

CANDOR

At the Heart of Patient Safety

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“Quality-the relentless striving for excellence and improvement.” – Walt Disney

ABSTRACT Experience suggests that changes to the 1986 Health Care Quality Improvement Act’s name-based reporting requirement would provide a regulatory path capable of fostering effective open communication about preventable medical error without the fear of malpractice claiming. The Agency for Healthcare Research and Quality (AHRQ) developed the Communication and Optimal Resolution (CANDOR) Toolkit with reliance on expert industry input and lessons learned from the AHRQ’s \$23 million Patient Safety and Medical Liability grant initiative launched in 2009. CANDOR processes proactively engage healthcare providers, patients and their family in preventable harm communications. Experience has shown that this culture of open dialogue about preventable medical harm leads to organizational accountability and, when appropriate, successful early resolution. Lessons learned responses; applied system-wide have empirically demonstrated a reduction in future medical error and affiliated costs. Regulatory change has the power to help ally provider fear of litigation, provides for patient and family participation in care while addressing the reputational and economic concern providers face following medical error.

“Fear of the kind engendered by the disciplinary approach poisons improvement in quality, since it inevitably leads to the loss of chance to learn...When one is clear and constant in one’s purpose, when fear does not control the atmosphere (and thus the data), when learning is guided by accurate information... and when the hearts and talents of all workers are enlisted in the pursuit of better ways, the potential for improvement in quality is nearly boundless.”¹

Introduction

Each day across this country, at varying points of service, delivery of high quality health care is the goal.² But that is not the complete picture.³ There are Americans whose encounters fall short.⁴ “Health care in the United States is not as safe as it should be – and can be.”⁵ Curbing most efforts targeting quality improvements and reductions in patient harm is the chilling effect that a “deny-and-defend” approach poses in situations of patient harm by limiting information to patients that have been harmed and by the avoidance of admission of fault – approaches that are destructive to learning and improving.⁶

A 1999 report, based on studies conducted by the Institute of Medicine (IOM) estimated that at least 44,000 people, and perhaps as many as 98,000 people, die in hospitals each year as a result of medical errors that could have been prevented.⁷ Ten years beyond the IOM study, *To Err is Human*, and despite intense focus on patient safety, persistent high incidences of medical error remained.⁸ A 2013 review of four key studies analyzed the methods used to find adverse

¹ Berwick, D., *Continuous improvement as an ideal in health care*, N Engl J Med. 1989; 320:53-56

² Bodenheimer, T., Grumbach, K., *Understanding Health Policy A Clinical Approach*, McGraw Hill, 7th Edition (2016) at 117.

³ Id at 117.

⁴ Institute of Medicine, *To Err is Human: Building a Safer Health System*, (1999) at 1, <http://iom.nationalacademies.org/~media/Files/Report%20Files/1999/To-Err-is-Human/To%20Err>

⁵ See Berwick supra note 1, at 53.

⁶ Communication and Optimal Resolution (CANDOR). Content last reviewed May 2016. Agency for Healthcare Research and Quality, Rockville, MD. <http://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/candor/index.html>

⁷ Id at 1. Defining medical error broadly as the, “failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.”

⁸ Landrigan CP, Parry GJ, Bones CB, Hackbarth AD, Goldmann DA, Sharek PJ, N Engl J Med. 2010; 363:2124-2134. Landrigan et al. conducted a retrospective study of a stratified random sample of 10 hospitals in North Carolina; reviewing a total of 100 admissions per quarter from January 2002 through December 2007 (total of 2341 admissions). A team of both internal and external nurse reviewers conducted the review using the Global Trigger Tool (GTT). Suspected harms, which were identified on initial review, were then evaluated by two independent

events in medical records.⁹ Variations were found in the tools used to detect adverse events leading to potentially greater numbers of medical errors than previously thought, suggesting more assertive action must be taken in addressing patient safety.¹⁰

Pockets of excellence in patient safety have emerged today due to improvements in specific services at individual health care facilities.¹¹ And while excellence across the board is emerging on some important measures, what has eluded the industry is attainment of consistent high-level measures of quality and patient safety over time.¹² Complicating widespread quality improvement and patient safety efforts is the fact that health care delivery has become increasingly complex and fragmented.¹³ This fact heightens the necessity to develop quality and safety solutions that will uniformly and systematically measure and guide health care providers.¹⁴

Communication and Optimal Resolution (CANDOR) is a principled and standardized approach to addressing patient harm, which was developed by the Agency for Healthcare Research and Quality (AHRQ) and represents the largest federal investment in research linking improved patient safety to reduced medical liability.¹⁵ CANDOR domains consist of, (1)

physician reviewers. The study found that harms remain common, with little evidence of widespread improvement.

⁹ James, JT., *A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care*, *Journal of Patient Safety*: September 2013 - Volume 9 - Issue 3 - p 122–128 doi: 10.1097/PTS.0b013e3182948a69 at 124.

¹⁰ Id pp.128. Noting that IOM's *To Err is Human* 1999 Report was based on 1984 data developed from reviews of medical records of patients treated in New York hospitals. James' literature review identified 4 limited studies that used primarily the search capability of the Global Trigger Tool (GTT) to flag specific evidence in medical records. Using a weighted average of the 4 studies however, James determined that a lower limit of the 1999 IOM *To Err is Human* data is 210,000 deaths per year associated with preventable harm in hospitals. The higher limit of the 1999 IOM *To Err is Human* data is 440,000 deaths per year associated with preventable harm in hospitals. The difference in number of preventable adverse events (PAE), even given the limited nature of James' study, was attributed to prevailing views of preventability of an adverse event linked to the commission of an identifiable error that caused an adverse event. The GTT depends on systematic two-tier review of medical records by persons trained to find specific clues or triggers suggesting that an adverse event has taken place.

¹¹ Chassin, M., Loeb, J., *The Ongoing Quality Improvement Journey: Next Stop, High Reliability*, *HealthAffairs*, 2011: 30:559-568.

¹² Id at 562. Stating that pockets of excellence coexist with enormous variability across delivery systems.

¹³ Id at 562. Noting evidence suggests that complexity greatly increases the likelihood of error, especially in systems that perform at low levels of reliability.

¹⁴ Id at 563. Suggesting that available evidence has demonstrated that the risk of harmful error in health care may be increasing. As new devices, equipment, procedures, and drugs are added to our therapeutic arsenal, the complexities of delivering effective care increase.

¹⁵ NPSF News & Press: Industry News, May 23, 2016, *AHRQ Toolkit Helps Health Care Providers Communicate With Patients and Families When Harm Occurs*, <http://www.npsf.org/news/290734/AHRQ-Toolkit-Helps-Health-Care-Providers-Communicate-With-Patients-and-Families-When-Harm-Occurs-.htm> (AHRQ is a health services research

obtaining organizational buy-in and support, (2) preparing for implementation through gap analysis, (3) event reporting, event investigation and analysis, (4) communicate and communication, (5) care for the caregiver and, (6) resolution.¹⁶

CANDOR is systematically applied to respond in a timely, thorough, and just way when unexpected events cause patient harm.¹⁷ Over ten years of empirical data has evidenced that patient safety and quality of care improves when healthcare institutions are empathetic, fair, and just in their approach to medical errors – this approach becoming the catalyst for cultural change, patient safety innovation, and system-wide response mechanisms expediting certain unexpected patient harm events.¹⁸ CANDOR’s in-depth event investigation, analysis, and resolution tools provide a principled framework for avoiding costly malpractice litigation.¹⁹

Openness, honesty, and apology for unexpected patient harm, as embodied by CANDOR processes, has, traditionally, leveled fear in providers of massive payouts due to these actions being construed as admission of guilt.²⁰ And while CANDOR does include admitting liability, in certain circumstances, and offering early financial resolution, a growing number of doctors and hospitals are pushing back against fear believing that protecting patients from preventable harm is the right thing to do.²¹ Preventing future patient harm requires resolution mechanisms that engage stakeholders from within the context and culture surrounding the harm.²²

agency within Health and Human Services that invests in evidence and research to understand how to make the health care system safer and improve quality).

¹⁶ Communication and Optimal Resolution (CANDOR). Content last reviewed May 2016.

Agency for Healthcare Research and Quality, Rockville, MD.

<http://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/candor/index.html>

¹⁷ Communication and Optimal Resolution (CANDOR). Content last reviewed May 2016.

Agency for Healthcare Research and Quality, Rockville, MD.

<http://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/candor/index.html>

¹⁸ Implementation Guide for the CANDOR Process. Content last reviewed May 2016. Agency for Healthcare Research and Quality, Rockville, MD. <http://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/candor/impguide.html>

¹⁹ Diamond, R., *CANDOR Toolkit: Physicians Now Have the Right Tools to Do the Right Thing After an Adverse Event*, The Doctors Company, July 2016.

<http://www.thedoctors.com/KnowledgeCenter/PatientSafety/articles/risk-articles?sub=12>

²⁰ Whitman, E., *Best Practices: Addressing errors with Candor*, Modern Healthcare: 2016,

<http://www.modernhealthcare.com/article/20160813/MAGAZINE/308139997>

²¹ Diamond, R., *CANDOR Toolkit: Physicians Now Have the Right Tools to Do the Right Thing After an Adverse Event*, The Doctors Company (2016). CANDOR toolkit has been tested in 14 pilot hospitals across three U.S. health systems: Christiana Care in Delaware, Dignity Health in California, and MedStar Health in the Baltimore/Washington, D.C. metropolitan area. CANDOR helps hospitals and physicians avoid malpractice litigation, especially the lawsuits motivated not by actual errors or substandard care but by patients and family members who were left angry and abandoned.

²² Committee on Diagnostic Error in Health Care; Board on Health Care Services; Institute of Medicine; The National Academies of Sciences, Engineering, and Medicine; Balogh EP, Miller BT, Ball JR, editors. *Improving Diagnosis in Health Care*. Washington (DC): National

Malpractice insurers hold a range of views about communication-and-resolution programs (CRP) such as CANDOR.²³ However, ideally a CRP would have multiple channels for identifying and investigating a patient harmful event, even if the event were not likely to lead to litigation.²⁴ Richard Boothman, who pioneered the CRP approach at the University of Michigan, stated, “CRP reflects an ethical obligation and a commitment to patient safety.”²⁵

One proponent of approaching medical error using different mechanisms is the Physician Insurers Association of America (PIAA), a leading association representing the medical and healthcare professional liability community.²⁶ PIAA provided expert input and non-financial support to the development of the AHRQ CANDOR toolkit released in May 2016.²⁷ PIAA states that one intent of AHRQ CANDOR toolkit is to improve communications between healthcare professionals and patients and their families when unexpected patient harm occurs.²⁸

The Doctors Company, one of the nation’s largest physician-owned medical malpractice insurers, provided expert input in the development of the AHRQ CANDOR toolkit.²⁹ Over the past decade The Doctors Company has found that the actual effect of acknowledging error with genuine sympathy and concern, is the healing of relationships between health care providers and patients, which in turn has helped hospitals and physicians avoid costly malpractice litigation.³⁰

Academies Press (US); 2015 Dec, *The Path to Improve Diagnosis and Reduce Diagnostic Error* <https://www.ncbi.nlm.nih.gov/books/NBK338589/>. Stating that it is very important to consider diagnosis from a patient-centered perspective, as patients bear the ultimate risk of harm.

²³ Boothman, R., *When There’s Harm in the Hospital: Can Transparency Replace “Deny and Defend”?* Forum Session, March 11, 2016, National Health Policy Forum, www.nhpf.org Suggesting that communication and resolution programs (CRP’s) help remove barriers to the reporting of near misses and errors and encourage open communication about how to prevent future harms.

²⁴ Id at 2.

²⁵ Id at. 2. Noting that the University of Michigan Health Systems CRP program continues today.

²⁶ PIAA News Release: PIAA Comments on Release of AHRQ CANDOR Toolkit, Rockville, MD (May 26, 2016),

https://www.piaa.us/docs/News_Releases/2016_News_Release_CANDOR.pdf

²⁷ Supra note 17. Noting CANDOR toolkit is customizable and available at no charge, providing materials to teach, train, and catalyze health care providers to build capacity to make care safer.

²⁸ Supra note 26. Atchinson, President and CEO, of PIAA states, “ We are hopeful that by promoting a culture of open communication, the CANDOR toolkit will help resolve unanticipated outcomes, and at the same time, diminish the likelihood of subsequent litigation.” PIAA has implemented similar programs to enhance patient-healthcare professional communications finding that they successfully promote a process that healthcare institutions and practitioners can follow to respond rapidly, thoroughly, and equitably in the face of unexpected events.

²⁹ Diamond, R., *CANDOR Toolkit: Physicians Now Have the Right Tools to Do the Right Thing After Adverse Event*: July 2016,

<http://www.thedoctors.com/KnowledgeCenter/PatientSafety/articles/CANDOR-Toolkit-Physicians-Now-Have-the-Right-Tools-to-Do-the-Right-Thing-After-an-Adverse-Event>

³⁰ Id at 1. Stating that physicians have moved progressively toward a culture that expects an adverse event to be followed by a full disclosure of the facts to the patient and family.

The Doctors Company found that where there exists clear-cut circumstances of preventable error, acknowledgement and early resolution of that error avoids the need to file a lawsuit.³¹

One public policy focus is linking patient safety improvements with reductions in medical malpractice risk.³² Improving health care quality and patient safety has been shown to have a significant positive impact on the volume of malpractice claims.³³ This paper will argue that modifications to the 1986 Health Care Quality Improvement Act (HCQIA) are necessary in order to break down barriers that counter addressing growing public concern about quality of care and patient safety. Modifications of the HCQIA will provide the regulatory pathway for widespread adoption of CANDOR processes, which will lead to system-wide open, transparent, honest communications about quality of care and patient safety. Systemwide communications drive change that facilitates sustainable widespread improvements in quality of care and patient safety.

This paper explains CRP's evolution and application across varying institutional settings and its affect on patient safety, medical error and medical liability cost. Part II discusses institutional obstacles to be considered when implementing CANDOR programs. Part III discusses the negative impact on patient safety and quality of care that results from the actual impact of our current medical liability system. Part IV focuses on relevant liability reform measures and their potential affect on implementation of CANDOR-like programs. Lastly, Part V proposes modification to the HCQIA, related to the licensed name-based reporting requirements and peer review protections. These HCQIA modifications provide physicians with the type of communication protections and tools necessary to effectuate widespread improvements in health care quality and patient safety.

Part I

*"The reality is that providers can do everything right and still have poor patient outcomes. We've done a very poor job of explaining that to the public."*³⁴

³¹ Id at 1. Stating that hospital administrators and physicians both can say they're sorry for what happened and even acknowledge they made a mistake in some circumstances when a clear-cut error has occurred that could have been prevented.

³² Greenberg, et al, *Is Better Patient Safety Associated with Less Malpractice Activity? Evidence from California*, RAND, Institute for Civil Justice: 2010, http://www.rand.org/content/dam/rand/pubs/technical_reports/2010/RAND_TR824.pdf

³³ See Berwick supra at 1. Where the authors examined the relationship between safety outcomes in hospitals and malpractice claiming against providers, using administrative data and measures from California from 2001 to 2005. They found that decreases in county-level frequency of adverse safety outcomes were positively and significantly associated with decreases in the volume of malpractice claims, as captured by records from four of the largest malpractice insurers in the state.

³⁴ Whitman, E., *Best Practices: Addressing errors with Candor*, Modern Healthcare, August 13, 2016. <http://www.modernhealthcare.com/article/20160813/MAGAZINE/308139997>

A statement from Julia Hallisy, founder and president of the Empowered Patient Coalition, which is an advocacy group that surveyed patients on adverse medical events and is devoted to

The Lexington, Kentucky, Veterans Affairs (VA) Medical Center pioneered CRP.³⁵ “In 1987, the Lexington VA implemented its CRP, which provided a full disclosure of the occurrence that led to harm as well as an expression of regret on behalf of the institution and its personnel.”³⁶ “A patient had died because of a medical error, and the family had no idea.”³⁷ The doctors decided they had an ethical duty to tell the family leading the hospital to handle all subsequent cases the same way, a policy that remained unwritten for a decade.³⁸

As a result of this initiative, the \$1.33 million that the Lexington VA paid out in total malpractice claims and liability payments from 1990 through 1996 was in the bottom third of 35 other VA facilities, although that facility ranked in the top third for the number of claims filed.³⁹ During this seven-year period, the Lexington VA facility had 88 malpractice claims and paid out an average of \$190,113 per year with average payment per claim of \$15,622.⁴⁰ And while the financial consequence was moderate, it is important to note that the Lexington VA did not simultaneously track metrics on quality and patient safety.⁴¹ The VA eventually created an institutional-wide policy and adopted a clear and systematic process for disclosure of adverse events to patients, believing this approach to be the right thing to do, however, no other VA facility adopted this approach and process improvement and resolution were never linked to Lexington VA’s patient disclosure policy.⁴²

helping the public improve the quality and the safety of their healthcare

<http://empoweredpatientcoalition.org/>.

³⁵ Kass, J., Rose, R., *Medical Malpractice Reform-Historical Approaches, Alternative Models, and Communication and Resolution Programs*, AMA Journal of Ethics, March 2016, Vo 18, Number 3: 299-310, <http://journalofethics.ama-assn.org/2016/03/pfor6-1603.html>

³⁶ Id.

³⁷ See Berwick supra note 1.

³⁸ Id. Noting that Dr. Steve Kraman, a professor at the University of Kentucky, pioneered a CRP program while heading up the risk management committee at Lexington VA in 1987.

³⁹ Id.

⁴⁰ Kraman, S., Hamm, G., *Risk Management: Extreme Honesty May Be the Best Policy*, *Annals of Internal Medicine*, Medicine and Public Policy, (December 21, 1999)

<http://annals.org/aim/article/713181/risk-management-extreme-honesty-may-best-policy>

⁴¹ Id at 964. Where a comparison was done of tort claim experience of Lexington VA with that of all similar Veterans Affairs medical centers located east of Mississippi (n=35). What was found was that Lexington VA’s liability payments have been moderate and was comparable to those of similar Veterans Affairs. There was a belief that the decrease in liability payments was attributable in part to the fact that the facility honestly notifies patients of substandard care and offers timely, comprehensive help in filing a claim thereby diminishing anger and desire for revenge that often motivates patients’ litigation. However, it should be noted that this VA paper did not look at the impact of their CRP approach on quality and patient safety metrics.

⁴² Dudzinski, DM, et al., *The Disclosure Dilemma – Large-Scale Adverse Events*, *N Engl J Med* 363, no. 10 (September 2, 2010): pp. 978-986,

<http://www.nejm.org/doi/full/10.1056/NEJMh1003134>, Kraman, S., Hamm, G., *Risk Management: Extreme Honesty May Be the Best Policy*, *Annals of Internal Medicine*, 131, no. 12 (December 21, 1999): pp. 963-967, <http://annals.org/aim/article/713181/risk-management->

It is difficult to accurately compare the VA's experience with the private sector because unlike the private sector, the VA's medical system provides comprehensive free universal coverage to veterans and government health care providers are protected from personal liability and pay no malpractice premiums.⁴³ However, this is one of the first full disclosure health care facility policy's suggesting that being extremely honest with the patient does not cause a financial disaster related to payouts for inappropriate or substandard care.⁴⁴

In 2001, the University of Michigan Health System (UMHS) became the first private sector health system to adopt a CRP-like model, explicitly providing for open discussion about medical error and, where warranted, settlement.⁴⁵ UMHS's program, called disclosure, apology and offer (DA&O) or the "Michigan Model", had dual goals, patient safety improvement⁴⁶ and malpractice cost reduction.⁴⁷ The Michigan Model initiated a vigilant institutionally cultural shift

extreme-honesty-may-best-policy. Noting that risk managers at other VA centers encouraged physicians to be honest and forthcoming with patients, but it seemed that no organized effort was made to standardize or track the notification of affected patients. The word apology is never used in their full disclosure process and no link exists to process improvement. Their process involved notifying the patient of negligence and a face-to-face meeting with subsequent claim preparation assistance. The article concludes singularly that honest and forthright risk management policy that puts the patient's interests first may be relatively inexpensive because it allows avoidance of lawsuit preparation, litigation, court judgments, and settlements at trial.

⁴³ Id. Noting that government health care providers are reported to the National Practitioner Data Bank (NPDB) and state licensure boards and must acknowledge their involvement with malpractice cases on all future employment applications. The greatest barrier to adopting CRP in nongovernmental hospitals was stated to be malpractice insurers. A special report from the Bureau of Justice Statistics indicated that the average medical malpractice judgment in the private sector was \$1,484,000 compared to the Veterans Affairs systems \$720,000.

⁴⁴ Kraman, S., Hamm, G., *Risk Management: Extreme Honest May Be the Best Policy*, *Annals of Internal Medicine*, 131, no. 12, pp. 963-67 (December 21, 1999) <http://annals.org/aim/article/713181/risk-management-extreme-honesty-may-best-policy>. Concluding that an honest and forthright risk management policy that puts the patient's interests first may be relatively inexpensive because it allows avoidance of lawsuit preparation, litigation, court judgments, and settlements at trial.

⁴⁵ The Michigan Model: Medical Malpractice and Patient Safety at UMHS, <http://www.uofmhealth.org/michigan-model-medical-malpractice-and-patient-safety-umhs#summary>. UMHS importantly notes that their approach to medical malpractice claims is closely linked with their patient safety.

⁴⁶ Boothman, R., Imhoff, S., Campbell, D., *Nurturing a Culture of Patient Safety and Achieving Lower Malpractice Risk through Disclosure: Lessons Learned and Future Directions*, *Frontiers of Health Services Management* 28:3, 17. Noting the initial backbone of the Michigan Model being claims management. Beginning in 2001, three principles were circulated for approval among those involved in UMHS claims management: 1) Compensate patients quickly and fairly when unreasonable medical care caused injury, 2) If the care was reasonable or did not adversely affect the clinical outcome, support caregivers and the organization vigorously, and 3) Reduce patient injuries (and therefore claims) by learning through patients' experiences.

⁴⁷ Bell, S., Smulowitz, P., Woodward, A., et al., *Disclosure, Apology, and Offer Programs: Stakeholders' Views of Barriers to and Strategies for Broad Implementation*, *Milbank Q.* 2012

toward reporting incidents, proactive data analysis of internally driven safety indicators, and review of patient and provider expectations, effectively displacing a focus on medical malpractice.⁴⁸

Administrators and providers at UMHS were initially concerned that full disclosure about errors would invite more claims and larger settlements but the opposite has been the case.⁴⁹ And while patient injury data was not reported, before and after claims experience was published showing ... “the average rate of monthly malpractice claims fell from 7.03 to 4.52 per 100,000 patient encounters, while the rate of lawsuits for the same period of encounters decreased from 2.13 to 0.75 ...with associated decline in average costs related to total liability, patient compensation, and legal costs”.⁵⁰ The Michigan Model has also been the catalyst for innovative honest and transparent peer review.⁵¹

Dec; 90(4): 682-705. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3530738/> and <http://www.uofmhealth.org/michigan-model-medical-malpractice-and-patient-safety-umhs>

⁴⁸ Id. DA&O models respond to patient injuries caused while rendering medical care. Initially using the opportunity offered by Michigan’s compulsory preliminary notice of intent to sue, unanticipated clinical outcomes are now identified quickly. While the process is tailored to each individual case, patients and families are generally contacted by risk management consultants, who ensure that new clinical care needs are met, oversee the hospital’s investigation, review patients’ and providers’ expectations, and ensure full disclosure. Patients and families are kept informed, receive full disclosure, and also receive an apology, with an offer of compensation when appropriate.

⁴⁹ Id. UMHS’s DA&O program is directly linked to the patient safety and peer review infrastructure that dominates the overriding institutional focus. Reports did find that culturally, the focus had shifted to safety, built on a commitment to honesty and transparency.

⁵⁰ Gavin, K., *Hospitals Can Break Through the ‘Wall of Silence’ with New Toolkit*, Industry DX (May 23, 2016), <http://labblog.uofmhealth.org/industry-dx/hospitals-can-break-through-wall-of-silence-new-toolkit>.

Boothman, R., et al., *When There’s Harm in the Hospital: Can Transparency Replace “Deny and Defend”?* National Health Policy Forum, Forum Session (March 11, 2016) <http://www.nhpf.org/library/details.cfm/3008>

⁵¹ Boothman, R., Imhoff, S., Campbell, D., *Nurturing a culture of patient safety and achieving lower malpractice risk through disclosure: lessons learned and future directions*, Front Health Serv. Manage, 2012 Spring; 28(3): 13-28. Stating that as a direct consequence of UMHS’s embracement of honesty and transparency, they boldly refined their innovative approach to peer review. Reasoning that peer review should be relevant and proactive, departments were challenged to identify events particular to their practice that would mark potential patient safety concerns. In many departments, caregivers’ clinical performances are measured directly against those of their colleagues, and outliers can be identified and corrected early. As the metrics are clinically relevant, the system was embraced as an integral part of departmental quality initiatives. The approach loses its disciplinary feel with earlier intervention and its promise to embrace and improve. This kind of peer review would not be possible in a deny-and-defend environment. It is important to note that this early data was critical to the disclosure movement. <https://www.ncbi.nlm.nih.gov/pubmed/22432378>

In 2007, Stanford University Medical Network developed a CRP program called Process of Early Assessment, Resolution and Learning (PEARL).⁵² Growing national dialogue concerning preventable patient medical errors and rising litigation and claim costs provided the catalyst for Stanford when they initiated a proactive approach to claims management, which was better aligned with Stanford's beneficent mission.⁵³ Initially, Stanford's PEARL program was strictly a claims management process, with no connection to quality of care or patient safety.⁵⁴ Eventually The Risk Authority Stanford included mechanisms to increase patient safety and reduce additional risks.⁵⁵ Stanford University Medical Networks PEARL, which was well received by patients, experienced, in the first 3.5 years after implementation, a claim frequency drop of 36% leading to cost savings of \$3.2 million per fiscal year.⁵⁶

University of Illinois Medical Center (UIC) and the University of Washington (UW) were among four health systems piloting disclosure and resolution programs (DRPs) under President Obama's 2009 directive to the U.S. Department of Health and Human Services (HHS) authorizing the Patient Safety and Medical Liability (PSML) demonstration project.⁵⁷

UIC's demonstration project intended to answer the question of whether UIC's existing Seven Pillar DRP model, in place since 2006, was a good fit for other community hospitals.⁵⁸ The data inconclusively showed portability of Seven Pillars outside UIC, however, the project experience proved that it was possible to package training and tools to disseminate DRP to other community hospitals settings.⁵⁹ Longitudinally, UIC's DRP data showed a 42% reduction in the number of malpractice claims, a 51% reduction in cost per malpractice claim, and a 47% reduction in the number of lawsuits.⁶⁰

⁵² Wilhelm, S., *The Value of Communication and Resolution Programs*, The Risk Authority Stanford (May 19, 2014), <http://theriskauthority.com/communication-resolution-programs/>

⁵³ Id. Commenting on recommendations for mitigating the challenges brought to health care by litigation. A position paper, "Medical Liability Reform: Innovation Solutions for a New Health Care System," as released by the American College of Physicians endorsed CRP's aimed at avoiding legal expenses, learning from unintended medical outcomes, bringing healing to patients and improvements to patient safety.

⁵⁴ <http://www.stanfordchildrens.org/en/patient-family-resources/pearl>

⁵⁵ <http://theriskauthority.com/solutions/pearl/>

⁵⁶ See Wilhelm *supra* note 52.

⁵⁷ James Bell Associates, RAND Corporation, *Longitudinal Evaluation of the Patient Safety and Medical Liability Reform Demonstration Program Demonstration Grants Final Evaluation Report*, AHRQ Publication No. 16-0038020EF (May 2016). Noting that UIC had previously employed a relatively strong research design for assessing the impact of the DRP (Seven Pillars) intervention and their longitudinal data suggested significant impact of the intervention (DRP) on both patient safety and malpractice outcomes. UIC massively increased event reporting over time. Published research showed major increases in interdisciplinary event review and process improvements. The intervention studied at UW was disclosure and apology coaching training, which UW reports provided no statistical conclusion about impact, however; overall, the project trained almost 400 disclosure and apology coaches.

⁵⁸ Id at 15.

⁵⁹ Id at 15.

⁶⁰ Id at 3, Table 1.

Over the course of the three-year demonstration project, a large number of health care providers at the UW trained in disclosure and apology (over 1,300) gaining strong teaching skills in DRP.⁶¹ This project helped set standards for identifying organizational champions and change teams which subsequently was utilized by other organizations undertaking DRP implementation.⁶²

The Patient Protection and Affordable Care Act (ACA) of 2010 provided for various alternative payment models, the largest of which was the Accountable Care Organization (ACO) model.⁶³ ACO's operate as integrated health care delivery configurations with redesigned care processes piloted with the goal to improve quality, efficiency, and health care costs.⁶⁴ ACOs create large concentrations of physicians, which organizationally have their own internal systems for monitoring quality issues and patient outcomes - both measures being directly tied to reimbursement.⁶⁵ However, ACO's shift the focus of care outcomes from the individual to the organization.⁶⁶

Transparent communication, a key tenet of a 2012 coalition in Massachusetts, led to implementation of the Communication, Apology and Resolution (CARE) program approach which, focused on avoiding medical injury through reform of the medical liability system in Massachusetts.⁶⁷ Partnering in CARE's implementation and study were unusual participants: the Massachusetts Bar Association, the Massachusetts Academy of Trial Attorneys and the Massachusetts Medical Society.⁶⁸ Plaintiff and defense attorney's support CARE-like approaches to medical injury because CARE-like programs encourage and support disclosure of medical errors, improve patient-provider relationships, and produce innovative open-mined patient safety initiatives.⁶⁹

⁶¹ Id at 20-21.

⁶² Id at 20-21.

⁶³ Pub. L. No. 111-148, Sec. 3022 Mar 23, 2010, *Medicare shared savings program; What's an ACO?* <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ACO/index.html?redirect=/Aco>

⁶⁴ Furrow, B., Greaney, T., Johnson, S., et al., *Health Care Reform Supplementary Materials*, West 2012 Edition, Ch. 11 at 210-216.

⁶⁵ Ho, P., *HCQIA Does Not Provide Adequate Due Process Protection, Improve Healthcare Quality And Is Outdated Under "Obamacare"*, 11 Ind. Health L. Rev. 303 at 338 (2014).

⁶⁶ *Infra* note 111, at 693.

⁶⁷ Catalano, J., Buchsbaum, L., *CARE: an alternative to medical malpractice litigation*, Lawyers Journal, MASSBAR Association (March 2015) <http://www.massbar.org/publications/lawyers-journal/2015/march/care-an-alternative-to-medical-malpractice-litigation>. Stating that CARE was modeled after programs like the University of Michigan Health System and Stanford, promoting early resolution in cases of avoidable medical injury.

⁶⁸ *Id.* Noting that this partnership originated from the Massachusetts Alliance for Communication and Resolution following Medical Injury (MACRMI) funded by AHRQ in 2010 and included teaching hospitals and their insurers, patient safety and advocacy groups, and state-wide organizations dedicated to improving the medical liability system.

⁶⁹ *Id.* Noting the CARE program is ongoing. The Massachusetts Bar Association and MACRMI have produced best practice tools based on data from the eight pilot health systems studied providing attorneys and health care providers with guidance when CARE program is implicated.

In 2012, Massachusetts Alliance for Communication and Resolution following Medical Injury (MACRMI) partnership aided in the passage of Massachusetts enabling legislation comprehensively adopting the CARE program for resolution of medical harm claims in varying practice environments having differing insurance arrangement, which, included a 182-day wait period⁷⁰ to permit for disclosure, apology and offer processes - providing for strong apology protections, sharing of pertinent medical records, and expectations of full disclosure.⁷¹ However, Massachusetts's not-for-profit hospitals have legal immunity limiting the amount of tort damage awards.⁷² Not-for-profit health systems with legal immunity have less incentive to try innovative transparent responses to medical harm because the legal immunity changes the dynamics of hospital malpractice cases and draws attention to differing interests among defendants thereby presenting a barrier to adoption of CRPs.⁷³

Oregon's Early Discussion and Resolution (EDR) process became law in 2013 and represents one of the first statewide efforts in open and transparent communications towards resolution of adverse events.⁷⁴ Either the patient or healthcare professional initiates EDR conversations and while currently no mechanism exists in Oregon to capture the number of statewide medical malpractice cases, two years of provider Resolution Reports indicated that 47% of discussions resulted in early resolution.⁷⁵

Medstar Health⁷⁶, Christiana Care⁷⁷, and Dignity Health⁷⁸ are among a few health systems piloting AHRQ's CANDOR processes, customizing CANDOR's framework to

⁷⁰ Mass. Gen. Laws, chap. 231, sec. 60L.

⁷¹ Waltham, *Landmark Agreement Between Physicians and Attorneys Provides for Medical Liability Reforms in Massachusetts*, Massachusetts Medical Society (August 7, 2012) <http://www.massmed.org/News-and-Publications/MMS-News-Releases/Landmark-Agreement-Between-Physicians-and-Attorneys-Provides-for-Medical-Liability-Reforms-in-Massachusetts/>

⁷² Mass. Gen. Laws, chap. 231, sec. 85K

⁷³ Sage, W., Gallagher, T., Armstrong, S., et al., *How Policy Makers Can Smooth The Way For Communication-And-Resolution Programs*, *Health Affairs* 33, no. 1 (2014): 11-19. doi: 10.1377/hlthaff.2013.0930. Noting that hospitals with immunity have less incentive to try new approaches to responding to medical injuries, while physicians may resist transparency because they become the "deep pocket" from which the plaintiff in any lawsuit hopes to collect damages. Massachusetts's hospitals have nonetheless moved forward with CRPs. The principles of the communication-and-resolution process suggest that hospitals should make offers of greater than the maximum payout if the amount is needed to fairly compensate the patient for his or her losses.

⁷⁴ OR SB 483, effective July 1, 2014.

⁷⁵ Oregon Patient Safety Commission, *Early Discussion & Resolution Annual Report July 2014 – June 2016*, (Oct. 2016) at 4 – 12. Noting malpractice data collection limitations in Oregon, which may be remedied through the recent transition to the eCourt system.

⁷⁶ <https://www.medstarhealth.org/quality-and-safety/communication/candor-program/#q={ }>

⁷⁷ <http://news.christianacare.org/2015/10/christiana-care-implements-candor/>

⁷⁸ AHRQ Toolkit Helps Health Care Organizations and Providers Communicate With Patients and Families When Harm Occurs. Content last reviewed May 2016. Agency for Healthcare Research and Quality, Rockville, MD. <http://www.ahrq.gov/news/newsroom/press-releases/2016/candor.html>. CANDOR process was tested and applied in 14 hospitals across three health systems at press release time with expansion of use underway.

accommodate their organizational structures, and continue as leaders, journeying with other health care organizations deploying significant system transformations such as just culture and sustainable comprehensive patient safety improvements.⁷⁹

The significance of a relationship between patient safety, quality of care and malpractice claiming suggests that tools seated in reducing the footprint of preventable patient harm in the health care delivery setting have the greatest potential for reducing provider malpractice pressures, which, in turn, sets up an environment conducive to learning and teaching sustainable system-wide improvement in safe care.⁸⁰ This relationship between patient safety and malpractice, historically rooted in deterrence of provider negligence, has been incompletely analyzed because deterrence of provider negligence does not entirely equate to patient safety, having *its* roots instead in a very different logic model of systems.⁸¹

Part II

A healthcare provider who makes a patient safety error should be at no risk to openly acknowledge that error, with, or without statutory protections and should be provided with responses and tools that are directly targeted at what might drive a patient to seek legal recourse in the first place.⁸²

CANDOR's principled approach incorporates triggered actions with response broadly including; 1) early patient harm event reporting, 2) careful analysis at the institution level, 3) prompt, supportive, and compassionate ongoing communication to the patient and/or family, 4) fast, fair resolution for the patient and/or family where warranted, and, 5) lesson learning applied system-wide in a just environment.⁸³ CANDOR, as a quality and patient safety program, rises around clinicians when supported by leadership and champions who embrace the idea that cultural change can be challenging while also realizing that metrics and internal stakeholders side by side will shift cultural ideologies paving the way for system-wide peer support transformation.⁸⁴

⁷⁹ Quigley, K., et al., *On a Journey to High-Reliability – A Systems Approach to Communication & Resolution Program Implementation*, MedStar Health Research Institute (Nov 9, 2015) http://www.marylandpatientsafety.org/documents/minogue/On_A_Journey_to_High_Reliability.pdf

⁸⁰ Greenberg, M., Haviland, A., Ashwood, J., Main, R., *Is Better Patient Safety Associated with Less Malpractice Activity? Evidence from California*, Technical Report, RAND Institute For Civil Justice (2010)

⁸¹ *Id.* at 15.

⁸² Boothman, R., Blackwell, A., Campbell, D., Commiskey, E., Anderson, S., *A Better Approach to Medical Malpractice Claims? The University of Michigan Experience*, Jr Health & Life Sciences Law, Vo 2, N 2, (Jan 2009) pp. 133-134.

⁸³ *Id.*

⁸⁴ Module 6: Care for the Caregiver. Content last reviewed February 2017. Agency for Healthcare Research and Quality, Rockville, MD. <http://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/candor/module6-notes.html>

Studies have shown patients and families want to hear from their healthcare provider when something has gone wrong with their care.⁸⁵ Studies also show that the top priorities of patients and families, when receiving information about medical error include, readily presented explanation, acknowledgement of responsibility in a non-defensive manner, sincere regret in the form of apology, and a commitment to prevent recurrence.⁸⁶

The American Medical Association Code of Medical Ethics, modernized in June 2016, states that “a physician shall ... be honest in all professional interactions and ... recognize a responsibility to seek change ... when laws are contrary to the best interest of the patient”.⁸⁷ This language implies strong healthcare industry consensus that today’s healthcare providers endorse disclosure of all patient harmful events.⁸⁸ Studies show, however, that the biggest barrier to honest open disclosure of medical error is fear of litigation.⁸⁹

A seeming barrier to disclosure is the potential that early disclosure will result in more settlements.⁹⁰ Another barrier is lack of education on the merits of early disclosure, which leads some plaintiff attorneys to advise their clients to reject early settlement because similar cases have, in the past, reaped high awards in malpractice litigation.⁹¹ And while state laws such as damage caps and charitable immunities may have to be considered in traditional settlement negotiations, in the context of CANDOR, with compensatory goals nonaligned to approximate jury awards but rather directly aligned with the patients and families needs, caps and legal immunities pose less of a barrier.⁹² Further, some form of legal representation ensures that distressed patients and families are able to present their claims with clarity and helps reduce apprehension that hospitals and liability insurers might feel initially in working directly with patients and families in resolution of claims.⁹³

⁸⁵ Wu, A., Boyle, D., Wallace, G., Mazor, K., *Disclosure of adverse events in the United States and Canada: an update, and a proposed framework for improvement*, Jr Public Health Research, Vo 2:e32 (2013) pp. 187.

⁸⁶ Id.

⁸⁷ Brotherton S, Kao A, Crigger BJ. *Professing the Values of Medicine*The Modernized AMA Code of Medical Ethics. JAMA. 2016; 316(10): 1041-1042. doi: 10.1001/jama.2016.9752

⁸⁸ Wu, A., et al., *Disclosure of adverse events in the United States and Canada: an update, and a proposed framework for improvement*, Jr Public Health Research, Vo 2:e32 (2013) pp. 188-189. However noting a 2013 survey of 1891 physicians found that only two thirds completely agreed with disclosing serious medical errors to the patient and almost one fifth did not completely agree that doctors should never tell a patient something untrue; a total of 20% admitting they had not fully disclosed an error because of fear of litigation which suggests, in total, and based on other studies, that physicians do not routinely disclose errors when they occur.

⁸⁹ Id at 188. Noting that despite the universal endorsement of disclosing adverse events, studies suggest disclosure of errors is not ubiquitous, occurring in only approximately 30% of medical error cases.

⁹⁰ Id at 188-189.

⁹¹ Infra note 141, at 13.

⁹² Id.

⁹³ Id at 15. Noting CRPs may require assistance from state courts, legislatures, and bar associations to develop low-cost alternatives to traditional legal representation. For example, AHRQ’s project in Washington State assembled a task force of attorneys, patient advocates, and risk management experts to explore models of hourly legal representation for CRP patients.

Literature is replete with recommendations on how to communicate medical error however gaps remain between actual practice and recommendations.⁹⁴ Compounding communication problems is information flow barriers, the result of silo-type organizational design, which has been found to lead to substandard communication patterns having long-term implications for patient-safety perceptions and attitudes among staff.⁹⁵ This communication problem brings challenges to procurement of organizational champions capable of identifying and advancing system-wide disclosure buy-in.⁹⁶ Systematic collection of all types of patient data in a non-silo fashion, compiled as the patient moves through the health care setting is not new ideology.⁹⁷ In 1920 Ernest Codman, a Boston doctor, advocated strong approaches to patient data extrapolation and error reduction by suggesting hospitals and physicians track “end-result” information.⁹⁸ Codman’s systematic approach to data collection built upon a comprehensive patient medical record was revolutionary, pursuing the ‘why not’s’ of treatment failure or error and was meant to serve as an auditing function to be used to evaluate procedures, compare outcomes and benchmark provider performance.⁹⁹

A culture of silence is multi-faceted and contains many contributory factors including, attitudinal perfectionism, lack of control over the healthcare provider’s part once disclosure has occurred, lack of institutional and peer support after disclosure, uncertainties as to how and what to disclose, and of course, the fear of legal and professional ramifications subsequent to a disclosure.¹⁰⁰ And should litigious proceedings ensue, breakdowns in communication, a creature of the culture of silence, is further exacerbated by laws meant to protect confidentiality and restrictions on communications, ultimately leading to maladaptive coping behaviors in healthcare providers.¹⁰¹

In one study, focus group provider participants reported that the impact of restricted communication after exposure to a traumatic patient adverse event was significant; the participants explained,

⁹⁴ Supra note 88, at 188.

⁹⁵ Scott, S., *Second Victim Support: Implications for Patient Safety Attitudes and Perceptions*, Patient Safety & Quality Healthcare (2015) <http://www.psqh.com/analysis/second-victim-support-implications-for-patient-safety-attitudes-and-perceptions/>

⁹⁶ Id.

⁹⁷ Furrow, B., *Regulating Patient Safety: Toward A Federal Model Of Medical Error Reduction*, 12 Widener L. Rev. 1 (2005).

⁹⁸ Id at 28-29.

⁹⁹ Id. Codman’s analysis compared bad outcomes to waste products and would have provided hospitals and providers with both patient outcomes and provider performance and would have established a culture of reporting and would have assessed a hospital’s efficiency in therapeutic, outcome-based terms.

¹⁰⁰ Hill-Davis, N., Youngberg, B., *Full Disclosure As A Risk Management Imperative*, Principles of Risk Management and Patient Safety, Jones & Bartlett Learning (2011), pp. 216-218 (noting that the culture of silence is not easily dismantled and that to eliminate disclosure barriers, institutions must address these factors).

¹⁰¹ Trent, M., Waldo, K., Wehbe-Janek, H., et al., *Impact of health care adversity on providers: Lessons learned from a staff support program*, Jr of Healthcare Risk Management, American Hospital Association, Vo 36:2 pp. 27-31 (2016)

And they tell you not to talk about it, so you don't feel at liberty to talk about it, not even to your boss. And my friends became the litigation people up there, the people I could talk to.¹⁰²

If leadership isn't supportive and compassionate [toward] staff, if they don't have empathy toward us, how can we have empathy for the patient and take care of them? It is not OK just to say you need to grow some skin and get over it.¹⁰³

Unaddressed traumatized physicians suffer in silence leading to a health care environment where physicians become 'second victims' of health care errors, which exposes the 'third victim', the institution, to aftershock.^{104 105} 'Second victims' often drop out and often face reputational damage in their current occupational framework.^{106 107} The 'second victim' reality faces a time in our country when research confirms that a supply shortage of physicians exists – something that may increase the potential for an occurrence of patient medical error while demand for services is increasing.¹⁰⁸

Additionally, the second victims' emotional state interferes with subsequent patient encounters and increases the risk of committing subsequent errors which has been found to erode the physician's confidence leading to loss of emotional and cognitive empathy, burnout and depression.¹⁰⁹ These effects lead physicians to feelings permanently wounded and

¹⁰² Id at 31.

¹⁰³ Id at 32.

¹⁰⁴ Scott, S., McCoig, M., *Care at the point of impact: Insights into the second-victim experience*, Jr of Healthcare Risk Management, American Hospital Association, Vo 35:4 pp. 6-13 (2016)

¹⁰⁵ Daniels, R., McCorkle, R., *Design of an Evidence-Based "Second Victim" Curriculum for Nurse Anesthetists*, AANA Journal, Vo 84:2 pp. 107-108 (April 2016). The authors pointing out little to no training occurs in the actual management of intraoperative morbidities or death, including the aftermath of such events; however, other stressful occupations, such as firefighters, pilots, and police officers, receive education about the expected stressors and potential catastrophic events that can and do occur.

¹⁰⁶ Id at 108.

¹⁰⁷ National Patient Safety Foundation, Lucian Leape Institute, *Shining A Light Safer Health Care Through Transparency* (2015) <http://www.npsf.org/?shiningalight>

¹⁰⁸ Kirch, D., *New Research Confirms Looming Physician Shortage*, Presidential Statements and Speeches, Association of American Medical Colleges (2016) https://www.aamc.org/newsroom/newsreleases/458074/2016_workforce_projections_04052016.html

¹⁰⁹ West, C., Huschla, M., Novotny, P., et al., *Association of Perceived Medical Errors With Resident Distress and Empathy A Prospective Longitudinal Study*, JAMA 2006; 296(9): 1071-1078. doi: 10.1001/jama.296.9.1071. Noting that many reports on medical errors focus on the rate at which errors affect patients while few report on the proportion of physicians who commit errors.

depersonalized, which, coupled with a complex patient care delivery setting, sets up significant coping hurdles to effective management of medical errors.¹¹⁰

Studies provide strategies to overcome physician disclosure discomfort, which included organizational ‘coaching’ models in the form of peer mentoring, led by champion physicians, experienced in error disclosure that rely on clear disclosure protocols incorporating the patient and family in training.¹¹¹ Study respondents also viewed disclosure as a critical skill for health care providers that should be incorporated into medical education at the university level and could be set forth as one requirement in state licensing.¹¹²

Adopting and implementing CANDOR processes require a type of onboarding of *all* organizational stakeholders having a shared vision and support from strong leadership to be successful.¹¹³ Gap Analysis is performed for this purpose— to prepare an organization for successful implementation of CANDOR processes.¹¹⁴ Once implemented, however, CANDOR’s proactive approach cultivates attitudinal shifts consistent with those of an environment of openness and inquiry leading to reporting of all medical error, including near misses.¹¹⁵ Just culture organizational structures have been shown to lead to higher quality patient safety metrics, provide an ethical pathway to preventable error disclosure, which reduces future medical liability claiming and costs.^{116 117}

¹¹⁰ Id. Noting that previous studies showed a link between personal distress and empathy - in turn personal distress negatively affects patient care.

¹¹¹ Bell, S., Smulowitz, P., Woodward, A., et al., *Disclosure, Apology, and Offer Programs: Stakeholders’ Views of Barriers to and Strategies for Broad Implementation*, *Milbank Quarterly*, Vol. 90 No. 4 at 693 (2012).

¹¹² Id at 693. Stakeholders in the study noted that most physicians are not adequately trained or supported in disclosure processes, since such open communication about error is a radical departure from prior practices and prevailing medical culture.

¹¹³ Module 3: Preparing for Implementation: Gap Analysis. Content last reviewed April 2016. Agency for Healthcare Research and Quality, Rockville, MD.

<http://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/candor/module3-notes.html>

¹¹⁴ <https://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/candor/module3-notes.html>

¹¹⁵ Hu, Y., Fix, M., Hevelone, N., et al., *Physicians’ needs in coping with emotional stressors: the case for peer support*, *Arch Surg*. 2012, 147(3): 212-217. doi: 10.1001/archsurg.2011.312

¹¹⁶ Module 8: Organizational Learning and Sustainability. Content last reviewed April 2016. Agency for Healthcare Research and Quality, Rockville, MD.

<http://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/candor/module8-notes.html>

¹¹⁷ Mello, M., Boothman, R., McDonald, T., et al. *Communication-And-Resolution Programs: The Challenges And Lessons Learned From Six Early Adopters*, *Health Affairs* 33, no.1 (2014): 20-29. doi: 10.1377/hlthaff.2013.0828

Part III

According to the weight of evidence, traditional efforts to reform the malpractice system in the United States have failed to address the two main purposes of the malpractice system – that of compensating patients negligently injured and deterrence of those who provide substandard patient care.¹¹⁸ Tort reform faces the legal barrier of immunity, which place limitations on not-for-profit providers’ or government providers’ tort liability damages and/or bars suits.¹¹⁹ Legal immunity presents an obstacle to the use of CANDOR-like programs because immunity shields provider’s financial responsibility for patient harm (thereby reducing patient harm deterrence), which will lead to diminished interest in patient safety investments.^{120 121} And while fundamental widespread change to immunity laws would level the playing field among providers,¹²² change is unnecessary where compensation for medical harm reflects a fair value irrespective of immunity insulations.¹²³ The emergence of Accountable Care Organizations, where focus is on organizational accountability for safety and care outcomes¹²⁴ reflects policy and public sentiment shifting toward shining a light on efforts that will create greater transparency and increased accountability while providing a path away from traditional deny and defend.¹²⁵

Patient harm viewed through the lens of the court produces results demonstrating a lack of ability to consistently determine meritorious from non-meritorious claims when making compensation determinations.¹²⁶ Patient compensation for injury, as empirically studied by Mello and Studdert, reinforces other studies indicating that only 2.5 % of negligently injured

¹¹⁸ Mello, M., Studdert, D., Kachalia, A., *The Medical Liability Climate and Prospects for Reform*, doi: 10.1001/jama.2014.10705

¹¹⁹ See Sage et al. note 141, at 13.

¹²⁰ See Bell et al. note 111, at 690. Noting, at the time of this study, Massachusetts’s law limited to \$20,000 the tort liability of any charitable corporation, trust, or association (which includes nonprofit hospitals and health care institutions. However, Massachusetts, in its effort to move forward with CRP’s, recently modified its charitable immunity to increase the limit on nonprofit hospitals’ malpractice liability to \$100,000, which is still a small amount (Mass. Gen. Laws, chap. 231, sec. 85K).

¹²¹ See Sage et al. note 141, at 14.

¹²² *Id.*

¹²³ See Bell et al. note 111, at 690-693. Pointing out that since the charitable immunity law does not affect settlements, hospitals could (and often do) choose to offer compensation above the cap, out of a sense of fairness, compassion, and/or regret over avoidable injuries.

¹²⁴ *Id.* at 693. Where organizational accountability stands above individual responsibility for outcomes - a voluntary assumption of responsibility for system-based errors reflects a more appropriate level of institutional accountability.

¹²⁵ Boothman, R., Scott, S., Mayer, D., Catalano, J., Haskell, H., *When There’s Harm in the Hospital: Can Transparency Replace “Deny and Defend”?* National Health Policy Forum Speaker Presentation (March 2016) https://www.nhpf.org/library/forum-sessions/FS_03-11-16_PatientSafety.pdf

¹²⁶ Liang, C., *Rethinking The Tort Liability System And Patient Safety*, 12 Ind. Health L. Rev. 327 at 344.

patients actually can and will bring a claim, which speaks to a tort system unable to connect in a significant way to deterrence, and unable to compensation intended injured patients.¹²⁷

Deterring negligent behavior therefore is compromised in a tort system unable to compensate where evidence exists to support a meritorious medical negligence claim.¹²⁸ Mello and Studdert study data confirmed that, “evidence of a deterrent effect is (1) limited and (2) vulnerable to methodological criticism.”¹²⁹ Limited in the sense that ‘severity’ of injury rather than ‘occurrence’ of injury drove claims and was predictive of compensation.¹³⁰ Vulnerable to methodology in the sense that malpractice insurance is rarely experience-based, which minimizes any deterring effects on physician behavior based on insurance premiums.¹³¹ Because few costs associated with medical error are internalized by providers there exists a widening disconnect between tort liability and the ability to change physicians’ behavior.¹³²

Hindsight biases also has a negative impact on quality and patient safety by causing reviewers to focus on a single element with narrow thinking about causation – eliminating root cause inquiry at a larger system level.¹³³ A tort liability system that retroactively assigns responsibility and liability through hindsight biases helps explain the tort liability systems inability to distinguish meritorious claims from non-meritorious ones.¹³⁴

Patient harm viewed through the lens of the patient produces three main deficits in how medical harm is compensated; (1) the current mechanisms degrade health care provider-patient relationships, (2) in order to avoid lawsuits, patients are exposed to costly and dangerous defensive medicine, and (3) the inefficiencies in the medical malpractice system lead not only to long delays between medical injury and resolution but also to under claiming and under compensation of legitimate claims.¹³⁵

¹²⁷ Mello, M., Studdert, D., *The Medical Malpractice System: Structure and Performance, Medical Malpractice and the US Health Care System: New Century, Different Issues*, at 345.

¹²⁸ *Id* at 345 - 346.

¹²⁹ *Id* at 346.

¹³⁰ *Id* at 346. Studdert and colleagues study showed that only a small fraction of claims lacked documented injuries but approximately one third of claims were without merit in the sense that the alleged adverse outcomes were not attributable to error. Claims without merit were generally resolved appropriately: only one in four resulted in payment. When close calls were excluded, claims without evidence of injury or error accounted for 13 percent of total litigation costs. (Studdert, D., et al., *Claims, Errors, and Compensation Payments in Medical Malpractice Litigation*, 354 *New Eng. J. Med.* 2024, 2029 (2006).

¹³¹ *Id* at 346. In addition, only a small portion of the costs associated with medical errors lead to internalization by providers. Instead, public and private medical insurers as well as patients absorb much of the burden.

¹³² *Id* at 346.

¹³³ *To Err is Human*; *supra* note 4, at 53-54.

¹³⁴ Mello and Studdert, *supra* note 118, at 17.

¹³⁵ Raper, S., *Announcing Remedies For Medical Injury: A Proposal For Medical Liability Reform Based On The Patient Protection And Affordable Care Act*, *Jr of Health Care Law & Policy*, Vol. 16:309 pp.310-311 (2013).

Studies show that the cornerstone of the doctor patient relationship is good communication.¹³⁶ Physicians who do not communicate caringly, especially when care is painful, difficult, or provided sub-optimally or end in unexpected results, risk anger and frustration on the part of the patient, which causes that patient to seek the advice of an attorney because poor communication has been shown to lead to the patient's belief that poor care was administered, even where care was entirely appropriate.¹³⁷ Informed consent processes offer a physician an opportunity to recognize and address patient vulnerabilities and uncertainties thereby building trust through forthright dialogue.¹³⁸ Lack of honesty remains a frequent cause of litigation.^{139 140} Importantly implied in informed consent, is a continued obligation to inform patients about things that did or did not happen *when* care was provided.¹⁴¹

The practice of defensive medicine, defined as a departure from normal clinical guidelines to reduce risk of litigation, is not limited to increased costs in healthcare but is also associated with risks to patients and quality of care.¹⁴² Studies measuring the effect of malpractice pressure on malpractice premiums and claim frequency and claim severity have found inconclusively a tendency toward unproductive and costly defensive patient care.¹⁴³ In fact, studies question whether an association even exists between resource use and medical error.¹⁴⁴ Studies do suggest however, that a significant level of malpractice claims arise from communication breakdown and therefore more effort should be expended to foster closer

¹³⁶ Huntington, B., Kuhn, N., *Communication gaffes: a root cause of malpractice claims*, BUMC Proceedings 200; 16:1570161

¹³⁷ Id at 158. Noting that in the area of physician liability, the burden of “successful” physician-patient communication lies with physicians, noting also that patients do share a communication burden, but society and the courts have deemed that physicians have the ultimate responsibility for initiating, clarifying, facilitating, documenting, and reinforcing discussions related to their patients’ condition, treatment, and prognosis.

¹³⁸ Id at 159. The authors’ pointing out that studies show that what patients want from their physicians following error is an apology and the assurance that what happened to then will not happen to another patient.

¹³⁹ Id at 160.

¹⁴⁰ Witman AB, Park DM, Hardin SB., *How do patients want physicians to handle mistakes* ? A survey of internal medicine patients in an academic setting. Arch Intern Med. 1996; 156: 2565-2569

¹⁴¹ Sage, W., Gallagher, T., Armstrong, S., et al., *How Policy Makers Can Smooth The Way For Communication-And-Resolution Programs*, Health Affairs 33, no. 1 (2014) at 11, doi: 10.1377/hltaff.2013.0930.

¹⁴² Sekhar MS, Vyas N. *Defensive Medicine: A Bane to Healthcare*, Annals of Medical and Health Sciences Research. 2013; 3(2): 295-296. doi: 10.4103/2141-9248.113688.

¹⁴³ Kass, J., Rose, R., *Medical Malpractice Reform-Historical Approaches, Alternative Models, and Communication and Resolution Programs*, AMA Journal of Ethics Vo 18 No 3:299-310 (2016). Moreover, there is some evidence that improvements in process measures of quality are associated with reductions in malpractice claims.

¹⁴⁴ Jena, A., Schoemaker, L. Bhattacharya, J., et al., *Physician spending and subsequent risk of malpractice claims: observational study*, BMJ 2015; 351:h5516, doi: 10.1136/bmj.h5516.

relationships between patients and physicians.¹⁴⁵ Long-term data analysis at the University of Illinois concluded that a communication and resolution approach to patient safety incidences was associated with positive long-lasting clinical and financial changes in medical liability processes and patient safety measures.¹⁴⁶

Medical malpractice litigation is complicated, stressful, and lengthy with many transaction costs and while states have enacted reform measures such as caps on the amount sought in noneconomic damages; early resolution programs, such as CANDOR, have the potential to positively and fundamentally affect institutional malpractice liability costs more than any other malpractice litigation system reform effort to date because CANDOR shifts the focus to system wide reparation.¹⁴⁷ Early disclosure programs positively reinforce and support shifting legislative policy and public sentiment supporting structured processes for quick and predictable out of court resolution and early settlement.¹⁴⁸

Part IV

States are tasked with monitoring quality of patient care through three systems, (1) state medical malpractice, (2) state licensure, and (3) hospital peer review.¹⁴⁹ And while tort law and durable healthcare reform have the power to positively affect patient safety and quality of care,¹⁵⁰ the fact that the two speak different languages makes sustainable national patient safety and quality improvements ad hoc at best furthering the challenge of widespread adoption of any proven measures.¹⁵¹ Tensions therefore exist between health policy reform and malpractice laws and

¹⁴⁵ Id. The findings concluding that despite evidence that that majority of US physicians report practicing defensive medicine, no evidence exists on the broader question of whether greater resource use by physicians is associated with fewer malpractice claims.

¹⁴⁶ Lambert, B., Centomani, N., Smith, K., et al., *The Seven Pillars Response to Patient Safety Incidents: Effects on Medical Liability Processes and Outcomes*, Health Serv. Research, Vo. 51, No. 6, Dec. 2016. Study objectives were to determine whether a communication and resolution approach to patient harm is associated with changes in medical liability processes and outcomes. Principal findings indicated that the Seven Pillars patient safety incident intervention nearly doubled the number of incident reports, halved the number of claims, and reduced legal fees and costs as well as total costs per claim, settlement amounts, and self-insurance costs.

¹⁴⁷ Hersch, J., O'Connell, J., Viscusi, W., *Evaluation Of Early Offer Reform Of Medical Malpractice Claims: Final Report*, U.S. Dept of Health and Human Services (2003) <https://aspe.hhs.gov/basic-report/evaluation-early-offer-reform-medical-malpractice-claims-final-report>. Noting that some claimants who are injured through medial error receive significant awards or settlements, but often after long delays. In this study, closed claims from Texas and Florida were used to assess the performance of the early offer proposal; the study concluding that early offer could lead to insurer savings and speedy resolution (two years sooner on average) of many cases if early offer were adopted.

¹⁴⁸ Id at 309-311.

¹⁴⁹ Ho, P., *HCQIA Does Not Provide Adequate Due Process Protection, Improve Healthcare Quality And Is Outdated Under "Obamacare,"* 11 Ind. Health L. Rev. 303, at 313-314.

¹⁵⁰ Hyman, D., Sage, W., *So Health Reform and Malpractice Reform Fit Together?*, American Enterprise Institute for Public Policy Research (2011), <http://www.aei.org/paper/100209>

¹⁵¹ Id.

while some health policy reform efforts readily intersect with malpractice laws, others mostly do not.¹⁵²

Most state tort reform measures include caps on noneconomic damages (pain and suffering) - aimed at reducing costs associated with litigation.¹⁵³ Caps may apply to both the plaintiff (limiting the amount receivable in damages) and the defendant (limiting total amount of liability).¹⁵⁴ Another state tort reform provision provides legal immunity for providers, with goals of also limiting the amount of recovery of damages; this reform efforts impact on reducing patient harm, however, is unclear.¹⁵⁵ ¹⁵⁶ Caps, or their absence thereof, do not pose a barrier to CRP implementation because a significant number of the CRP-type injuries fall well below state cap amounts. Legal immunities for providers however, may need to be evaluated by legislatures for modification in order to level the playing field among providers because CRPs, in their principled approach to resolution, suggests fair compensation of patient harm leading to the reality that damages may be greater than the immunity caps.¹⁵⁷

More than three-fourths of states¹⁵⁸ provide communication protection in the form of a apology law that creates an evidentiary privilege eliminating or restricting a plaintiff's ability to introduce into evidence at trial statements or gestures by the defendant expressing not only apology but also sympathy or compassion.¹⁵⁹ Most state apology laws however protect only the "I'm sorry" aspect of an apology rather than the full explanation of the information that patients reportedly need when confronted with an unexpected outcome.¹⁶⁰

Apology laws reflect a significant cultural shift away from fear of disclosure and the associated deny and defend approach to medical harm that is a product of claims outcomes and

¹⁵² Id. Noting that health policy is typically described three dimensionally as; access to care, cost of care and quality of care, whereas malpractice policy terminology involves; the ability to make victims whole by obligating injurers to pay compensation, with the prospects of paying damages inducing deterrence.

¹⁵³ Id.

¹⁵⁴ Supra note 141, at 13.

¹⁵⁵ See Boothman et al., supra note 82, at 134.

¹⁵⁶ See Sage et al., supra note 141, at 13.

¹⁵⁷ Id at 14. The doctrine of charitable immunity limits the amount of tort damages for which not-for-profit organizations and other entities pursuing charitable work can be held liable. The doctrine of sovereign immunity holds that a government cannot be sued for a tort without its consent; statutes provide procedures through which states and federal government allow tort suits but usually limit the damages that plaintiffs may recover. Massachusetts, for example has a charitable immunity law limiting not-for-profit hospitals' malpractice liability recently increased to \$100,000 from \$20,000 - the states near-total charitable immunity being the most frequently mentioned barrier to the widespread adoption of CRPs.

¹⁵⁸ American Medical Association Advocacy Resource Center, *Apology Inadmissibility Laws: Summary of State Legislation* [Internet] AMA; 2012 [cited 2017 Mar 23]. Available from: http://www.akleg.gov/basis/get_documents.asp?session=28&docid=23660

¹⁵⁹ Sage et al., supra note 141, at 15. Stating that apology protection laws may also apply to statements of fault or explanation of how an injury occurred.

¹⁶⁰ Id at 14.

risk controls void of intrinsic investment in quality of care and patient safety.¹⁶¹ And while apology laws are reassuring to health care providers when standard of care has been met, expressions of empathy or compassion could be misinterpreted as admission of fault.¹⁶² CRPs, such as CANODR, work to settle claims outside of court and apology laws work to protect communications expressing apologies or compassion inside a court, therefore apology laws seem less important to the adoption of CRPs.¹⁶³ As an example, the University of Illinois Medical Center at Chicago (UIMCC) implemented the “Seven Pillars” patient safety incident disclosure response process, which operated effectively in Illinois from 2006 through 2008, without state apology law protections.¹⁶⁴

A statute, advancing federal-level data collection of patient error and adverse events, the Patient Safety and Quality Improvement Act of 2005, authorized the creation of patient safety organizations (PSO).¹⁶⁵ Certification as a PSO, governed by AHRQ, is significant in that the statute provides preempted evidentiary and disciplinary protection for patient safety work product disclosures.¹⁶⁶ PSOs reflect the federal governmental attempt to foster institutional-level patient safety activity and extend strong federal privilege to providers who voluntarily communicate errors.¹⁶⁷ Patient safety work product is any data ...“which could result in improved patient safety, health care quality or health care outcomes”, reflecting a method to encourage physician error reporting.¹⁶⁸

In 2005 Centers for Medicare and Medicaid Services (CMS) issued rules requiring hospitals to develop a quality assessment and performance improvement (QAPI) program as a Condition of Participation.¹⁶⁹ The QAPI program requires systematic examination of “performance improvement activities”¹⁷⁰ while noting in the comments that error detection is difficult because error usually affects, a single patient at a time, and often is treated as an isolated incident which, draws little attention to a problem despite documentation suggesting high prevalence of that particular type of error.¹⁷¹ CMS, historically viewed as a funding agency

¹⁶¹ Boothman, R., Blackwell, A., Campbell, D., et al., *A Better Approach to Medical Malpractice Claims? The University of Michigan Experience*, Jr of Health & Life Sciences Law, V0 2 No 2:133 (Jan 2009).

¹⁶² Sage et al., supra note 141, at 14.

¹⁶³ Id. Noting plaintiffs’ attorneys seldom introduce apologies into evidence at trial because doing so would contradict their narrative of uncaring physicians.

¹⁶⁴ McDonald TB, Helmchen LA, Smith KM, et al, *Responding to patient safety incidents: the “seven pillars”*, Qual Saf Health Care 2010;19:e11. Noting in the first two years post-implementation, the “seven pillars” process led to more than 2,000 incident reports annually, prompted more than 100 investigations with root cause analysis, translated into close to 200 system improvements and served as the foundation of almost 106 disclosure conversations and 20 full disclosures of inappropriate or unreasonable care causing harm to patients.

¹⁶⁵ Pub. L. No. 109-41, 119 Stat. 424 (2005)

¹⁶⁶ 119 Stat. at 426.

¹⁶⁷ 119 Stat. at 428.

¹⁶⁸ 119 Stat. at 426.

¹⁶⁹ 42 C.F.R. § 482.21 (2005).

¹⁷⁰ Id.

¹⁷¹ Medicare and Medicaid Programs; Hospital Conditions of Participation: Quality Assessment and Performance Improvement, 68 Fed. Reg. 3435.

rather than a regulatory agency¹⁷², takes a gradualist approach in its error rule expectations, requiring hospitals to implement internal error reduction systems to track and analyze underlying causes of adverse events with an emphasis on assessing processes and systems that affect patient care and quality paralleling and relying on efforts of private contractors and private accreditors such as The Joint Commission (TJC).¹⁷³

A state-level reform effort that aids CANDOR implementation is pre-suit notification, which requires the plaintiff to provide the defendant with advanced notification of the plaintiffs' intent to file a medical malpractice suit.¹⁷⁴ Pre-suit notification statutes seek to promote settlement and compensation for claims without the need for lengthy and costly litigation.¹⁷⁵ Pre-suit notification provides a structured mechanism for proactive communication by the defendant, allowing time for investigation of a claim and provides an opportunity for honest communication with patient and family.^{176 177}

Successful early dispute resolution of patient harm does not necessarily hinge on statutorily derived structured mechanisms discussed above however, and claims management is not dependent upon statutes either.¹⁷⁸ Increasingly, institutional system-wide online incident reporting is being used by trained staff, (1) to report patient injuries or potential patient injuries early through online reporting systems, and (2) who understand the importance of maintaining and tracking trend and pattern data and the companion responsibility to intercept patient injuries thereby reducing the patient harm footprint of the entire organization.¹⁷⁹

In addition, significant evidentiary peer review protections were granted through provisions of the HCQIA and, as envisioned by Congress, these protections were necessary to foster improvements in quality of health care.¹⁸⁰ Physician peer review participation is encouraged through this granting of immunity - where physician participants become shielded from personal monetary liability that may result from adverse professional peer review actions.¹⁸¹ HCQIA's first provision promotes professional peer review immunity to medical peer

¹⁷² Astrue, M., *Health Care Reform and the Constitutional Limits on Private Accreditation as an Alternative to Direct Government Regulation*, 57 Law & Contemp. Probs. 75, 79 (1994).

¹⁷³ Id at 16. Astrue notes CMS becomes a reluctant regulator stating the error rule reflects the culture and history of CMS. The error rule requires hospitals to develop QAPI programs. 42 C.F.R. § 482.21 (2005). Under systematic examination hospitals are to continuously study and improve the processes of healthcare and delivery of service. The lack of explicit mandates for error reporting removes teeth from this error rule promulgated by CMS.

¹⁷⁴ Morreim, H., *Mediating Med-Mal Without The Data Bank Report*, Ohio State Journal on Dispute Resolution v.27 #1, (2011) <http://hdl.handle.net/1811/76976>.

¹⁷⁵ Id. Noting that states that have pre-suit notification statutes range in their notice requirements; shortest being West Virginia at 30 days' notice, longest being Michigan at 182 days' notice.

¹⁷⁶ Id at 108.

¹⁷⁷ Mello, M., Studdert, D., Kachulia, A., *The Medical Liability Climate and Prospects for Reform*, JAMA. doi: 10.1001/jama.2014.10701

¹⁷⁸ See Boothman supra note 125.

¹⁷⁹ Id.

¹⁸⁰ Infra note 181 and 182.

¹⁸¹ 42 U.S.C. § 11101. Both federal and state statutes govern the peer review process.

review committees.¹⁸² Grant of professional peer review immunity extends to prevent not only private monetary damages¹⁸³ but also liability under Federal antitrust law.¹⁸⁴ HCQIA's second provision requires medical peer review committees, who have taken adverse action against a physician's privileges, to report said action to a national databank (NPDB).¹⁸⁵ The NPDB is maintained by the federal government and requires that most malpractice judgments and settlements and disciplinary actions taken by hospital peer review committees be reported.¹⁸⁶

The significance of having a protected forum to openly and honestly discuss patient safety issues cannot be understated.¹⁸⁷ However, the distinct divergent tracks that the HCQIA's two objectives take – that of future-oriented nationwide improvement in quality of medical care and that of process-oriented individualistic professional disciplining - require separate efforts and actions.¹⁸⁸

Part V

Modification To The HCQIA NPDB Reporting Requirement Is Necessary In Order To Meet The HCQIA Primary Objective Of Improving Quality of Care. Providing A Qualified Status Within The NPDB For CANDOR-Certified Organizations Would Provide A Nationwide Mechanism For Organizational Honesty In Communication About Medical Error Absent Fear Of Name-Based Reporting. Organizational Honesty Leads To Discovery Of Correctable System Failures Associated With Medical Error.

Nondisclosure of previous censorship of performance by a relocating physician was a concern when Congress enacted the HCQIA in 1986.¹⁸⁹ In addressing that concern, Congress established a control mechanism over nondisclosure through NPDB reporting, which began collecting

¹⁸² Id. §§ 11111-15. HCQIA officially contains a third part, definitions. Id. §§ 11151-52. States also require that hospitals have medical staffs that conduct peer review as a condition of licensure. In addition, Medicare and Medicaid programs require that hospitals have medical staffs and engage in peer review in order to participate in these programs. 42 C.F.R. § 482.22 (2008).

¹⁸³ 42 U.S.C. § 11111(a). HCQIA does not, however, restrict a physician from seeking injunctive or declaratory relief. H.R. Rep. No. 99-903, at 9 (1986). In addition, the limitation on damages does not apply to damages under any law relating to civil rights. 42 U.S.C. § 11111(a)(1).

¹⁸⁴ 42 U.S.C. § 11101.

¹⁸⁵ Id. §§ 11131-37; 45 C.F.R. §60.9 (2005). The second provision of HCQIA also requires reporting of medical malpractice payments by insurers and sanctions taken by State Boards of Medical Examiners. 42 U.S.C. §§ 11131-32; 45 C.F.R. §§ 60.7-60.8 (2005).

¹⁸⁶ 42 U.S.C. § 11101-11115; 42 U.S.C. § 11131-11153.

¹⁸⁷ Lang, B., Small, S., *Communicating About Care: Addressing Federal-State Issues In Peer Review And Mediation To Promote Patient Safety*, 3 Hous. J. Health L. & Pol'y 219, 230 (2003).

¹⁸⁸ Nowakowski, G., Nowakowski, M., Mantese, T., et al., *Health Care Quality Improvement Act: Peer Review, Procedure, Process, And Privacy*, 33 W. Mich. U.T.M. Cooley L. Rev. 111 at 129-131 (2016).

¹⁸⁹ 42 U.S.C. § 11101

reported data in 1990.¹⁹⁰ The NPDB reporting requirement applies when any medical malpractice payment is made on behalf of a practitioner as a result of a written claim.¹⁹¹ NPDB reportable events include most malpractice judgments and settlements and disciplinary actions taken by hospital peer review committees.¹⁹² A medical malpractice payment that resulted from a claim against an organization is not reported – effectively bypassing reporting requirements through a mechanism called the corporate shield.¹⁹³ Corporate shield allows practitioners to escape reporting after care that brought about a medical malpractice claim¹⁹⁴ and effectively reduces detection and tracking of incompetent practitioners in approximately 50% of all malpractice settlements.¹⁹⁵

The marketplace and legal ramifications for practitioners advocating patient safety and quality of care issues are hampered by NPDB reporting requirements and less than 5% of physicians that have been reported to the NPDB successfully mount an appeal.¹⁹⁶ NPDB reporting requirements are effectively bypassed when providers pay out-of-pocket¹⁹⁷ and waive patient's bills and/or refund payments.¹⁹⁸ NPDB reporting loopholes impede the health care

¹⁹⁰ 42 U.S.C. § 11101-11115

¹⁹¹ 42 U.S.C. § 11131. Noting that to be considered a reportable claim under the NPDB, a claim must be written. Verbal requests for compensation for malpractice are, thus, not covered.

¹⁹² Supra note 204.

¹⁹³ US Dept. of Health and Human Services, National Practitioner Data Bank Guidebook at E-3. Noting that through the corporate shield, when payment of a medical malpractice claim is made by the entity rather than the practitioner a medical malpractice victim thereby agrees to drop or dismiss a medical practitioner as a defendant to a medical malpractice lawsuit. This generally occurs during settlement negotiations as the entity or hospital substitutes as the defendant in the place of the practitioner.

¹⁹⁴ Smarr, L., *A Comparative Assessment of the PIAA Data Sharing Project and the National Practitioner Data Bank: Policy, Purpose, and Application*, 60 L. & Contemp. Probs. 59, 71 (1997).

¹⁹⁵ Teninbaum, G., *Reforming The National Practitioner Data Bank To Promote Fair Med-Mal Outcomes*, William & Mary Policy Review, Vol. 5.1, 86 (2013). Noting the coupling of hospital immunity with required reporting was intended to protect hospitals from charges of malfeasance for reporting information about doctors with imperfect records. The NPDB would not make hiring decisions, per se, but if it worked correctly, it would assure that employers had applicants' complete history of paid claims and discipline. To discourage non-compliance, the NPDB rules imposed a \$10,000 fine for any failure to report a malpractice payment. History reveals that the NPDB has been unable or unwilling to enforce the rules: in response to a Freedom of Information Act request made during drafting of this article, HHS has never, in the entire history of the NPDB, levied a single fine against any person or entity for failure to report a malpractice claim.

¹⁹⁶ Panella, M., *The Legal Ramifications Under the Health Care Quality Improvement Act of Physicians Labeled Disruptive For Advocating Patient Quality of Care Issues*, 24 J.L. & Com. 281, 288 (2005)

¹⁹⁷ Morreim, H., *Malpractice, Mediation, and Moral Hazard: The Virtues of Dodging the Data Bank*, 27 Ohio St. J. on Disp. Resol. 109, at 132-133. Detailing mechanisms of paying out-of-pocket to avoid NPDB report.

¹⁹⁸ NPDB Guidebook, supra at 193, at E-12.

industry's attempt to innovate solutions to system flaws, which, as shown in the science behind the IOM report, accounts for the vast majority of patient injury.¹⁹⁹ NPDB reporting requirements have caused many practitioners, from as early on as 1992, to refuse to settle any claims, insisting all cases go to trial in an effort to avoid reporting.²⁰⁰ Conversely, substandard care, which may have been administered under a host of system flaws or criticized hospital policies rather than directly by a physician become NPDB reportable events.²⁰¹ Circumvention of reporting not only significantly reduces detection of incompetency but also skews data and poses a barrier to claims settlement.²⁰²

In 1998 HHS proposed NPDB reporting changes, which would have required that all paid claims be reported, recognizing a need to eliminate corporate shield non-reporting practices that result in under reporting and data integrity problems.²⁰³ In presenting this proposal, HHS sought to avoid reporting bypass practices, recognizing a need to qualify NPDB reporting when system error was the result of patient harm as opposed to injury directly caused by a practitioner.²⁰⁴ Under the HHS proposal, when system failure was found to have caused the error, the payment reporter would 'simply explain the sequence of events and explain why no negligent individual could be identified.'²⁰⁵ This proposal failed however and eventually vanished in 2007.²⁰⁶

¹⁹⁹ Leape, L., et al. *Systems Analysis of Adverse Drug Events*, 274 JAMA 35 (1995). Stating Leape and Berwick have bemoaned the failure of health care to move safety to a central concern: 'A truly national response to the IOM's call to reduce preventable patient injuries by 90% requires that every health care board, executive, physician, and nurse make improving safety an absolutely top strategic priority fully equal to the corporate priority of financial health. At the national level, such a commitment has yet to emerge; indeed, it is not in sight.'

²⁰⁰ Supra at note 195, 97. Noting that by 1992 medical facilities were already using corporate shield tactics by dropping doctors before any settlement was paid so it appeared that only the doctors' hospital-employer was liable.

²⁰¹ Kinney, E., *Hospital Peer Review of Physicians: Does Statutory Immunity Risk of Unwarranted Professional Injury?* 13 Mich. St. L.J. of Med. and L. 57, 79 (2009).

²⁰² See Teninbaum at note 195, 109. Noting a published piece describing an experience as plaintiffs' lawyers stating how commonly the NPDB served as a settlement barrier:

'Based on personal experience in a number of cases, it is not uncommon to encounter a situation where the malpractice carrier and/or defense counsel recommends settlement, but the physician, who may have the right to preclude settlement under the terms of his or her insurance policy and is concerned about the effects of reporting to the NPDB (on obtaining subsequent hospital privileges, licensure issues, and increased malpractice premiums, etc.), refuses to authorize settlement.'

²⁰³ 63 Fed. Reg. 71255 (Dec. 24, 1998).

²⁰⁴ 63 Fed. Reg. at 71256.

²⁰⁵ Id. Noting that with the proposed rule ready to implement after a normally performed comment period, HHS decided against immediate finalization. HHS, as a reason explained that more than 120 comments on the proposed rule were received and given the large number of thoughtful comments and the high level of concern that was voiced about the potential impact of the proposal as published, HRSA believed it was imperative to gather additional data and conduct further analyses before proceeding. There is no evidence that further data was gathered, nor any suggestion that there was further analysis of the issue. The rule was eventually withdrawn.

In 2015, Washington State developed a statewide policy solution addressing name-based reporting and its traditional malpractice and disciplinary triggering responses believed to impede and discourage reporting of medical error.²⁰⁷ Participants in this collaboration included health care institutions, liability insurers, and the Medical Quality Assurance Commission (MQAC).²⁰⁸ The objective was to show that collaboration with regulators around CRPs could enhance health care quality.²⁰⁹ The Commission concludes that CRP Certification programs promote patient focused accountability and lesson learning following adverse patient events and that in working directly with entities the state will be able to proactively reduce medical harm.²¹⁰ The Commission noting “CRP Certification [does] not shield incompetent providers.”²¹¹

Washington State Commission directly answered the IOM reports’ call by being a force for error reduction absent concealment and endorsement of just culture principles and activities in error reduction that have proven successful in other high-risk industries such as aviation.²¹² Just culture institutions encourage open honest communications and fairness, which leads to learning tools developed among regulatory collaborators that better protect the public. Washington State CRP Certified organizations require independent review of unanticipated outcomes.²¹³ When patient error occurs, independent reviewers determine whether CRP process elements were satisfied, that patient safety improves as a result of system-wide changes deployed and that system changes are appropriate to effectively reduce future error.²¹⁴ When the event is

²⁰⁶ 72 Fed. Reg. 22538 (April 20, 2007).

²⁰⁷ Gallagher, T., Farrell, M., Karson, H., et al., *Collaboration with Regulators to Support Quality and Accountability Following Medical Errors: The Communication and Resolution Program Certification Pilot* (Dec 2016) <https://www.ncbi.nlm.nih.gov/pubmed/27601424>

²⁰⁸ Id.

²⁰⁹ Id. Study design: MQAC has collaborated with the Foundation for Health Care Quality (FHCQ) on a CRP Certification Pilot. A panel of physicians, risk managers, and patient advocates at FHCQ will review cases for use of the CRP key elements (responding to adverse events using transparency with patients, event analysis, recurrence prevention, and compensation). Cases meeting this standard will be “CRP Certified.” If MQAC determines that the CRP enhanced patient safety comparable or better than board action, the Commission may close the case.

²¹⁰ Id. Noting that the CRP Certification program is a promising example of collaboration among institutions, insurers, and regulators to promote patient-centered accountability and learning following adverse events.

²¹¹ Id. Noting the CRP process is limited to cases of human error. The CRP Independent Review Board will not certify cases involving reckless or intentional conduct, gross negligence, sexual misconduct, boundary violations, patient abuse, drug diversion, criminal activity, and other unethical or unprofessional behavior.

²¹² State of Washington Medical Quality Assurance Commission Guideline, *A Collaborative Approach to Reducing Medical Error and Enhancing MD2015-08 Patient Safety*, at 2.

²¹³ Id. The CRP Event Review Board serves as a neutral panel to review and certify CRP events. The Board is composed of individuals from across the health care spectrum, including patient safety advocates, risk managers, insurers, and physicians.

²¹⁴ Id.

certified through this independent quality review process the certified event qualifies for non-reporting.²¹⁵

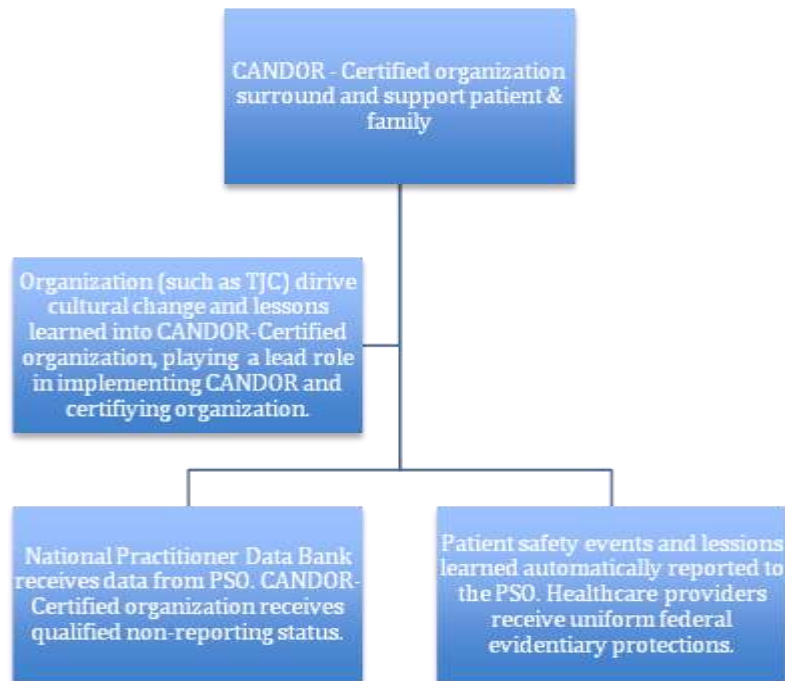
The ability to innovate solutions addressing faulty systems²¹⁶ requires collaboration and open communication in bringing patient safety and quality of care issues into sharp focus. Shifting public policy supports evidence-based payment structures²¹⁷ and CRP's prompt identification and resolution of medical error under a shining light.²¹⁸ A protected domain within the NPDB for CRP payments and qualified certified health care institutions would reduce fear of litigation associated with communicating error and would foster a culture of honesty, which would broaden implementation and stakeholder support. Washington State CRP certification policy demonstrates that collaborative regulatory support can be accomplished at the state level. CANDORs toolkit, developed with federal grant support could receive similar collaborative support through existing quality regulatory agencies and the federal government. The figure below depicts such collaboration.

²¹⁵ Id. Noting when an unanticipated patient outcome occurs and an institution completes a CRP process, the institution may request an independent review by submitting an application for certification to the Board. The Board reviews the application and all relevant records and documents, and determines whether all key elements of the CRP process have been satisfied, particularly that the system changes are appropriate and effective. If all the elements are fully satisfied, and patient safety has improved as a result, the Board will send a report back to the institution stating that the event is certified. This step provides an additional level of objective quality review of the CRP process.

²¹⁶ Supra note 4.

²¹⁷ Centers for Medicare & Medicaid Services, Hospital Quality Initiative Overview (2013), https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/index.html?redirect=/hospitalqualityinits/30_hospitalhcahps.asp. Noting that evidence-based quality measures have been extensively validated through research.

²¹⁸ See Sage supra note 141, at 11.



Patients and families engagement in care represents information strategies health care systems have readily met and distilled over time. However, a failure to respond to medical injury plagues the health care industry. Medical injuries continue to threaten patient safety. CANDOR processes provide empirically tested tools shown to improve quality and safety and a pathway to honest communication about medical injury. CANDOR is culturally transformative and is likely to continue to play a role in decreasing medical malpractice claiming as its proactive approach to medical harm enjoys bipartisan support. The potential role for CANDOR, in broadly improving quality of care, can be accomplished readily through HCQIA modification. HCQIA NPDB modification should provide a qualified non-reporting status for CANDOR-Certified organizations. Such reform would provide a mechanism for wide-scale adoption of CANDOR, similar to Washington’s statewide program, which sought and effectively accomplished patient safety collaboration. HCQIA NPDB modification or amendment could create nationwide effective patient safety focus at little cost, could better meet legislative intent primarily focused on improved quality of care and could better protect the public from failures in our healthcare systems.

About the Author

Nancy Fadling holds undergraduate and graduate degrees in Business and Economics as well as a Juris Doctor degree. She recently graduated with a Master in Health Laws from Loyola University Chicago School of Law. Ms. Fadling has fifteen years’ experience in medical group operation and financial management and ten years hospital experience as a critical care nurse. Her passion for improving quality of care and patient safety is demonstrated through recent engagements at Dignity Health System where she assisted in the performance of seven AHRQ CANDOR Gap Analyses.