Frederick W. Cheney, *The American Society of Anesthesiologists Closed Claims Project: The Beginning*, 113 ANESTHESIOLOGY 957, 957 (2010); Robert A. Caplan et al., *Unexpected Cardiac Arrest During Spinal Anesthesia: A Closed Claims Analysis of Predisposing Factors*, 68 ANESTHESIOLOGY 5, 5 (1988) (noting that the Professional Liability Committee of the American Society of Anesthesiologists had been conducting closed claim malpractice claims for the previous two years); John H. Tinker et al., *Role of Monitoring Devices in Prevention of Anesthetic Mishaps: A Closed Claims Analysis*, 71 ANESTHESIOLOGY 541, 541–46 (1989); Robert A. Caplan et al., *Adverse Respiratory Events in Anesthesia: A Closed Claims Analysis*, 72 ANESTHESIOLOGY 828, 828–33 (1990); Frederick W. Cheney, *The American Society of Anesthesiologists Closed Claims Project: What Have We Learned, How Has It Affected Practice, and How Will It Affect Practice in the Future?*, 91 ANESTHESIOLOGY 552, 552–56 (1999) (discussing the American Society of Anesthesiology's Closed Claims Project findings from 1984 through 1999).

125. Cf. William M. Sage, *The Forgotten Third: Liability Insurance And The Medical Malpractice Crisis*, 23 HEALTH AFFS. 10, 13 (2004) (noting that the malpractice insurance crisis harshly affects the specialties of obstetrics, surgery, radiology, and emergency medicine the most).

126. Gawande et al., *supra* note 121, at 69.

127. See Griffen & Turnage, *supra* note 43, at 207.

128. Rogers et al., *supra* note 46, at 25; Caprice C. Greenberg et al., *Patterns of Communication Breakdowns Resulting in Injury to Surgical Patients*, 204 J. AM. COLL. SURGEONS 533, 539–40 (2007); Scott E. Regenbogen et al., *Patterns of Technical Error Among Surgical Malpractice Claims*, 246 ANNALS SURGERY 705, 705 (2007).

129. F. Dean Griffen et al., *The American College of Surgeons' Closed Claims Study: New Insights for Improving Care*, 204 J. AM. COLL. SURGEONS 561, 561–62 (2007).

130. Griffen & Turnage, *supra* note 43, at 206.

Harvard study examined the role of human and systems factors and errors in surgical practice.¹³¹

The Harvard group reviewed 444 surgery claims—closed between 1986 and 2004—from four malpractice insurance companies based throughout the United States.¹³² The claims covered 21,000 physicians, forty-six acute care hospitals, and 390 outpatient facilities.¹³³ The four most common types of operations that were the subject of this study included gastrointestinal surgery (twenty-two percent), spinal surgery (fourteen percent), nonspine orthopedic surgery (ten percent), and cardiothoracic surgery (nine percent).¹³⁴ Of the 444 surgical claims studied, 422 involved injuries, and of these injuries, 258 (sixty-one percent) were attributed to error by reviewers and 164 (thirty-nine percent) were not due to error.¹³⁵ Errors were found to occur most often in commonly performed operations by experienced surgeons where patient complexity or systems failure were present.¹³⁶

The ACS study collected data from 460 closed surgical claims at five malpractice insurance companies.¹³⁷ Claims were excluded if no indemnity payment had been made and if the associated loss expense was less than \$25,000.¹³⁸ Injuries associated with care that fell below accepted standards were present in fifty percent of claims, and the standard of care was met in thirty-six percent.¹³⁹ The incidence of closed claims in which no breach of the standard of care was identified was remarkably similar between the Harvard and ACS studies (thirty-nine percent and thirty-six percent, respectively).¹⁴⁰

A more recent study of 1,452 closed malpractice claims examined whether patients had suffered a medical injury and, if so, if the injury was due to medical error.¹⁴¹ In three percent of the claims, medical injuries were not present, and thirty-seven percent of claims were for error-free injuries.¹⁴² Although a low percentage of errorless claims led to compensation (twenty-eight percent, compared to

131. *Id.*

132. Rogers et al., *supra* note 46, at 27.

133. *Id.* at 26.

134. *Id.* at 28.

135. *Id.* at 27.

136. See Regenbogen et al., *supra* note 128, at 709 tbl.3 (illustrating the frequencies of various contributing factors to surgical technical error).

137. Griffen et al., *supra* note 129, at 563.

138. *Id.* at 562.

139. *Id.* at 565 tbl.4.

140. Rogers et al., *supra* note 46, at 27 (providing percentages for the Harvard study); Griffen et al., *supra* note 129, at 565 tbl.4 (providing percentages for the ACS study).

141. David M. Studdert et al., *Claims, Errors, and Compensation Payments in Medical Malpractice Litigation*, 354 NEW ENG. J. MED 2024, 2025 (2006).

142. *Id.* at 2026–28.

seventy-three percent of claims with errors), error-free injuries accounted for ten percent of total liability costs in the system.¹⁴³

Another measure of the inefficiency of the malpractice system is the timeline for claims resolution.¹⁴⁴ These are long periods for plaintiffs to await decisions about compensation and for defendants to endure the uncertainty, acrimony, and time away from patient care that litigation entails. Among the studied claims, the average time between injury and resolution was five years, and one in three claims took at least six years to resolve.¹⁴⁵

IV. A PATIENT'S COMPENSATION PROGRAM: PROPOSAL FOR A STATE DEMONSTRATION PROJECT

Much has been written regarding the implementation of a State Demonstration Project, advocating an alternative to tort-based reform.¹⁴⁶ Little has been done, despite recommendations to implement state pilot programs for nearly forty years.¹⁴⁷ To date, funds have been awarded sparingly, if at all.¹⁴⁸ The Agency for Healthcare Research in Quality (AHRQ) has funded a number of demonstration projects outside of the Affordable Care Act, but none involves a scheduled approach to remedy for medical injury or other administrative compensation.¹⁴⁹ Any proposal for Patient's Compensation insurance should take advantage of the experience of State programs which have already been enacted—in particular the Florida and Virginia birth injury compensation programs—to learn what has

143. *Id.* at 2027–28.

144. See RANDALL R. BOVBERG & BRIAN RAYMOND, KAISER PERMANENTE INST. FOR HEALTH POLICY, ISSUE BRIEF: PATIENT SAFETY, JUST COMPENSATION AND MEDICAL LIABILITY REFORM 8 (2003) (reporting that, in 2000, the average time to resolve a medical malpractice claim was forty-five months).

145. Studdert et al., *supra* note 141, at 2031.

146. The Patient's Compensation program I propose has its roots in proposals suggested by a number of health care law specialists. See PATRICIA M. DANZON, MEDICAL MALPRACTICE: THEORY, EVIDENCE, AND PUBLIC POLICY 213–17 (1985) (discussing largely the negatives of a no-fault approach); WEILER ET AL., *supra* note 113, at 149–52 (1993) (highlighting the advantages of a voluntary program as an initial step towards a no-fault approach); BAKER, *supra* note 32, at 163–64 (part of a proposed Patient Protection and Healthcare Responsibility Act includes a Patient Compensation Program for injuries not currently compensated, and specifically designed to avoid conflict with common law tort).

147. See DEP'T OF HEALTH, EDUC., & WELFARE, DHEW PUB. NO. (OS) 73–88, REPORT OF THE SECRETARY'S COMMISSION ON MEDICAL MALPRACTICE 102 (1973) (suggesting that states should implement tort reform projects).

148. See David A. Hyman & William M. Sage, *Do Health Reform and Malpractice Reform Fit Together?* 3 (Am. Enter. Inst., Health Policy Working Paper No. 2011-02, 2011) (noting that the Affordable Care Act's provision authorizing demonstration grants to states for alternative tort litigation dispute has yet to be funded).

149. See Allen Kachalia & Michelle M. Mello, *New Directions in Medical Liability Reform*, 364 NEW ENG. J. MED. 1564, 1569–70 (2011) (discussing the seven funded demonstration projects and thirteen year-long planning grants, none of which involve a scheduled approach to remedy for medical injuries).

worked and what has not.¹⁵⁰ It may be desirable, but not necessary, to enact a Patient's Compensation program in a state which has existing legislation capping non-economic damages. For instance, Virginia has adopted a total cap on damages in medical malpractice litigation, and the total amount available under the cap is similar to that available through the state's birth injury program, so there is little to be gained by avoiding Virginia's Birth Injury Compensation Program (BICP) jurisdiction.¹⁵¹ Virginia's eligibility standard is also more permissive in some ways, making establishing eligibility for compensation easier than under common law tort action.¹⁵² Conversely, claimants in Florida have an incentive to try and circumvent jurisdiction of the Florida birth injury program and pursue tort remedies for claims that may have a high probability of success as a negligence action.¹⁵³ In 2003, caps on malpractice awards began in Florida; but no systematic study of the effect of the complex sliding scale formula for non-economic damages currently exists.¹⁵⁴

V. A PROPOSAL FOR A PATIENT'S COMPENSATION PROGRAM

Success in obtaining a grant for Patient's Compensation Insurance, or Patient's Compensation Program, would be enhanced by emphasizing three main elements in the grant, all of which are explicitly set forth in the Affordable Care Act. First, such a Patient's Compensation Program would require input from stakeholders, including, but not limited to, patients, health care providers, attorneys, insurers, and those with expertise in patient safety.¹⁵⁵ Second, the Patient's Compensation Insurance grant should attempt to enhance patient safety by incorporating mechanisms detecting, analyzing, and reducing medical injuries.¹⁵⁶ Third, the proposal should improve access to liability insurance.¹⁵⁷

In addition to the considerations mentioned above, the proposed alternative should resolve disputes over injuries caused by health care providers or health care organizations.¹⁵⁸ This may be the most important of the elements Congress enacted. There are three possibilities by which patients can sustain bad outcomes:

150. See Gil Siegal et al., *Adjudicating Severe Birth Injury Claims in Florida and Virginia: The Experience of a Landmark Experiment in Personal Injury Compensation*, 34 AM. J.L. & MED. 493, 499–501 (2008) (discussing the Florida and Virginia programs and their operations, viability, and legality as two primary models for proposals related to birth injury funds).

151. See *id.* at 495–96.

152. See *id.* at 500 (listing the distinctions between Florida's eligibility standard and Virginia's eligibility standard).

153. See *id.* at 499–500 (discussing the compensatory damages cap and the restrictive eligibility criteria for claimants in Florida, which are more restrictive than Virginia's birth injury program).

154. *Id.* at 495.

155. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 10607(c), 124 Stat. 119, 1009–10 (2010).

156. *Id.*

157. *Id.*

158. *Id.*

progression of the patient's underlying disease, non-negligent injuries, and negligent injuries. A Patient's Compensation program, to comply with the Affordable Care Act's requirements, must be able to distinguish the first possibility from the second and third. One approach would be to adapt the worker's compensation formula, in which a patient would recover for any injury more likely due to treatment received than underlying illness. However, such a comprehensive definition could make the goal of dispute resolution difficult to accomplish. In particular, failure of early diagnosis, some infections, and drug side effects could lead to a dramatic increase in claims for which resolution would be difficult.¹⁵⁹ For this reason, the Patient's Compensation proposal below will focus on a discrete set of injuries.

A. Scheduling Remedies for Medical Injury

The use of scheduling in cases of medical injury has been proposed for decades, although initially as a way to constrain the discretion of legal decision makers in assigning damage awards.¹⁶⁰ To be fundamentally fair, similarly situated parties should be treated similarly; although tort valuations in the aggregate may be reasonable, awards in individual cases vary greatly.¹⁶¹ Scheduling of damages for medical injury, by improving the accuracy and predictability of costs, allows both the injured and those under whose watch medical injury happens to more precisely understand the consequences of such injuries.¹⁶² Other types of tort reforms are generally perceived as a "zero sum game" in which plaintiffs lose while defendants gain.¹⁶³

Three alternative types of scheduling reforms were advanced: matrices, scenarios, and ranges.¹⁶⁴ Of the three options, systematizing standard awards by developing a matrix of dollar value remedies based on type of injury and injury severity appears the best option; minimizing variability and predictability while maintaining a degree of flexibility.¹⁶⁵ Setting remedies for medical injury requires careful consideration of the spectrum of conduct to be covered. To cover all injuries—physical or otherwise—would extend the range of variation in individual

159. See *One Size Does Not Fit All: The Promise of Pharmacogenomics*, NAT'L CENTER BIOTECHNOLOGY INFO. (Mar. 31, 2004), <http://www.ncbi.nlm.nih.gov/About/primer/pharm.html> (noting that adverse drug reactions result in 2.2 million serious cases and over 100,000 deaths in the United States and that pharmaceutical companies are limited to developing "one size fits all" drugs).

160. See Randall R. Bovbjerg et al., *Valuing Life and Limb in Tort: Scheduling "Pain and Suffering"*, 83 NW. U. L. REV. 908, 924 (1988) (citation omitted) (discussing scheduling in medical injury cases and demonstrating that jury awards for individual cases vary according to injury type and severity).

161. See *id.* at 923–24.

162. See *id.* at 975.

163. *Id.*

164. *Id.* at 938–39.

165. *Id.* at 975.

cases to an unworkable system. There are several approaches to announcing remedies for medical injury, one includes those euphemistically called Medicare “never events.”¹⁶⁶ Such events were initially termed Hospital Acquired Conditions.¹⁶⁷ The concept was expanded by the Affordable Care Act to include Medicaid.¹⁶⁸ Further tailoring of the remedy can be made by stratifying the severity of injury based on one of several standardized scales of severity. Announcing remedies makes sense in such cases, where the array of claims is narrow, and the phenomena associated with each claim is precise.¹⁶⁹ Scheduling of medical injuries requires consideration of a number of factors, including a mandate for disclosure, types of claims to be scheduled, the standard for compensating, what elements should be included in a compensation package, and the threshold at which injury is deemed compensable.

1. Mandate for Disclosure

Patients need to know when injuries sustained as a result of medical care have happened so they can receive compensation. As patient safety initiatives have grown in importance, so have reporting obligations to state and national entities. Pennsylvania has a progressive statutory provision in this regard in the “M-CARE” Act 13.¹⁷⁰ A number of other states have also enacted patient safety statutes which

166. Deficit Reduction Act of 2005 § 5001(c), 42 U.S.C. § 1395ww(d)(4) (2011) (directing the Secretary of HHS to select diagnosis codes for conditions which have a high cost or high volume, or both; codes which result in the assignment of a case to a diagnosis-related group that has a higher payment when the code is present as a secondary diagnosis; and codes which describe such conditions that could reasonably have been prevented through the application of evidence based guidelines).

167. See Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System Changes and FY2011 Rates, 75 Fed. Reg. 50042, 50080 (Aug. 16, 2010) (to be codified in scattered parts of 42 C.F.R.). The codes chosen represent what were termed Hospital Acquired Conditions (HAC) for which higher payments related to the HAC were prohibited and which were limited in scope to hospitals participating in the Inpatient Prospective Payment System. Hospital-acquired conditions for which higher payment is disallowed include foreign objects retained after surgery, air embolism, blood incompatibility, Stage III and IV pressure ulcers, falls and trauma (fractures, dislocations, intracranial injuries, crushing injuries, burns, electric shock), manifestations of poor blood sugar control, catheter-associated urinary tract infection, vascular catheter-associated infection, certain surgical site infections, deep vein thrombosis and pulmonary embolism. *Id.* at 50080–85.

168. See Prohibition on Payment for Provider-Preventable Conditions, 42 C.F.R. § 447.26 (2011); Medicaid Program; Payment Adjustment for Provider-Preventable Conditions Including Health Care-Acquired Conditions, 76 Fed. Reg. 32816, 32837 (June 6, 2011) (demonstrating that section 2702(a) of the Affordable Care Act requires that, as of July 1, 2011, the Secretary of HHS must also prohibit Medicaid payments to States for health care-acquired conditions (HCACs) as defined *supra* in section 1886(d)(4)(D)(iv)); Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 2702(a), 124 Stat. 119, 156 (2010).

169. See Bray, *supra* note 10, at 786–87 (arguing that the legitimate range of variation for some wrongs, such as all defamation cases, breaches of contract, or intangible injury, is too large).

170. 40 PA. CONS. STAT. ANN. § 1303.308 (West Supp. 2012) (requiring health care workers to report serious events no later than twenty-four hours after the event).

also require analysis and reporting of error.¹⁷¹ Resolution of most scheduled injuries should operationally resemble health or disability insurance, not liability.¹⁷² Several Massachusetts health care organizations received a health planning grant from the AHRQ to examine the potential for a disclosure, apology, and offer (DA&O) program.¹⁷³ Massachusetts, in a recent law also aimed at imposing cost growth controls on health care entities, also requires health care providers to fully inform patients about mistakes leading to unanticipated outcomes and medical complications.¹⁷⁴

2. Types of Claims

Scheduling injuries for which claims are allowed is one of the most important decisions. If the definition of injury is too wide, uncertainty enters regarding whether a claim fits jurisdiction under the schedule.¹⁷⁵ Defining a narrower subset of injuries makes claiming predictable, but compensation is limited to a smaller number of injured.¹⁷⁶ An alternative approach is to use a defined list of injuries, all of which are highly likely to arise as a result of treatment, not an underlying disease. Medical adversity insurance, a form of no-fault compensation for medical injuries, was proposed as an alternative to malpractice during the malpractice insurance crisis of the 1970s.¹⁷⁷ Building on the medical adversity insurance concept, a system of designated compensable events was championed as a form of

171. See, e.g., CAL. HEALTH & SAFETY CODE § 1279.3 (West 2007) (mandating that the state's health agency provide the public with information regarding reported adverse events and outcomes of inspections and investigations of health facilities in the state); FLA. STAT. ANN. § 429.23 (West Supp. 2013) (requiring facilities to establish internal risk management and quality assurance programs and to report adverse incidents).

172. Randall R. Bovbjerg & Laurence R. Tancredi, *Liability Reform Should Make Patients Safer: "Avoidable Classes of Events" Are a Key Improvement*, 33 J.L. MED. & ETHICS 478, 489 (2005).

173. See MASS. MED. SOC'Y, A ROADMAP FOR REMOVING BARRIERS TO DISCLOSURE, APOLOGY AND OFFER IN MASSACHUSETTS 1 (2012) (citing strong support for the DA&O approach among survey respondents).

174. S. 2400, 187th Gen. Court, Reg. Sess. (Mass. 2012) (enacted) ("An Act improving the quality of health care and reducing costs through increased transparency, efficiency and innovation.").

175. MICHELLE M. MELLO & ALLEN KACHALIA, MEDPAC, EVALUATION OF OPTIONS FOR MEDICAL MALPRACTICE SYSTEM REFORM 30 (2010) ("[L]egal wrangling may arise over whether a particular claim meets the defined categories for jurisdiction.").

176. *Id.*

177. See Clark C. Havighurst & Laurence R. Tancredi, "Medical Adversity Insurance"—A No-Fault Approach to Medical Malpractice and Quality Assurance, 51 MILBANK MEMORIAL FUND Q. HEALTH & SOC'Y 125, 133–34 (1973) (suggesting, as a start, events arising generally from surgical treatment and post-operative patient management: "post-operative infections, thrombophlebitis and embolism, catheter infections, allergic and toxic reactions to antibiotics and other drugs, blood transfusion reactions, foreign bodies, hospital accidents, adverse consequences during experimental treatment . . . , [and] secondary injuries from surgery").

limited no-fault by Danzon in her analysis of medical malpractice.¹⁷⁸ Neither commentator tried to further define such events.

Decades ago, Bovbjerg and Tancredi first suggested the National Quality Forum's (NQF) list of serious reportable events as the basis for "Avoidable Classes of Events."¹⁷⁹ The NQF threshold criteria appear to hold the promise of the best starting point for a schedule of medical injuries, and balance predictability with compensation for many injured by health care (Appendix 1). The NQF serious reportable events have been updated, and require that such events be unambiguous, largely or entirely preventable, and serious.¹⁸⁰ Twenty-nine events have been recommended for endorsement as voluntary consensus standards.¹⁸¹ Additional specialty-specific and diagnostic injuries (failure to diagnose), including those caused by independently practicing physicians with admitting privileges to the hospital, and those caused by diagnostic or treatment decisions made in the physicians' offices could also be added once the original compensation plan is up and running.¹⁸²

A second consideration is when to update the scheduled remedies. Two options are, first, to update at frequent intervals increasing information costs, hence emphasizing precision over communication.¹⁸³ Alternatively, updates could be infrequent but in larger increments, improving communication at the expense of precision.¹⁸⁴ Lastly, a more theoretical concern is the crowding out of a social norm, that of preventing medical injury. If the remedies for injury are not set high enough, health care institutions may view compensation for injuries as a cost of doing business rather than as an imperative for improving patient safety.

3. *Compensation Standard*

Defining a schedule of injuries creates a broader standard that does not require proof of fault or negligence. The NQF's list of twenty-nine injuries that should not happen in a quality health care organization are clear, easily decided, and encompass most of the unexpected outcomes likely to award patients compensation. Further, none of these injuries—with the exception of suicide—is easily accomplished by a patient who might wish to profit by creating an injury. Lastly, the negative effect on a health care organization that injures patients aligns

178. DANZON, *supra* note 146, at 217–18.

179. Bovbjerg & Tancredi, *supra* note 172, at 487.

180. NAT'L QUALITY FORUM, SERIOUS REPORTABLE EVENTS IN HEALTHCARE—2011 UPDATE: A CONSENSUS REPORT ii (2011).

181. See Press Release, Nat'l Quality Forum, NQF Releases Updated Serious Reportable Events (Jun. 13, 2011), available at http://www.qualityforum.org/News_And_Resources/Press_Releases/2011/NQF_Releases_Updated_Serious_Reportable_Events.aspx.

182. See WEILER ET AL., *supra* note 113, at 151.

183. See Bray, *supra* note 10, at 789.

184. See *id.* at 790.

safety principles with compensation; there is an institutional incentive to prevent such injuries.¹⁸⁵

Other alternatives to negligence as a standard are found in foreign systems that have moved to a “no-fault” form of compensation for medical injury. Avoidability is the standard applied in Sweden and Denmark; patients are compensated for injuries that would not have happened if treated by skilled, experienced specialists.¹⁸⁶ In New Zealand, the standard is currently treatment by a registered health professional causing a physical injury that is not a necessary or usual outcome of the treatment.¹⁸⁷ Such avoidability or treatment injury standards, rather than negligence, as the standard for compensation of medical injuries would likely increase—not decrease—the direct expenditure of resources of a scheduled compensation Patient’s Compensation.¹⁸⁸ Rightly so: the intent is to compensate more, not fewer, injured patients, and scheduling injuries may also improve ease of adjudication.¹⁸⁹

4. Financing

From where will the money come? Congress authorized appropriation of \$50,000,000 for the five year period beginning fiscal year 2011 to carry out authorized State Demonstration Projects.¹⁹⁰ Under the Affordable Care Act, each state desiring a tort reform grant must identify the sources from and methods by which compensation is paid for claims under the proposed alternative to current tort litigation, which may include public private funding sources, or a combination of such sources.¹⁹¹ The Affordable Care Act also requires that money incentives be provided for patient safety activities to the extent possible.¹⁹²

The Patient’s Compensation program should be funded through a combination of state funds, assessments on physicians and hospitals, and participation fees. The Florida Birth Injury Compensation Program (Florida Program) is a good model. In 1988, when the Florida Program was established, the

185. See MELLO & KACHALIA, *supra* note 175, at 31 (noting that a compensation standard that provides compensation for a greater number of patients is more in tune with the goal of preventing overall harm).

186. See MICHELLE M. MELLO ET AL., COMMONWEALTH FUND, ADMINISTRATIVE COMPENSATION FOR MEDICAL INJURIES: LESSONS FROM THREE FOREIGN SYSTEMS 4 (2011), available at http://www.commonwealthfund.org/~t/media/Files/Publications/Issue%20Brief/2011/Jul/1517_Mello_admin_compensation_med_injuries.pdf.

187. *Id.*

188. See DANZON, *supra* note 146, at 215; see also RICHARD A. EPSTEIN, *Medical Malpractice: Its Cause and Cure* 258, in *THE ECONOMICS OF MEDICAL MALPRACTICE* (Simon Rottenberg ed., 1978).

189. See MELLO & KACHALIA, *supra* note 175, at 31.

190. Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111–148, § 10607(k), 124 Stat. 119, 1013 (2010).

191. § 10607(c)(3).

192. *Id.*

Florida Legislature set aside a one-time appropriation of \$20 million.¹⁹³ These funds came from the Insurance Commissioner's Regulatory Trust Fund.¹⁹⁴ A second \$20 million installment that could have been transferred was not necessary to maintain the program on an actuarially sound basis.¹⁹⁵ In addition to these funds, the Florida Program receives annual assessments from participating and non-participating physicians, participating midwives, and hospitals.¹⁹⁶ Appropriate adjustments could be made in the revenues received for services—for example, direct agreements between a given hospital and attending staff physicians regarding risky procedures¹⁹⁷—or based on physician specialty with certain specialties paying higher premiums into the Patient's Compensation Program.¹⁹⁸

As physicians inexorably become employees, Patient's Compensation Program costs could be a point of negotiation for physician compensation. Physicians appear to be seeking the stability offered by employment, while hospitals are looking for more physician-integration with physicians to earn the incentives offered by the Affordable Care Act, which encourages the use of integrated health care models such as Accountable Care Organizations, bundled payments, and medical homes.¹⁹⁹

5. *Compensation Package*

Another question is what should be compensated for the scheduled medical injuries? The medical liability reform provisions of the Affordable Care Act look remarkably like a bill that died in committee in 2003, the Reliable Medical Justice Act.²⁰⁰ The unenacted Reliable Medical Justice Act also described models for

193. OFFICE OF PROGRAM POLICY ANALYSIS & GOV'T ACCOUNTABILITY, FLA. LEGISLATURE, REP. NO. 04-04, NICA ELIGIBILITY REQUIREMENTS COULD BE EXPANDED, BUT THE COSTS WOULD INCREASE SIGNIFICANTLY 3 (2004), available at <http://www.oppaga.state.fl.us/reports/pdf/0404rpt.pdf>.

194. *Id.*

195. *Id.*

196. *See id.* at 4. The Florida Program is funded by hospitals and participating and non-participating health care providers are assessed as entity participants. *Id.* Physicians pay \$5,000, midwives pay \$2,500, non-participating physicians pay \$250, and hospitals pay \$50 per live birth. *Id.*

197. *See* WEILER ET AL., *supra* note 113, at 151.

198. *See* Anupam B. Jena et al., *Malpractice Risk According to Physician Specialty*, 356 NEW ENG. J. MED. 629, 632 (2011) (reporting that physicians' claims varied each year across specialties: neurosurgery (19.1%), thoracic-cardiovascular surgery (18.9%), general surgery (15.3%), family medicine (5.2%), pediatrics (3.1%), and psychiatry (2.6%)).

199. *See* MERRITT HAWKINS, 2011 REVIEW OF PHYSICIAN RECRUITING INCENTIVES 4 (2011), available at <http://www.merrithawkins.com/pdf/mha2011incentivesurvPDF.pdf>.

200. *Compare* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 10607(c)(2), 124 Stat. 119, 1009 (2010) (“(A) makes the medical liability system more reliable by increasing the availability of prompt and fair resolution of disputes; (B) encourages the efficient resolution of dispute; (C) encourages the disclosure of health care errors; (D) enhances patient safety by detecting, analyzing, and helping to reduce medical errors and adverse events; (E) improves access to liability insurance; (F) fully informs patients about the differences in the alternative and current tort litigation; (G) provides

alternative liability regimes in some detail.²⁰¹ The Reliable Medical Justice Act defined “Net Economic Loss,” elements of which a Patient’s Compensation program could encompass as a compensation package for patients who sustain a medical injury.²⁰² Net economic loss, as defined in the Reliable Medical Justice Act, includes four components:

(A) reasonable expenses . . . needed for health care . . . and other remedial care of an injured individual; (B) . . . expenses for rehabilitation treatment and occupational training; (C) 100 percent of the loss of income from work that an injured individual would have performed if not injured . . . ; and (D) reasonable expenses incurred in obtaining ordinary and necessary services to replace services an injured individual would have performed for the benefit of the individual or the family of such individual if the individual had not been injured.²⁰³

A similar approach has been used by the Virginia Birth Injury Compensation Program.²⁰⁴ The Virginia program identifies three broad categories of benefits. First, reasonably necessary medical expenses, costs of rehabilitation and custodial care, and any special facilities or equipment exclusive of reimbursement by other government social programs or private insurers.²⁰⁵ Second, there is a calculation for lost earnings from ages eighteen to sixty-five.²⁰⁶ Lastly, there is an allowance resulting from filing the claim and attorney fees.²⁰⁷ An alternate proposal was put forth in a proposal by Weiler and colleagues suggesting legislation to require payment for self-paid medical expenses, a percentage of net lost earnings up to twice that of the state’s average wages, and non-pecuniary damage for certain physical disabilities.²⁰⁸

patients the ability to opt out of or voluntarily withdraw from participating in the alternative at any time and to pursue other options, including litigation, outside the alternative; (H) would not conflict with State law at the time of the application in a way that would prohibit the adoption of an alternative to current tort litigation; and (I) would not limit or curtail a patient’s existing legal rights, ability to file a claim in or access a State’s legal system, or otherwise abrogate a patient’s ability to file a medical malpractice claim.”), *with* Reliable Medical Justice Act, S. 1518, 108th Cong. § 3990(c)(2) (1st Sess. 2003) (proposing an alternative to the current malpractice regime that “(A) makes the medical liability system more reliable; (B) enhances patient safety; and (C) maintains access to liability insurance”).

201. S. 1518 § 3990(d) (describing the Early Disclosure and Compensation Model, the Administrative Determination of Compensation Model, and the Special Health Care Court Model).

202. S. 1518 § 3990(j)(4).

203. *Id.*

204. *See* VA. CODE ANN. § 38.2-5009 (Supp. 2012) (establishing the factors and conditions that affect granting of commission awards for birth related injuries).

205. *Id.*; *see also* JOINT LEGISLATIVE AUDIT & REVIEW COMM’N, VA. GEN. ASSEMBLY, *supra* note 60, at ii–iii.

206. JOINT LEGISLATIVE AUDIT & REVIEW COMM’N, VA. GEN. ASSEMBLY, *supra* note 60, at iii.

207. *Id.*

208. WEILER ET AL., *supra* note 113, at 151.

6. *Establishing an Injury Threshold*

The health care acquired conditions should be further stratified by severity of injury so appropriate thresholds for compensation can be set.²⁰⁹ Such thresholds ensure that compensation is given to those who are more severely injured.²¹⁰ There is experience with establishing thresholds. New Zealand provides payment for only for permanent injuries of body parts or loss of function.²¹¹ Sweden and Denmark compensate non-disabling pain and disfigurement.²¹² One useful classification system is that of the National Association of Insurance Commissioners (NAIC),²¹³ Another detailed classification system is that promulgated by the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP).²¹⁴ The Patient's Compensation schedule could compensate medical injuries at or above a given NCC MERP category sustained by patients, including those caused by independently practicing physicians with admitting privileges to the hospital, and those caused by diagnostic or treatment decisions made in the physicians' offices.

Both the NAIC and NCC MERP injury scales allow for the separation of injuries into lesser and greater degrees, from errors that do not reach the patient—"near misses"—to death.²¹⁵ Creating a modest threshold would direct limited

209. See MELLO & KACHALIA, *supra* note 175, at 30 (finding a "potential benefit" of stratifying health care acquired conditions because it would create a "more predictable set of claims to adjudicate").

210. Studdert & Brennan, *supra* note 57, at 232.

211. See MELLO ET AL., COMMONWEALTH FUND, *supra* note 186, at 7.

212. *See id.*

213. M. Patricia Sowka, *The Medical Malpractice Closed Claims Study: Executive Summary* 45 CONN. MED. 91, 93 tbl.5 (1981) (detailing a nine-point classification system created by NAIC). The nine-point scale includes the following categories (examples): (1) Emotional only (fright, no physical damage); (2) Temporary insignificant (lacerations, contusions, minor scars, rash; no recovery delay); (3) Temporary minor (infections, fracture, fall in hospital; recovery delayed); (4) Temporary major (burns, surgical material left, drug side effect, brain damage; recovery delayed); (5) Permanent minor (loss of fingers, loss or damage to organs; includes non-disabling injuries); (6) Permanent significant (deafness, loss of limb, loss of eye, loss of one kidney or lung); (7) Permanent major (paraplegia, blindness, loss of two limbs, brain damage); (8) Permanent grave (quadriplegia, severe brain damage, lifelong care or fatal prognosis); (9) Death. *Id.*

214. See NAT'L COORDINATING COUNCIL FOR MEDICATION ERROR REPORTING & PREVENTION, THE COUNCIL: MOVING INTO THE SECOND DECADE 48 fig.1 (2010) (illustrating the NCC MERP Index for Categorizing Medication Errors). The NCC MERP Index separates medication errors into nine categories: (1) Circumstances or events that have the capacity to cause error; (2) An error occurred but the error did not reach the patient; (3) An error occurred that reached the patient but did not cause patient harm; (4) An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm; (5) An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention; (6) An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization; (7) An error occurred that may have contributed to or resulted in permanent patient harm; (8) An error occurred that required intervention necessary to sustain life; (9) An error occurred that may have contributed to or resulted in the patient's death. *Id.*

215. *Id.*

resources towards compensation for the injured while expanding coverage beyond those whose serious or catastrophic injuries would allow them to pursue a malpractice lawsuit.²¹⁶ At the same time, a threshold would prevent the administrative costs of adjudicating a large number of claims for minor temporary or insignificant injuries.²¹⁷

B. Announcing Remedies for Patients Suffering Medical Injury

1. Announcing Remedies as an Alternative to Medical Malpractice

Samuel Bray has observed that for most violations of legal rules, remedies are tailored to fit a specific wrong.²¹⁸ Announcing remedies for injuries sustained as a result of medical care holds promise of three important patient benefits. First, there is greater equality: an injured patient's right to compensation is not constrained by what a plaintiff's attorney would consider to be a "valuable" case or other factors such as race or socioeconomic status.²¹⁹ Second, announcing remedies for medical injury produces greater compliance with rules designed to enhance patient safety, as well as helps to control positive and negative defensive medicine behaviors.²²⁰ Lastly, announcing such remedies eliminates the costs of recovery from injury, or hedonic adaptation.²²¹ Telling a successful story in a medical malpractice setting

216. Studdert & Brennan, *supra* note 57, at 232.

217. David M. Studdert & Troyen A. Brennan, *Toward A Workable Model Of "No-Fault" Compensation For Medical Injury In The United States*, 27 AM. J.L. & MED. 225, 230 (2001) (finding that a medical injury system without a disability threshold wastes significant administrative resources on a large number of claims for relatively minor incidents).

218. Bray, *supra* note 10, at 754.

219. See Daryl J. Levinson, *Rights Essentialism and Remedial Equilibration*, 99 COLUM. L. REV. 857, 886 (1999) (arguing that incorporating a prophylactic remedy into a right may be more efficient; Levinson's taxonomy would consider announcing remedies for medical injury as remedial incorporation).

220. See Ernst Fehr & Simon Gächter, *Cooperation and Punishment in Public Goods Experiments*, 90 AM. ECON. REV. 980, 993 (2000) (concluding that cooperators in social dilemma situations will punish "free riders" even if there are no material benefits for punishers); Robert Boyd et al., *Coordinated Punishment of Defectors Sustains Cooperation and Can Proliferate When Rare*, 328 SCIENCE 617, 619 (2010) (documenting that costs of punishing free-riders decreases as the number of punishers increases). *But see* Helen Bernhard et al., *Parochial Altruism in Humans*, 442 NATURE 912, 913 (2006) (showing that punishment is more likely if the victim and punisher are from the same social "ingroup," but less likely if they are from different social groups).

221. See Stan V. Smith, *Measuring the Loss of Enjoyment in Personal Injury Cases in Washington – Hedonic Damages*, TRIAL NEWS, Jan. 1997, at 29, 29–30 (commenting that defense testimony on hedonic damages can prevent runaway damage awards). *But see* Ayers v. Robinson, 887 F. Supp 1049, 1064 (N.D. Ill. 1995) (holding in that case that Stan V. Smith's testimony on the issue of hedonic damages was inadmissible); Brendan I. Koerner, *What's Your Happiness Worth?*, LEGAL AFFAIRS, Jan.–Feb. 2004, at 54 (noting that expert testimony on the issue of hedonic damages is often considered inadmissible, but when admitted leads jurors "to dole out millions").

impairs hedonic adaptation, an important process for letting patients recover and move on.²²²

These three benefits of announcing remedies for medical injury—equality for the injured, compliance by providers, and costs of telling—are achieved through one of several functions as articulated by Bray.²²³ A first function is that of reducing information costs by announcing remedies for medical injury.²²⁴ Overhead costs have been estimated at between forty and fifty-four percent of the total cost of litigation.²²⁵ By announcing a remedy for an entire class of injuries, a decision on remedy only needs to be made once.²²⁶ Patients, often unsophisticated in medical knowledge, may underestimate the injury sustained, while health care providers—sophisticated repeat players—know an injury to be caused by the provision of health care.²²⁷ Announcing a schedule of injuries for which remedy exists would level the playing field with respect to medical injury.

Second, announcing remedies has a precommitment function that reduces information costs for sophisticated repeat players, the health care providers.²²⁸ By knowing the cost of a given medical injury, providers can not only forecast total costs of care, but also generate priorities for further injury reduction strategies.²²⁹ External costs of a given health care encounter can be defined as changes in consumption less changes in production.²³⁰ The trend towards evidence-based medicine in assisting with the definition of socially optimal behavior has many proponents, but forging consensus on even basic medical treatments can be difficult.²³¹ Health care should be controlled by pricing if external costs are easier to assess, and if it is easier to identify socially optimal behavior, then sanctions should be imposed for non-optimal behavior.²³² And yet, precommitment to a

222. Bray, *supra* note 10, at 755–56; Bagenstos & Schlanger, *supra* note 11, at 785.

223. Bray, *supra* note 10, at 764–74.

224. *Id.* at 780.

225. Compare MELLO & KACHALIA, *supra* note 175, at 34 (citing overhead costs to be forty percent), with Studdert et al., *supra* note 141, at 2031 (citing overhead costs to be over fifty percent).

226. Bray, *supra* note 10, at 774.

227. *See id.* at 785–86 (explaining that announcing serves as communication, which allows for the remedy to be publicized, and therefore, the public is less likely to underestimate it).

228. *See id.* at 780.

229. *See id.* at 778 (explaining that announcing remedies ensures that the gap between the cost and its perception would decrease).

230. Magnus Johannesson, *The Willingness To Pay For Health Changes, The Human-Capital Approach And The External Costs*, 36 HEALTH POL'Y 231, 232 (1996).

231. *See* Ronen Avraham, *Clinical Practice Guidelines: the Warped Incentives in the U.S. Healthcare System*, 37 AM. J.L. & MED. 7, 16 (2011) (noting that medical guidelines have led to an increase in the practice of evidence-based medicine and explaining that variation of medical practices across geographic areas, has led to a lack of consensus on medical treatments).

232. Robert Cooter, *Prices and Sanctions*, 84 COLUM. L. REV. 1523, 1533 (1984).

schedule of remedies for medical injury takes the “yoke of liability”²³³ off the vast majority of physicians who otherwise would be tempted to engage in poorly-informed attempts at positive or negative defensive behaviors, and who rarely intend injury to their patients.²³⁴

Cost-saving is a third function. Cost-saving as the term is used here does not refer to all costs of remedies for medical injury. In fact, total costs of such a program have been predicted to increase with the increase in paid claims for medical injury.²³⁵ Instead, the savings are in administrative costs, which in the medical malpractice litigation regime—win or lose—are high.²³⁶ In case-by-case remedies, such as those sought in malpractice suits, negligence must be proved under a preponderance of evidence standard, and courts must decide a remedy in each case.²³⁷ Announcing a remedy *ex ante* for a class of injuries would reduce administrative costs.²³⁸

Overhead associated with malpractice claims is a major source of costs that do not directly benefit injured patients. One Harvard study of medical malpractice observed that the overhead costs of malpractice litigation are exorbitant, with the average costs of defending claims going to trial nearly three times the cost for claims resolved out of court.²³⁹ Defense costs and standard plaintiffs’ attorneys’ contingency fees, other expenses notwithstanding, brought the total costs of litigation to fifty four percent of that paid out to plaintiffs.²⁴⁰

Claims involving harmful errors were responsible for eighty percent of overhead expenses.²⁴¹ The data are remarkably consistent over time. A 1976 study estimated that the malpractice system returned at the most only twenty-eight cents of the malpractice premium dollar to injured patients; only 12.5 cents reimbursed the patient for losses not otherwise compensated.²⁴² Analysis of over 26,000 malpractice claims closed in the decade ending in 2005 showed a mean defense

233. Richard N. Waldman, *Together We Can Do Something Wonderful*, 115 OBSTETRICS AND GYNECOLOGY 1116, 1118 (2010).

234. See Cooter, *supra* note 232, at 1537–38 (“Sanctions increase with the need for deterrence, as indicated by the actor’s state of mind, whereas prices increase with the amount of external harm caused by the act, which is invariant with respect to the actor’s state of mind.”).

235. DANZON, *supra* note 146, at 217–18 (explaining that the downside in implementing a “no-fault plan” is that it provides automatic compensation when there is a “strong presumption of negligence”).

236. See MELLO ET AL., *supra* note 59, at 3.

237. See, e.g., *Todd v. United States*, 570 F. Supp. 670, 677 (D.S.C. 1983) (noting that the burden of proof in a medical malpractice case requires a plaintiff to establish the defendant’s liability through a preponderance of the evidence).

238. See *supra* notes 221–24 and accompanying text.

239. Studdert et al., *supra* note 141, at 2026–27, 2031.

240. *Id.*

241. *Id.*

242. Jeffrey O’Connell, *An Alternative to Abandoning Tort Liability: Elective No-Fault Insurance for Many Kinds of Injuries*, 60 MINN. L. REV. 501, 509 (1976).

cost of about \$23,000, with non-paid claims payment still at an average cost of about \$17,000.²⁴³

The Affordable Care Act has made health care insurance a statutory responsibility for all and not a luxury for a select few.²⁴⁴ Cost sharing for all covered individuals is capped, so out of pocket expenses—whether for underlying disease or as a result of medical injury—are limited.²⁴⁵ Further, there is no good way for such a system to provide prevention of similar future injuries.²⁴⁶ Although patient costs for direct care are limited to \$5,000, there are still costs borne by the injured and their families in terms of lost wages while healing from such injuries.²⁴⁷ In the past, physicians and hospitals could bill for additional services incurred when patients suffered medical injuries.²⁴⁸ CMS has promulgated guidelines proscribing payment for “never events,” citing the cost to Medicare.²⁴⁹ With the inability of health care providers to be paid for care necessary for the treatment of certain injuries, and yet liable for medical injuries under common law torts, health care organizations currently pay twice for injuries, once by absorbing the cost of care-related injuries, and again by indemnification against liability claims.

2. *Uniting Patient Safety Enhancements and Compensation*

a. *Experience Rating of Physicians and Health Care Organizations*

One concern of eliminating the requirement of negligence is a moral imbalance, that health care providers will develop a cavalier attitude towards patient safety if negligence no longer serves as a means for holding doctors responsible for mistakes.²⁵⁰ This concern can be overcome by implementing experience rating for health care provider contributions and a strong reporting mechanism. The Patient’s Compensation program should require contributions to

243. Seth Seabury et al., Letter to the Editor, *Defense Costs of Medical Malpractice Claims*, 366 *NEW ENG. J. MED.* 1354, 1355 (2012).

244. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010); see also *Focus on Health Reform: Summary of New Health Reform Law*, KAISER FAM. FOUND., 1 (Apr. 15, 2011), <http://www.kff.org/healthreform/upload/8061.pdf>.

245. Patient Protection and Affordable Care Act § 1302(c)(1)(A).

246. See Kachalia & Mello, *supra* note 149, at 1565 (noting that evidence suggests that the medical malpractice liability system does not adequately incentivize physicians from engaging in negligent care).

247. 26 U.S.C. § 223(c)(2)(A)(ii) (2011) (stating that current dollar values for coverage are \$5,000 for individual coverage, and twice that amount for family coverage, leaving all other costs for the injured parties to bear).

248. See Barry R. Furrow, *Regulating Patient Safety: The Patient Protection And Affordable Care Act*, 159 *U. PA. L. REV.* 1727, 1752 (2011).

249. *Id.* at 1753.

250. See BAKER, *supra* note 32, at 113–14 (discussing how tort lawsuits seek to correct the moral imbalance between a patient living with the consequences of a medical mistake and the doctor potentially responsible for that mistake).

the compensation funds for individual physicians and health care organizations to be “experience-rated,” where health care providers (individual or organizational) with higher than average numbers of announced injuries have higher contributions.

Experience rating would likely be complex; adjustments could be made for certain injuries or levels of payouts.²⁵¹ A physician’s specialty, age, and years remaining in practice could also be factors to consider.²⁵² Such “experience rating” is designed to maintain provider responsibility and is an incentive to minimize medical injuries. Further, announcing the costs for each class of compensable events permits allocation of specific risks in such a way as to focus attention on particular quality questions (for example, hospital acquired infections).

b. Medical Reviews of Physicians and Hospitals Should Be Rigorous

Institutions, rather than individual physicians or providers groups, should be the participants, as they have the best means of announcing remedies for medical injury and linking the compensation program to patient safety incentives.²⁵³ The health care facilities’ quality assurance program should include internal oversight measures for assessing accountability for medical injuries identified through the Patient’s Compensation claims process. Immunity from antitrust liability should be extended to cover the physician-members of hospital peer review committees responsible for alteration of the practice privileges of “repeat offender” physicians.²⁵⁴ Criteria for deciding upon sanctions and censure should be clear and unambiguous; perhaps a point system similar to that used for vehicle licensing could be considered.

External oversight should also be included in Patient’s Compensation legislation, which should direct the State’s Board of Medicine (BOM) and Department of Health (DOH) to register and review all submitted medical injury claims.²⁵⁵ The Board of Medicine should be required to assess whether the physician(s) involved in the injury claim provided substandard care that would warrant disciplinary action by the BOM. The DOH would selectively review claims to determine whether the hospital and its staff provided inadequate medical care that should impact the hospital’s license. The State could mandate, by statute, that its BOM and DOH develop a plan for ensuring that all injury claims are submitted to the State’s BOM and DOH for review. Further, the BOM and DOH could

251. Havighurst & Tancredi, *supra* note 177, at 129–30.

252. *Id.* at 130.

253. Studdert & Brennan, *supra* note 57, at 231.

254. 42 U.S.C. § 11111–112(a) (2011) (stating that certain bodies or persons who participate in a professional review action found to be “in the furtherance of quality health care,” among other factors, should not be liable to pay damages for such action).

255. *See, e.g.*, VA. CODE ANN. § 38.2-5004 (2007) (outlining the state of Virginia’s review process for investigating birth-related medical injuries).

conduct selective investigations of the claimant and other relevant parties of the events surrounding the claims injury and to notify claimants concerning the outcome of the review.

3. *Filing Method and Adjudication*

Announcing the remedy for medical injury means that the Patient's Compensation program claims process would be navigable without attorneys. Representation for injured patients would not be barred, and attorneys could still represent the injured for a reasonable, but likely not contingent, fee.²⁵⁶ Access to legal counsel would provide protection regarding eligibility and payment.²⁵⁷ At the time patients are notified of their injury, they should be encouraged to file a claim for compensation. Claims should be received at a central organization, preferably at the state level.²⁵⁸ This central organization would have responsibility for receipt of claims, adjudication, and dispensing compensation.²⁵⁹

Initial adjudication would fall to an administrative claims manager with a background in law or health care, preferably both.²⁶⁰ Claims administrators should have access to experts appointed by the Patient's Compensation program, and not the parties.²⁶¹ Claims administrators and neutral experts would not necessarily need to be grounded in evidence-based medicine. The list of compensable medical injuries as announced would require little additional knowledge. A database of all claims, kept by the State's department of health or medical licensure would insure that precedent would be documented, improving the accuracy of the claims administrators' adjudication. The New Zealand and Swedish administrative models both rely on such administrators.²⁶²

The claims administration procedure should meet acceptable standards of accessibility, neutrality, and due process. Florida uses two independent experts in

256. See MELLO & KACHALIA, *supra* note 175, at 30–31 (noting that the need for an attorney may depend on the filing method's complexity and that removing the need for an attorney would potentially make filing easier).

257. Bovbjerg & Tancredi, *supra* note 172, at 490.

258. Studdert & Brennan, *supra* note 57, at 230.

259. *Id.*

260. See MELLO & KACHALIA, *supra* note 175, at 31 (discussing the possible adjudicators in an administrative model including administrative claims managers with or without a background in law or health care among others).

261. See *id.* at 31–32 (noting how some medical court models propose that an adjudicator, acting as a "physician-judge," receive assistance from neutral experts in an effort to produce more accurate decisions).

262. See Kachalia et al., *supra* note 58, at 390–91 (elaborating on how the Swedish and New Zealand models both employ claims handlers with clinical or legal backgrounds or with specialties in certain types of claims); see also Mello et al., *supra* note 211, at 6 (noting how New Zealand uses claims adjusters with clinical backgrounds).

the review of birth injury claims, while Virginia uses three.²⁶³ One argument in favor of Virginia's consensus-decision approach revolves around the complexities of the decisions. Deliberations and debate among a group of experts, each of whom contributes his or her own perspective and expertise, would appear to be a useful way to address complex clinical issues. Unlike the Patient's Compensation approach, in which a defined set of injuries and severity are clear cut, the use of a panel is also advantageous in ensuring transfer of knowledge and consistency of decision making when individual experts transfer out of and into the program. Overall, one claims administrator should be able to adjudicate most, if not all, claims.

4. *Informed Consent for Patients Admitted to Hospitals*

The Affordable Care Act requires participating states to notify patients if they are eligible for the Patient's Compensation Program (or other tort alternative) and the method by which they may decline to participate or withdraw from the program.²⁶⁴ The Patient's Compensation Program should inform, *ex ante*, all patients about the program, as well as those who are injured *ex post*.²⁶⁵ Patients would have to be fully informed, in easily comprehensible terms of both the tort rights they were surrendering and the no-fault benefits they would be eligible to receive, before they were asked to decide either to accept medical care under no-fault auspices or to use institutions and doctors still governed by the existing tort regime.

To encourage announcing, participating physicians and health care organizations should be mandated by legislation to obtain informed consent regarding program participation from all patients under their care.²⁶⁶ The Virginia Birth-Related Neurological Injury Compensation Program has used brochures to explain a patient's rights and limitations under the program, especially the exclusive remedy provisions.²⁶⁷ Participating physicians and hospitals that fail to obtain informed consent of patients could be made subject to sanctions, such as remedial work plans, monetary penalties, or, in the case of recalcitrant physicians, suspension of privileges for a period of time.

263. See Siegal et al., *supra* note 150, at 522–23.

264. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 10607(c), 124 Stat. 119, 1009–10 (2010).

265. See JOINT LEGISLATIVE AUDIT & REVIEW COMM'N, VA. GEN. ASSEMBLY, *supra* note 60, at vii, x. JLARC found that although the Virginia Birth-Related Neurological Injury Compensation Program supplied patient brochures to physician and health care for distribution, most of the claimant families indicated that the most common source of information about the program was an attorney. *Id.* at x.

266. *Id.* at x.

267. *Id.*

C. *Eliminating the Collateral Source Rule and Other Insurance Considerations*

The Affordable Care Act, by making health care a responsibility—not a right—has made application of the collateral source rule (the Rule) more complex.²⁶⁸ Institution of a Patient's Compensation program would further weaken the rationale for applying the Rule in determination of damages and may render it unnecessary. In general terms, the Rule prohibits reducing a claimant's medical expense damages by the amount of health insurance coverage.²⁶⁹ The intent is to prevent the fact-finder, usually a jury, from considering whether the claimant has health insurance in determining fault of the defendant.²⁷⁰ With the constitutionality of the individual mandate of the Affordable Care Act affirmed, fact-finders may now assume that claimants have health insurance.²⁷¹ Continued application of the Rule, therefore, protects only those individuals choosing to willfully forgo health insurance, and rewards such willfully uninsured claimants with full damages despite the decision to forgo coverage.²⁷²

Implementation of a Patient's Compensation program would require that the health care providers cover the medical costs of a health care-related injury. Regardless of insurance status, insurers and their insured customers would not bear the costs of paying for such injuries. Further, the scheduled injuries which are announced prior to injury are not expected to occur to anyone, insured or not. Neither would subrogation decrease the remedy to the injured, as these costs are not paid by insurers, who are not entitled to any recovery.²⁷³

Health insurers should be involved in setting up a Patient's Compensation program for two reasons. First, with recent exceptions, insurers currently pay for many of the costs associated with medical injury. If insurers can be persuaded that a Patient's Compensation approach would lead to improved patient safety through prevention of medical injury, they could be strong advocates for change.²⁷⁴

268. See generally Rebecca Levenson, *Allocating the Costs of Harm to Whom They are Due: Modifying the Collateral Source Rule After Health Care Reform*, 160 U. PA. L. REV. 921, 922–23 (2012).

269. *Matsyuk v. State Farm Fire & Cas. Co.*, 229 P.3d 893, 899 n.8 (Wash. Ct. App. 2010) (citing *Mahler v. Szucs*, 957 P.2d 632, 655 n.4 (Wash. 1998)) (“The collateral source rule is the ‘well settled rule in tort actions that a party has a cause of action notwithstanding the payment of his loss by an insurance company.’”). See generally James L. Branton, *The Collateral Source Rule*, 18 ST. MARY'S L.J. 883, 883 (1987).

270. See Levenson, *supra* note 268, at 924–25.

271. *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 132 S. Ct. 2566, 2600 (2012).

272. See Levenson, *supra* note 268, at 936.

273. *Id.* at 942–47 (defining subrogation as “a contractual arrangement through which a claimant's primary insurer is reimbursed for its coverage of the claimant's medical costs if the claimant recovers these costs from a tortfeasor”).

274. See Studdert & Brennan, *supra* note 57, at 252.

Second, health insurers should be consulted as any award to the injured patient might otherwise be considered subject to subrogation.²⁷⁵ By compensating injured patients according to an announced, scheduled program of injuries, there is no tortfeasor, so insurers could attempt to recover against the insured.²⁷⁶ Health insurance plans' benefits will still cover some of the patient's health care related expenses for the interval in which patients are injured. Patient's Compensation awards should not be reduced to reflect payments from collateral sources as collateral sources should still compensate injury-unrelated medical costs.²⁷⁷ The cost to the Patient's Compensation program of the total cost of remedying covered medical injuries would be off-set by decreasing administrative costs (e.g., less court time, lower legal expenses), and ending lengthy discovery about defendants' negligence, no-fault should provide faster, more efficient compensation.²⁷⁸ A Patient's Compensation approach would take on the burden of an amount approaching the total cost of the injuries which occur, and health insurers seeking subrogation may have those claims deflected by the requirements that the injured first be made whole.²⁷⁹

D. Other Administrative Requirements of the Affordable Care Act

A Patient's Compensation proposal would also have to account for a number of provisions of the Affordable Care Act. Some are expected of all grantees; such as an application²⁸⁰ and submission of an annual report to HHS, evaluating the effectiveness of funded activities and including the impact of the activities funded on patient safety.²⁸¹ The specific elements of the proposal would likely be the same as elements upon which the HHS Secretary is required to report.²⁸² A Patient's

275. See Studdert & Brennan, *supra* note 57, at 254. Therefore, any damages awarded to a plaintiff who has already received payment from the insurance company would otherwise, under subrogation, be used to reimburse the damages paid by the insurance company.

276. See *id.* at 247 (listing four possible subrogation arguments: 1) attempts to recover payments from the paid compensation to the insured; 2) in the case of an insured attempting to recover medical payments an imposed formal agreement subrogating the insurer to proceeds of any recovery; 3) an attempt to deflect strict liability on the grounds that an insured has received monies from the Patient's Compensation program; and 4) that with no tortfeasor other subrogation rights may be prejudiced).

277. See Havighurst & Tancredi, *supra* note 177, at 129–30 (discussing the concerns surrounding collateral sources of compensation for ancillary damages, such as lost wages, and their impact on damages).

278. See Studdert & Brennan, *supra* note 57, at 229 (discussing the advantages of a no-fault compensation scheme, in terms of cost reduction).

279. See *id.* at 246–47 (discussing issues relating to health insurers seeking subrogation for matters beyond compensating the injured patient first).

280. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 10607(d)(1), 124 Stat. 119, 1010–11 (2010).

281. § 10607(e)(1).

282. § 10607(g)(3)(A)–(H). The elements required by Congress include: “A) the nature and number of disputes over injuries allegedly caused by health care providers or health care organizations; B) the

Compensation program proposal will have to demonstrate how the proposed alternative increases the availability of prompt, fair, efficient resolution of disputes.²⁸³ The program will also have to enhance patient safety by encouraging the disclosure and reduction of medical errors and adverse effects.²⁸⁴ Further, the grant must provide a mechanism for the fully informed consent of patients regarding the differences in the alternative and current tort litigation.²⁸⁵

There are additional requirements. The Patient's Compensation Program must provide patients the ability to opt out of or voluntarily withdraw from participating in the alternative at any time and to pursue other options, including litigation.²⁸⁶ The Affordable Care Act is careful to make explicit the requirement that any Compensation Project must allow participants to withdraw at any time.²⁸⁷ One foreseeable problem with the Affordable Care Act's State Demonstration Project provisions as currently worded is the possibility that an injured patient could file a malpractice claim after settling with the Patient's Compensation program.²⁸⁸ It is likely the intent of Congress in enacting the Affordable Care Act with regard to a patient's ability to take advantage of both torts and the alternative would have to be decided by the courts. Other requirements require additional consideration.

1. Scope of Jurisdiction

A Patient's Compensation grant will have to determine a scope of jurisdiction sufficient to evaluate the effects of the tort alternative.²⁸⁹ As noted earlier, the scope of jurisdiction could be a state, a more limited geographical area, or even a specific group of health care providers, but could not be a single payer or single patient population.²⁹⁰

nature and number of claims in which tort litigation was pursued despite the existence of an alternative; C) the disposition of disputes and claims, including the length of time and estimated costs to all parties; D) the medical liability environment; E) health care quality; F) patient safety in terms of detecting, analyzing, and helping to reduce medical errors and adverse events; G) patient and health care provider and organization satisfaction with the alternative and with the medical liability environment; and the H) impact on utilization of medical services, appropriately adjusted for risk." *Id.*

283. § 10607(c)(2)(A)–(B).

284. § 10607(c)(2)(C)–(D).

285. § 10607(c)(2)(F).

286. § 10607(c)(4)(B).

287. *Id.*

288. § 10607(c)(2)(I) (stating that no limits would be placed on a patient's existing legal rights for purposes of a malpractice claim).

289. § 10607(c)(4)(A).

290. *Id.* See also *supra* notes 21–23 and accompanying text.

2. *Preference in Awarding Demonstration Grants*

Chances for successful funding of a Patient's Demonstration proposal will be enhanced by noting that the Secretary is required to give preference to proposals developed in consultation with relevant stakeholders.²⁹¹ One good example of "substantive consultation with relevant stakeholders" is the survey of leaders in medical care and health law detailed in a recent roadmap for a disclosure, apology, and early offer program developed in Massachusetts.²⁹² Interviewees included members of the Massachusetts legislature, hospital systems (academic and community hospitals), practicing physicians, liability insurers, health insurers, medical professional associations, patient advocacy organizations, malpractice attorneys, patient safety experts, major physician practice groups, and a major business association (otherwise unnamed).²⁹³

The proposal should also enhance "patient safety by detecting, analyzing, and helping to reduce medical errors and adverse events."²⁹⁴ Here, the Patient's Compensation proposal, by virtue of the documentation of claims submissions and outcomes will do exactly that. Lastly, The Secretary is to give preference to proposals that are likely to "improve access to liability insurance."²⁹⁵ For the schedule of announced remedies as proposed in this liability alternative, access to liability insurance is unlikely to be significantly changed. Any claim falling outside of the NQF criteria (Appendix 1) will still, initially, require litigation. Long-term, however, if successful, the schedule of injuries may be made more inclusive leading to a preference away from litigation, at which point decreased litigation may lead to less expensive—hence more accessible—malpractice insurance.

VI. CONCLUSIONS

Patient's Compensation insurance, or scheduling and announcing remedies for medical injury, is a novel option to current medical malpractice litigation. The proper framework for understanding the rationale of a no-fault based approach to medical injuries is to compensate a higher proportion of patients by eliminating the need to prove negligence. Systems research has shown that few injuries are due solely to the acts of one individual, often making negligence hard to prove. Further, the cost of litigating on a contingent basis severely limits the number of injured patients eligible for compensation. The Affordable Care Act has provided a template for the development of state-based demonstration projects. There is experience both domestically and abroad for how to structure such a program.

291. § 10607(c)(5).

292. See MASS. MED. SOC'Y, *supra* note 173, at 3–4.

293. *Id.* at 3, 22 tbl.2.

294. § 10607(c)(2)(D).

295. § 10607(c)(5)(C).

A number of the cases that would likely be brought to the Compensation Project are those with a potential payment of less than \$200,000—suggested as a cut-off value below which plaintiffs' attorneys will rarely take a malpractice case.²⁹⁶ Therefore, the lower value injuries are unlikely to be pursued by plaintiffs' attorneys. In tort, the requirement for serious or catastrophic injury limits the number of patients who can hope to receive compensation. This leaves a large number of patients injured by a complex health care system without remedy. For a defined schedule of medical injuries, compensation will be provided as scheduled and announced. The list of injuries for which such a remedy is available has been generally agreed upon as being not related to an underlying medical condition.

The development of a Patient's Compensation program such as described here is modest in size and intent. Worker's Compensation also started modestly; a 1902 Maryland Accident Fund was established for miners but was ruled unconstitutional.²⁹⁷ In 1908 Congress legislated an act for compensation to some federal employees in 1908.²⁹⁸ The first law held constitutional was passed in New Jersey and it was not until 1949 that all states passed Worker's Compensation Insurance.²⁹⁹

In summary, from a patient's point of view, the medical and legal professions can and should do better by those suffering the consequences of medical injury. Just as Worker's Compensation insurance began on a voluntary basis and expanded in scope slowly, state-by-state, a Patient's Compensation program would begin much the same way. By limiting early claims experience to a scheduled set of injuries, all of which are likely to generate little dispute as to whether or not the injury is caused by medical care, the overhead costs of administration on a per case basis are likely to decrease. Announcing the schedule to physicians and patients alike in a comprehensive but understandable way will be critical to the provision of fair and just compensation for those sustaining medical injury, negligent and non-negligent alike.

296. See BAKER, *supra* note 32, at 173 (suggesting that few lawyers accept medical malpractice cases that do not potentially have a damage award of at least \$200,000). *But see* ROBERT ZAUSNER, TWO BOYS DIVIDED BY FORTUNE, UNITED BY TRAGEDY: A TRUE STORY OF THE PURSUIT OF JUSTICE 45–46 (2009) (noting medical malpractice jury verdicts of between \$19.9 million and \$49.6 million returned for plaintiffs by a successful Philadelphia law firm); BARRY WERTH, DAMAGES 294–96 (1999) (documenting other large medical malpractice verdicts). See generally Orosco et al., *Surgical Malpractice in the United States, 1990–2006*, 215 J. AM. COLL. SURGEONS 480, 482 (2012) (noting the mean payment in 2006 was \$262,727).

297. Arthur Larson, *The Nature And Origins Of Workmen's Compensation*, 37 CORNELL L.Q. 206, 232 (1952).

298. *Id.*

299. *Id.* at 233 (stating that all but eight states had adopted the Compensation Acts by 1920 and that Mississippi was the last state to do so in January, 1949).

APPENDIX 1: SERIOUS REPORTABLE EVENTS IN HEALTH CARE—2011 UPDATE³⁰⁰

1. Surgical or Invasive Procedure Events

- A. Surgery or other invasive procedure performed on the wrong site
- B. Surgery or other invasive procedure performed on the wrong patient
- C. Wrong surgical or other invasive procedure performed on a patient
- D. Unintended retention of a foreign object in a patient after surgery or other invasive procedure
- E. Intraoperative or immediately postoperative/postprocedure death in an ASA Class 1 patient

2. Product or Device Events

- A. Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting
- B. Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended
- C. Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a healthcare setting

3. Patient Protection Events

- A. Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person
- B. Patient death or serious injury associated with patient elopement (disappearance)
- C. Patient suicide, attempted suicide, or self-harm that results in serious injury, while being cared for in a healthcare setting

4. Care Management Events

- A. Patient death or serious injury associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)
- B. Patient death or serious injury associated with unsafe administration of blood products
- C. Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting
- D. Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy
- E. Patient death or serious injury associated with a fall while being cared for in a healthcare setting

300. This appendix was adapted from NAT'L QUALITY FORUM, *supra* note 180, at iii–iv.

F. Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission/presentation to a healthcare setting

G. Artificial insemination with the wrong donor sperm or wrong egg

H. Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen

I. Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results

5. Environmental Events

A. Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in a healthcare setting

B. Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or are contaminated by toxic substances

C. Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process in a healthcare setting

D. Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a healthcare setting

6. Radiologic Events

A. Death or serious injury of a patient or staff associated with the introduction of a metallic object into the MRI area

7. Potential Criminal Events

A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider

B. Abduction of a patient/resident of any age

C. Sexual abuse/assault on a patient or staff member within or on the grounds of a healthcare setting

D. Death or serious injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a healthcare setting