

## COMMUNICATING ABOUT CARE:

### ADDRESSING FEDERAL-STATE ISSUES IN PEER REVIEW AND MEDIATION TO PROMOTE PATIENT SAFETY

Bryan A. Liang, M.D., Ph.D., J.D.\*  
& Steven D. Small, M.D.\*\*

#### INTRODUCTION

Medical error and patient safety are key policy issues.<sup>1</sup> In November 1999, the Institute of Medicine (IOM) released its highly publicized report on these topics, and with it, the sobering facts—that medical error accounts for the vast majority of patients injured in the United States, with up to 98,000 inpatient deaths annually due to it.<sup>2</sup> This figure represents an astounding 270 deaths each and

\* John & Rebecca Moores University Professor and Director *pro tempore*, Health Law & Policy Institute, University of Houston Law Center, Houston, TX; Adjunct Professor of Medicine, Baylor College of Medicine, Houston, TX; and Adjunct Professor of Medical Humanities, University of Texas Medical Branch, Galveston, TX. B.S., M.I.T.; Ph.D., Harris School of Public Policy Studies, University of Chicago; M.D., Columbia University College of Physicians & Surgeons; J.D., Harvard Law School.

\*\* Assistant Professor of Anesthesia and Critical Care, University of Chicago, Chicago, IL; Director, Developing Center for Patient Safety, University of Chicago, Chicago, IL. B.A., Brown University; M.D., Baylor College of Medicine.

<sup>1</sup> William C. Richardson, *Preface to COMMITTEE ON QUALITY OF HEALTH CARE IN AMERICA, INSTITUTE OF MEDICINE, TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* ix-x (Linda T. Kohn et al. eds., 2000).

<sup>2</sup> These figures are subject to some debate. Interested readers may wish to review COMMITTEE ON QUALITY OF HEALTH CARE IN AMERICA, INSTITUTE OF MEDICINE, *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* 26, 31 (Linda T. Kohn et al. eds., 2000) (hereinafter IOM REPORT) and compare the citations therein with Clement J. McDonald et al., *Deaths Due to Medical Errors Are Exaggerated in Institute of Medicine Report*, 284 J. AM. MED. ASS'N. 93 (2000), Lucian L. Leape, *Institute of Medicine Medical Error Figures Are Not Exaggerated*, 284 J. AM. MED. ASS'N. 95 (2000), and Rodney A. Hayward & Timothy P. Hofer, *Estimating Hospital Deaths Due to Medical Errors: Preventability Is in the Eye of the Reviewer*, 286 J. AM. MED. ASS'N. 415 (2001). Note, however, that other estimates of inpatient deaths are even higher than that described in the IOM REPORT. See, e.g., Ross Wilson et al., *The Quality in Australian Health Care Study*, 163 MED. J. AUSTRAL. 458, 459 (1995). As well, the specific number of errors may be an inappropriate focus given the progress medicine has made. See, e.g.,

every day, 365 days a year, and does not take into account preventable failures in care in ambulatory settings, nursing homes, or the home health care arena.<sup>3</sup> Importantly, the IOM report also focused some attention on successful efforts at addressing the problem—specifically, a focus on the systems nature of delivery,<sup>4</sup> the use of systems tools to develop and implement corrective action,<sup>5</sup> and, critically, the need for open and honest communications and discussions about error and safety.<sup>6</sup> This paradigm avoids the shame and blame of individuals acting in high error-inducing environments, norms antithetical to complex system improvement that serve to drive information of errors and failures underground.<sup>7</sup>

Currently, the litigation process is the primary forum for communicating information about an error that led to injury.<sup>8</sup> Yet, the litigation system provides little if any substantive information useful to promote systems improvements and corrective action in

Troyen A. Brennan, *The Institute of Medicine Report on Medical Errors—Could It Do Harm?*, 342 NEW ENGL. J. MED. 1123, 1125 (2000).

<sup>3</sup> IOM REPORT, *supra* note 2, at 27.

<sup>4</sup> *Id.* at 49.

<sup>5</sup> *Id.* at 51-52, 162-63.

<sup>6</sup> *Id.* at 178.

<sup>7</sup> Note, however, that this concept does not exclude individual accountability. The two go hand in hand:

because the system is now the focus of quality, all members of the healthcare team assume an even greater role: they must be vigilant in all aspects of care and note all actual or potential sources of error, going beyond their traditional activities and observations. A systems approach does not discern who acts to identify systems problems or the training he/she has, but simply that the problem is identified and that it provides an opportunity for corrective action.

Bryan A. Liang, Special Paper: *A System of Medical Error Disclosure*, 11 QUALITY AND SAFETY IN HEALTH CARE 64, 65 (2002) [hereinafter Liang, *A System of Medical Error*].

Aviation provides an excellent example. A team of air traffic controllers works together; however, due to an error, one of the team directs a flight into the wrong runway corridor, resulting in a near miss accident. Due to the professionalism of the controller, he notes his own error. The team leader then debriefs the controller as to the factors that contributed to the event, as well as discusses the matter with other members of the team. The controller is then asked to design his own remedial training. After the controller designs, and engages in, his training, all other members of the team also engage in the same training. In this manner, others on the team learn from the error and the system improves without a punitive environment and shame-and-blame approach. Roxanne Goeltz, Conference Presentation, *Promoting Patient Safety: An Ethical Basis for Policy Deliberation* (2001) (available from Hastings Center for Biomedical Ethics, Garrison, NY). Ms. Goeltz is an Air Traffic Controller.

<sup>8</sup> Brennan, *supra* note 2, at 1125; Bryan A. Liang, *The Perils of Law and Medicine: Avoiding Litigation to Promote Patient Safety*, 19(3) PREVENTATIVE L. REP. 10 (2001).

health care.<sup>9</sup> Indeed, as a win/lose, individually-oriented fault mechanism, the litigation system provides an exceedingly strong incentive to staunch patient-provider communications altogether in order to avoid any possibility that information discussed would or could be framed to influence a jury.<sup>10</sup> Even if some information does come to light, the information is likely tainted—that is, it is unlikely that the information will be unsullied by the twisting and tweaking of each side's attorney to favor his or her own client's case.

Hence, the litigation process does not promote effective communication, information exchange, or learning to improve systems performance in health care delivery. Importantly, it induces silence by one party who has significant knowledge of direct and indirect factors surrounding the events—the provider—and one party who has the greatest experience with all parts of the delivery system—the patient.

To continuously promote safe and effective health care, both providers and patients must be active partners and participants in a system of delivery.<sup>11</sup> From the outset, both should be educated about the systems nature of health care delivery and outcomes,<sup>12</sup> and should be strongly encouraged to report and discuss any “eyebrowraising events”—potential deviations of care that might be noted for improvement—that are observed.<sup>13</sup> By integrating providers and patients as true partners in the health delivery enterprise, the health delivery system can obtain marked progress in reducing errors, mitigating their negative effects, while also learning from them to improve system function.<sup>14</sup>

<sup>9</sup> Brennan, *supra* note 2, at 1125.

<sup>10</sup> See IOM REPORT, *supra* note 2, at 43.

<sup>11</sup> Liang, *A System of Medical Error*, *supra* note 7, at 65.

<sup>12</sup> *Id.*

<sup>13</sup> This term is used to describe the welter of conflicting inadequate judgmental terms that necessarily require attention but often are not easily articulated as to why. See Bryan A. Liang, *Themes for a System of Medical Error Disclosure: Promoting Patient Safety Using a Partnership of Provider and Patient*, STRATEGIC ISSUES IN HEALTH CARE MANAGEMENT 92 (H. Davies, M. Tavakoli, eds., forthcoming Jan. 2004); Bryan A. Liang, *Error Disclosure for Quality Improvement: Authenticating a Team of Patients and Providers to Promote Patient Safety*, PROMOTING PATIENT SAFETY: AN ETHICAL BASIS FOR POLICY DELIBERATION (V.A. Sharpe, ed. Forthcoming 2003) [hereinafter Liang, *Error Disclosure*].

<sup>14</sup> Liang, *Error Disclosure*, *supra* note 13.

## I. A BACKGROUND ON ERROR

### A. Medical Error and Patient Injury

Medical error can be defined as a mistake, inadvertent occurrence, or unintended event in health care delivery which may, or may not, result in patient injury.<sup>15</sup> Note, however, "what medical error is not: it is not purposeful or reckless actions that are intended to directly or indirectly harm the patient."<sup>16</sup> To improve the health delivery system, the primary concern centers upon the much more frequent problem of error by individuals who are acting in good faith, but are working in systems where errors occur that may potentially lead to adverse events.<sup>17</sup>

### B. Concepts of Human Error

Error by humans is inevitable.<sup>18</sup> It occurs as part of the interacting systems in which persons act to achieve social goals.<sup>19</sup>

Professor James Reason, a psychologist and leading human error investigator, has extensively studied human error and has described the paradigm of error in complex systems.<sup>20</sup> "Errors arise from two major sources: unintentional actions in the performance of routinized tasks and mistakes in judgment or inadequate plans of action."<sup>21</sup> Active failures—errors and violations of rules, and managerial or latent failures—those focused on and in the organizational or systemic processes, intimately involve the human component of complex systems.<sup>22</sup> But it is the latent failures, "those entwined with

<sup>15</sup> See Liang, *A System of Medical Error*, *supra* note 7, at 64.

<sup>16</sup> The distinction is crucial; first, these latter actions represent only a very small percentage of patient injuries associated with the health care system; and secondly, these actions are malicious and volitional rather than error. Bryan A. Liang, *The Adverse Event of Unaddressed Medical Error: Identifying and Filling the Holes in the Health-Care and Legal Systems*, 29 J. LAW MED. & ETHICS 346 (2001) [hereinafter Liang, *Adverse Event*].

<sup>17</sup> The complexity of care and the effect of error is daunting; even when providers are working at a 99% level of error-free proficiency—and medical personnel "are among the most careful professionals in our society"—this level is still less than industry, and even a 99.9% level of proficiency may still result in significant levels of patient injury. See Lucian L. Leape, *Error in Medicine*, 272 J. AM. MED. ASS'N. 1851 (1994); see also IOM REPORT, *supra* note 2, at 53.

<sup>18</sup> See JAMES REASON, *HUMAN ERROR* 2 (1990); see Liang, *Adverse Event*, *supra* note 16, at 347.

<sup>19</sup> See Liang, *Adverse Event*, *supra* note 16, at 347.

<sup>20</sup> See REASON, *supra* note 18, at 173.

<sup>21</sup> See Liang, *Adverse Event*, *supra* note 16, at 347; see also REASON, *supra* note 18, at 5-6.

<sup>22</sup> See Liang, *Adverse Event*, *supra* note 16, at 347; see REASON, *supra* note 18, at 173.

the design, organization, and structure of complex systems," that are the most dangerous failure types.<sup>23</sup> Latent failures often go unrecognized and remain within the system, "increasing the potential for adverse events in the future because they predispose the system to failure."<sup>24</sup> They are therefore "accidents waiting to happen" with the human operator "'set up' to fail" under these conditions.<sup>25</sup>

However, systems in which humans operate generally do have "several layers of activity" and, importantly, defenses against the potential adverse consequences of error.<sup>26</sup> In Reason's "swiss-cheese" depiction of systems, "each layer of activity has holes and solid areas—holes which represent active and latent failures within the system," and "solid areas which represent barriers against the occurrence of adverse events associated with error."<sup>27</sup> When the failure holes line up, an error penetrates the entire system's layers and defenses, "resulting in an accident or adverse event."<sup>28</sup> "The error may penetrate all but the last barrier within the system; these situations, which happen much more frequently than total penetration, are considered "near misses" and thankfully do not result in an adverse event."<sup>29</sup> However, these near misses provide important information about the system, and other complex systems, such as aviation, collect and analyze these data for successful system improvement.<sup>30</sup>

Complex systems, such as health care delivery, due to the very characteristics that make them complex, have a high potential for failures and error.<sup>31</sup> These characteristics include: high-level techni-

<sup>23</sup> See Liang, *Adverse Event*, *supra* note 16, at 347.

<sup>24</sup> *Id.*

<sup>25</sup> See *id.*; see Leape, *supra* note 17, at 1854.

<sup>26</sup> Liang, *Adverse Event*, *supra* note 16, at 347; see REASON, *supra* note 18, at 207-09.

<sup>27</sup> Liang, *Adverse Event*, *supra* note 16, at 347; see REASON, *supra* note 18, at 207-09 ("In highly protected systems, the various layers of defense can only be breached by the adverse conjunction of several different causal factors.").

<sup>28</sup> Liang, *Adverse Event*, *supra* note 16, at 347; see REASON, *supra* note 18, at 207-09.

<sup>29</sup> See Liang, *Adverse Event*, *supra* note 16, at 347; Lucian L. Leape et al., *Promoting Patient Safety by Preventing Medical Error* [editorial], 280 J. AM. MED. ASS'N. 1444, 1445 (1998) ("All complex systems contain such latent factors or failures, but only rarely do they combine to create the trajectory for an accident.").

<sup>30</sup> Bryan A. Liang, *Risks of Reporting Sentinel Events*, 19(5) HEALTH AFFAIRS 112, 118 (2000) [hereinafter Liang, *Risks of Reporting*]; Bryan A. Liang, *Comment: Other People's Money: A Reply to the Joint Commission*, 33 J. HEALTH LAW 657, 660 (2000) [hereinafter Liang, *Other People's Money*].

<sup>31</sup> Bryan A. Liang, *Error in Medicine: Legal Impediments to U.S. Reform*, 24 J. HEALTH POL., POL'Y & L. 27, 28 (1999) [hereinafter Liang, *Error in Medicine*].

cal needs, the need for quick reaction times, twenty-four-hour-a-day, seven-day-a-week operations, long hours, and trade-offs between service and safety.<sup>32</sup> In fact, a school of applied psychology has emerged emphasizing study of human performance in real field operations and high fidelity simulation laboratories as opposed to sterile, highly controlled laboratory settings.<sup>33</sup> Naturalistic Decision Making (NDM) practitioners note that complex performance in the real world is conditioned by the fact that there is a real risk to decision makers working under time pressure to resolve dilemmas with limited, ambiguous data at their disposal, as is typical in actual system settings.<sup>34</sup> Organizational, team dynamics and cultural factors come into play, in addition to open feedback loops that make decision making more difficult.<sup>35</sup> Remarkably, only a small fraction of errors actually lead to adverse events.

Under these precepts, the reality is that one individual cannot solely be responsible for the outcome of the entire system.<sup>36</sup> This latter point requires emphasis for legal and medical communities: using aviation as an example, the pilot is not the only person responsible for getting passengers to the appropriate destination without injury.<sup>37</sup> The pilot, the co-pilots, the stewards, the ground staff, the maintenance crew, the air traffic controllers—each and every one of these aviation system members contribute to the outcome, positive or negative. It is therefore not the last person who touches the controls or the last person who touches the patient that is solely responsible for the final outcome; it is the system that is the necessary and appropriate unit of analysis when the goal is leveraged, sustainable improvement.<sup>38</sup>

<sup>32</sup> *Id.*

<sup>33</sup> See, e.g., NATURALISTIC DECISION MAKING (EXPERTISE: RESEARCH AND APPLICATIONS) (Caroline E. Zsombok, Gary Klein, eds. 1997).

<sup>34</sup> See *id.* at 4-5 ("NDM is the way people use their experience to make decisions in field settings.").

<sup>35</sup> See *id.* at 4.

<sup>36</sup> See, e.g., H. Clayton Foushee & Robert L. Helmreich, *Group Interaction and Flight Crew Performance*, in HUMAN FACTORS IN AVIATION 192 (Earl L. Wiener & David C. Nagel, eds. 1988); Daniel Maurino, et al., BEYOND AVIATION HUMAN FACTOR: SAFETY IN HIGH TECHNOLOGY SYSTEMS 83 (1995); REASON, *supra* note 18.

<sup>37</sup> See Foushee & Helmreich, *supra*, note 36, at 192.

<sup>38</sup> Liang, *A System of Medical Error*, *supra* note 7, at 64-65. See also Leape, *supra* note 17, at 1854; Rebecca Voelker, "Treat Systems, Not Errors," *Experts Say*, 276 J. AM. MED. ASS'N 1537, 1538 (1996); Leape et al., *supra* note 29, at 1445.

Successful error reduction takes full advantage of the systems nature of error. There are a variety of appellations for such strategies, such as continuous quality improvement (CQI) and total quality management (TQM); these systems approaches can be seen on a basic level to involve a continuous process with several integral stages, with the underlying goal of preventing errors and/or their negative effects. The stages of in-process detection, process change/design, and process reassessment loop continuously for each detected deviation and corrective action intervention<sup>39</sup> (whether or not the action or decision resulted in an adverse event).

Work on the systems-based nature of error and successful methods to reduce it have also indicated that individually-oriented, "shame and blame" mechanisms will be ineffective in reducing the incidence and effects of error.<sup>40</sup> Shame and blame of the individual, unfortunately the standard legal and medical perception as the best means of error reduction,<sup>41</sup> is precisely incorrect and serves only to have error, failure, and system deviation information hidden.<sup>42</sup> Fear of punishment simply does not promote error elimination nor does it maximize system performance; instead, cooperative, nonpunitive approaches that promote communications about system weaknesses and corrective action strategies are essential for error reduction and mitigation of its occurrence.<sup>43</sup>

As part of the communication between system members to improve system performance, a first and fundamental step is for system members to report and communicate where, how, and why errors are occurring; one must know of the errors to allow system members to assess and identify interventions that can reduce them, filling the failure holes of the system.<sup>44</sup> Without such transparency

<sup>39</sup> Two important illustrations of the success of this approach are the aviation and nuclear power industries; after instituting systems analysis and corrective action efforts, errors and accidents were significantly reduced while productivity substantially improved in both industries. See Liang, *Other People's Money*, *supra* note 30, at 28-30; Leape, *supra* note 17, at 1855.

<sup>40</sup> See, e.g., REASON, *supra* note 18, at 199; Leape, *supra* note 17, at 1852; Leape et al., *supra* note 29, at 1445.

<sup>41</sup> Liang, *Themes for a System*, *supra* note 13, at 93; see Liang, *Error Disclosure*, *supra* note 13; Liang, *A System of Error*, *supra* note 7, at 64, 65; Liang, *Perils of Law*, *supra* note 8, at 11.

<sup>42</sup> Leape, *supra* note 17, at 1852.

<sup>43</sup> See J. Duncan Moore, JCAHO Urges "Do Tell" in Sentinel Event Fight: Aviation's Lesson—Learn From Experience, MOD. HEALTHCARE, Mar. 2, 1998, at 60 (quoting Lucian Leape).

<sup>44</sup> See Liang, *Error in Medicine*, *supra* note 31, at 39; D.A. Lucas, *Organizational Aspects of Near Miss Reporting*, NEAR MISS REPORTING AS A SAFETY TOOL 134 (T.W. van der Schaaf, et al., eds. 1991).



and multiple levels of communication and feedback, unaddressed failure pathways remain within the system, insidiously increasing the potential for future adverse events.

## II. UNSAFE COMMUNICATIONS: PROVIDER SAFETY DISCUSSION EFFORTS

### A. Background

As noted above, to reduce errors and injury in the health care system, communications and discussion about error is fundamental to improving quality of care. Using the presence of reported errors to localize and analyze system function and to design corrective action to prevent and/or minimize the effects of error can thus lead to significant improvement in health care delivery.

However, much of the information pertaining to undesirable deviations in care—particularly error that results in injury—is highly sensitive. If error information reported, analyzed, and used for corrective system action can be used and accessed for other purposes—such as supporting lawsuits—there will be a severe chilling effect on these activities. Unfortunately, it appears that this is the case under extant legal rules, particularly in the conflict between state and federal courts.

### B. General Discovery Issues: The JCAHO SEP as an Example

An effort to promote error reporting and analysis in health care is the JCAHO sentinel event policy (SEP).<sup>45</sup> The SEP serves as an important illustration of how general discovery rules may preclude and disincentivize organizational efforts to share and communicate specifics regarding medical errors and patient safety.

In the SEP, a sentinel event is defined as “an unexpected occurrence involving death or severe physical or psychological injury, or the risk thereof,” including unanticipated death or major loss of function unrelated to the patient’s condition, patient suicide, wrong-sided surgery, infant abduction/discharge to the wrong fam-

<sup>45</sup> There have been significant efforts resisting the sentinel event policy due to legal concerns of discovery of this sensitive information. See, e.g., Liang, *Risks of Reporting*, *supra* note 30, at 113; Bryan A. Liang & Kristopher Storti, *Creating Problems as Part of the “Solution”: The JCAHO Sentinel Event Policy, Legal Issues, and Patient Safety*, 33 J. HEALTH LAW 263, 267-69 (2000) [hereinafter Liang & Storti].

ily, rape, and hemolytic transfusion reactions.<sup>46</sup> In contrast to other error reporting systems such as the Aviation Safety Reporting System (ASRS),<sup>47</sup> SEP excludes “near miss” reporting.<sup>48</sup> Mandated review of organizational responses to sentinel events is integral to JCAHO accreditation,<sup>49</sup> and SEP activities are required if an event is discovered by JCAHO.

Under the SEP, once the sentinel event has occurred, the entity must perform a “root cause analysis” (RCA).<sup>50</sup> The RCA is a detailed systems analysis reviewing the characteristics and performance that led to the sentinel event. A corrective “action plan” responsive to the identified areas of system weakness must be created. These documents must be submitted to JCAHO within forty-five days of the actual event or of the organization learning of the event.<sup>51</sup> If, however, the organization does not report the event, and JCAHO discovers it through other means, the entity will be contacted and must submit documents under the same forty-five day schedule.<sup>52</sup>

As may be apparent, providers’ primary concern regarding the SEP and other safety activities is the potential for legal discovery of

<sup>46</sup> Joint Commission on Accreditation of Healthcare Organizations, *Sentinel Event Policy and Procedures*, revised July 2002. *available at* [http://www.jcaho.org/accredited+organizations/healthcare-network/sentinelvents/se\\_pp.htm](http://www.jcaho.org/accredited+organizations/healthcare-network/sentinelvents/se_pp.htm) (last modified July 13, 2003).

<sup>47</sup> Moore, *supra* note 43, at 60; Michael Dornheim, *ASRS Fights to Curb Dangerous Trends*, 145(19) AVIATION WEEK & SPACE TECHN. 17 (1996); Liang, *Risks of Reporting*, *supra* note 30, at 113.

<sup>48</sup> Jerod M. Loeb, et al., *Sentinel events and root-cause analysis: A Workshop By The Joint Commission*, PROCEEDINGS OF ENHANCING PATIENT SAFETY AND REDUCING ERRORS IN HEALTH CARE, Nov. 8-10, 1998 (available from National Patient Safety Foundation, Chicago IL). Such a strategy will also lose information; there are significant benefits associated with analyzing near miss events, including the limited legal exposure associated with such analysis for providers as well as the recognition that studying system successes in averting adverse events is much more fruitful for system function. Anecdotally, health care organizations responding to the JCAHO initiative have been voluntarily extending their activities to include selected near miss events for sentinel event analysis for internal learning notwithstanding the lack of a mandate for JCAHO submission in this category. See, e.g., Liang, *Risks of Reporting*, *supra* note 30 at 113; and Paul Barach & Stephen D. Small, *How the NHS Can Improve Safety and Learning: By Learning Free Lessons From Near Misses*, 320 BRIT. MED. J. 1683 (2000).

<sup>49</sup> Joint Commission on Accreditation of Healthcare Organization, *supra* note 46.

<sup>50</sup> Liang & Storti, *supra* note 45, at 265.

<sup>51</sup> *Id.*

<sup>52</sup> *Id.*

the communications and information created thereunder.<sup>53</sup> And this concern is not unfounded.

Legal discovery is, of course, a powerful method to obtain evidence from those who have it.<sup>54</sup> Discovery is also powerful because of the broad scope of evidence it mandates a party to produce. The Federal Rules of Civil Procedure, and similar state statutes modeled therefrom, indicate that during discovery, parties have the right to obtain information regarding *any* matter that is relevant and not protected by a specific evidentiary privilege.<sup>55</sup> Such accessible information includes evidence not admissible at trial if the information appears "reasonably calculated" to lead to the discovery of admissible information<sup>56</sup>—a low standard indeed.

For providers, in the medical error and lawsuit context, a set of documents reporting the error, describing the facts surrounding the error, analyzing the type of patient and circumstances relating to the error, investigating what caused the error, and detailing corrective action plans in response to the error analysis, is clearly relevant to the subject matter of that particular case and thus would seem quite likely to be discoverable. Further, this information would be discoverable because it can also lead to discoverable information (such as incident reports and patient charts/records that are similar to the

<sup>53</sup> These fears have been so prevalent that the American Hospital Association (AHA), which occupies seven seats on JCAHO's board, sent an advisory warning to member hospitals informing them of the potential discovery and liability exigencies that reporting could create. See J. Duncan Moore, *JCAHO Revises Self-Reporting Policy*, 28 MOD. HEALTHCARE 20 (1998); J. Duncan Moore, *Malpractice Insurance: JCAHO Pushes Bill to Protect Hospitals that Report Errors*, 28, MOD. HEALTHCARE 15, Apr. 1998, at 12; See also Liang & Storti, *supra* note 45, at 267-68; Thomas Wilder, *Hospitals Fear JCAHO's Sentinel Event Policy Could Create Added Legal Exposure*, 7 BNA HEALTH LAW REP. 261 (1998).

JCAHO's continuously attempted to reassure hospitals that it is safe to report. See, e.g., Harold J. Bressler, *Sentinel events and the JCAHO: The genesis of patient safety*, PROCEEDINGS OF ADDRESSING THE MEDICAL, LEGAL AND ETHICAL DILEMMAS IN MODERN HEALTHCARE, 39TH ANNUAL CONFERENCE OF THE AMERICAN COLLEGE OF LEGAL MEDICINE, March 11-13, 1999 (available from American College of Legal Medicine, Milwaukee WI). See also Harold J. Bressler, *The Sentinel Event Policy: A Response by the Joint Commission*, 33 J. HEALTH LAW 519, 520, 526-27 (2000) (Mr. Bressler is General Counsel of the JCAHO). Nevertheless, the AHA's warning is entirely appropriate. Recently, SEP information was held to be discoverable in a patient injury suit. See Bryan A. Liang, *The Effectiveness of Physician Risk Management: Potential Problems for Patient Safety*, 5 RISK DECISION AND POLICY 183-202 (2000). P.R. Risch, et al., *Role of Previous Claims and Specialty on the Effectiveness of Risk-Management Education for Office-Based Physicians*, 163 WESTERN J. OF MED. 346, 346-50 (1999). A response to Mr. Bressler's article is in Liang, *Other People's Money*, *supra* note 30.

<sup>54</sup> See JOSEPH W. GLANNON, *CIVIL PROCEDURE, EXAMPLES AND EXPLANATIONS*, 4th ed. 302-22 (2002).

<sup>55</sup> See FED. R. CIV. P. 26(b).

<sup>56</sup> See FED. R. CIV. P. 26(b)(1).

profile given in the RCA). Thus, by engaging proactively in error reporting, investigation, discussion, and analysis, a provider could be effectively creating the equivalent of a signed admission of liability due to the highly sensitive nature of these documents, the discoverability of these documents in a legal proceeding if not protected, and the hindsight and potential plaintiff bias of juries (and providers) when assessing injury.<sup>57</sup> The existing patchwork quilt of state statutes and case law only further serves to hamper discussion and learning, tools that are necessary to investigate systems to improve safety.

### C. PR/QA Privilege: Hope for Safe[ty] Communications?

However, all may not be lost. At the present time, under state statute, peer review/quality assurance (PR/QA) committee proceedings have potential immunity from legal discovery (i.e., the PR/QA privilege).<sup>58</sup> Thus, state PR/QA privilege may assuage the problem of discovery of error reports and safety information and hence encourage provider participation in error reporting and safety discussions and activities if these materials are protected and confidential.<sup>59</sup>

The importance of a protected forum to discuss quality issues cannot be understated. Effective PR/QA activities require confidentiality to promote candor.<sup>60</sup> Indeed, as one court put it,

<sup>57</sup> See Bryan A. Liang & David J. Cullen, *The Legal System and Patient Safety: Charting a Divergent Course*, 91 ANESTHESIOLOGY 609-611 (1999); Bryan A. Liang, *Assessing Medical Malpractice Jury Verdicts: A Case Study of an Anesthesiology Department*, 7 CORNELL J.L. & PUB. POL'Y 121, 123 (1997); Kim A. Kamin & Jeffrey J. Rachlinski, *Ex Post ? Ex Ante: Determining Liability in Hindsight*, 19 LAW & HUM. BEHAV. 89, 90-92 (1995); Susan J. LaBine & Gary LaBine, *Determinations of Negligence and the Hindsight Bias*, 20 LAW & HUM. BEHAV. 501, 502, 504 (1996); Bryan A. Liang, *Layperson and Physician Perceptions of the Malpractice System: Implications for Patient Safety*, 57 SOC. SCI. & MED. 147, 150-51 (2003).

<sup>58</sup> Barry Cepelewicz et al., *Recent Developments in Medicine and Law*, 33 TORT & INS. L.J. 583, 588 (1998).

<sup>59</sup> *Id.*

<sup>60</sup> See, e.g., *Weekoty v. United States*, 30 F. Supp.2d 1343, 1346 (D.N.M. 1998) (noting physicians would not be as candid in quality discussions if peer review information open to discovery, with concomitant negative effects on medical care); IOM REPORT, *supra* note 2, at 111-112 ("Congress should pass legislation to extend peer review protections to data related to patient safety and quality improvement that are collected and analyzed by health care organizations for internal use or shared with others solely for purposes of improving safety and quality."). It has been noted that:

Despite differing views on approaches to improving quality [of] care, quality experts almost universally agree that an important predicate to quality improvement is for providers themselves to identify medical errors and other quality problems through data analysis and the generation of self-critical quality of care

"[c]onfidentiality is essential to the effective functioning of these [PR/QA] staff meetings; and these meetings are essential to the continued improvement in the care and treatment of patients."<sup>61</sup> Further, a recent commentator has added,

information. Once deficient care is identified and analyzed, systemic solutions can be developed to prevent recurrence of such quality problems in the future. Quality experts assert that in order for this self-criticism to occur in a way that will actually improve the quality of care, health care providers must be encouraged to identify quality problems and implement corrective actions without fear of litigation or government enforcement related to those problems.

Yet, existing law inhibits the very types of quality improvement activities promoted by quality experts. Specifically, existing law does not adequately protect the confidentiality of self-critical quality improvement information from disclosure to non-governmental third parties. As a result, while quality experts are calling for providers to generate and report information on potential quality problems in an effort to improve the quality of patient care, providers are being subject to an unprecedented number of malpractice claims and government enforcement actions, that often rely on the same quality of care information generated by providers for quality improvement.

Jason M. Healy et al., *Confidentiality of Health Care Provider Quality of Care Information*, 40 BRANDEIS L.J. 595, 596-597 (2002) (citations omitted). They also note that:

without adequate confidentiality protections, there is a disincentive for health care providers to conduct self-critical quality reviews for fear of increased litigation costs and a resulting increase in malpractice insurance premiums. This creates a "chilling effect" on provider quality improvement initiatives as the health care provider's limited financial and human resources are diverted away from quality improvement initiatives and toward litigation defense. The inevitable result is limited improvement, and perhaps a decrease, in the quality of care patients receive.

*Id.* at 600 (citations omitted). Thus, "[r]ecent developments in [the areas of malpractice, fraud and abuse litigation] have created a punitive environment for health care providers who attempt to conduct thorough internal quality of care reviews." *Id.* at 616.

<sup>61</sup> *Bredice v. Doctor's Hosp., Inc.*, 50 F.R.D. 249, 250-51 (D.D.C. 1970), *aff'd mem.*, 479 F.2d 920 (D.C. Cir. 1973). Note that this case actually held that there was a federal self-evaluative privilege akin to peer review/quality assurance privilege; however, this holding has not been broadly accepted. See, e.g., Liang & Storti, *supra* note 45, at 272-75; George E. Newton II, *Maintaining the Balance: Reconciling the Social and Judicial Costs of Medical Peer Review Protection*, 52 ALA. L. REV. 723, 723-27 (2001) (peer review assessing provider training, competence, and licenses an essential part of credentialing process and statutes protecting participants critical in encouraging participation); and Katheryn Ehler-Lejcher, *The Expansion of Corporate Compliance: Guidance for Health Care Entities*, 25 WM. MITCHELL L. REV. 1339, 1388 (1999) (noting limited application of federal self-evaluative privilege). Unfortunately, no federal courts or federal agencies have accepted the self-evaluative privilege. *Id.* Indeed, the privilege is generally inapplicable when the United States is the named plaintiff. See, e.g., *United States v. Dexter Corp.*, 132 F.R.D. 8, 8-10 (D. Conn. 1980); and *FTC v. TRW, Inc.*, 628 F.2d 207, 208, 210-11 (D.C. Cir. 1990).

It should be emphasized that 'doctors' reluctance to participate in peer review without protection from liability [for statements and action therein] compelled fifty states and Congress to enact peer-review privilege legislation in order to have effective peer review. . . . While physicians ideally feel an ethical duty to keep the standard of health high, they are reluctant to police other members of their profession without protections peer-review privileges provide.

[c]learly, public access to a health provider's self-critical quality of care information inhibits effective review and correction of quality of care practices. Whether quality of care information is maintained by the provider or disclosed to government entities with authority to regulate or oversee compliance activities, that information must be protected from third parties.<sup>62</sup>

However, upon deeper inspection, reliance on PR/QA privilege may be fraught with risk. Broad jurisprudential holdings are of great concern. Specifically, the U.S. Supreme Court has noted that all evidentiary privileges should be construed narrowly.<sup>63</sup> As a result, although sometimes protected, a broad array of PR/QA records has been admitted in actions involving medical providers.<sup>64</sup> Of direct interest here is that such broad discovery has extended to quality-related documents, including provider-specific information.<sup>65</sup> These holdings would have a strong tendency to chill such reporting when litigation could be supported by these data,<sup>66</sup> partic-

Katherine T. Stukes, *The Medical Peer Review Privilege after Virmani*, 80 N.C. L. REV. 1860, 1873 (2002) (footnotes omitted).

<sup>62</sup> Healy et al., *supra* note 60, at 621-23.

<sup>63</sup> *Trammel v. United States*, 445 U.S. 40, 50-52 (1980).

<sup>64</sup> For example, broad requests for quality assurance information have been admitted over an objection based on the peer review immunity. In *State of Missouri, ex rel. Dixon v. Darnold*, 939 S.W.2d 66, 69-70 (Mo. App. 1997), a patient brought a medical action against a hospital and several physicians. The patient requested discovery of an extremely long laundry list of documents including

quality assurance/quality management flow sheet[s] . . . ; infection data . . . ; written documentation by the infection control nurse . . . ; [a]ny quality assessment (QA) . . . abstract forms . . . utilized by the quality assessment and/or quality management [QM] department . . . ; [a]ny trend sheet prepared from any QA and/or QM abstract for or work sheets . . . ; transmitted sheets or memos generated to or from the infection control nurse or infection control department . . . ; written minutes from an Infection Control Committee meeting . . . ; [a]ny transmittal written to the Infection Control Coordinator or nurse . . . ; [a]ny transmittal written to the Risk Management Department from any member of the QA department . . . ; [t]he 1994 Semi-Annual Reports of the nosocomial infection rates of [defendant] Drs. Wakeman, Kerber and Gibson compiled by the Infection Control Coordinator.

This extensive discovery request was resisted by the defendants on the basis of protected peer review; however, the appellate court disagreed, ordering the trial court to require that the defendants produce the plaintiff-requested documents. *Id.* at 71.

<sup>65</sup> See *id.* at 70.

<sup>66</sup> Even one event may trigger such a chilling effect. For example, as noted by other commentators:

In many cases, a single incident, such as a resident's fall, will lead to the filing of a complaint against a nursing home. The resident's attorney then uses the discovery phase of the litigation to request the nursing home's records, such as staffing reports, budgets, and incident reports that report all adverse events. By using these documents to create the appearance of a pattern of neglect, a single incident can turn into an indictment of the entire nursing home.



ularly in the context of the low "reasonably calculated" standard for allowable document discovery.<sup>67</sup>

Further, exacerbating the risk of discovery, in 1993, the Supreme Court approved and promulgated automatic disclosure requirements. Under these rules, at the beginning of the case and without a formal request from the opposing party, each must produce "a copy of, or a description by category and location of, all documents, data compilations, and tangible things in the possession, custody or control of the party that are relevant to disputed facts alleged with particularity in the pleadings."<sup>68</sup> Thus, in the health care context, because error reports, SEP documents, and related safety materials would likely be deemed as "relevant documents" in a patient injury suit, it may not even be necessary for the opposing party to request production of these documents since they fall within the automatic disclosure requirements. Hence, state PR/QA privilege alone may be significantly deficient in protecting error and safety communications and information, and indeed there may be a legal obligation to provide this information without request.

Beyond the potential for limited protection of error and safety discussions and information under the PR/QA privilege, it should be noted that, as state law, these privileges are quite varied across jurisdictions.<sup>69</sup> Some statutes may protect little to none of the infor-

Healy et al., *supra* note 60, at 618. See also Bryan A. Liang et al., *Which Syringe Did I Use? Anesthesiologist Confusion and Potential Liability for a Medical Error*, 14 J. CLIN. ANESTHESIA 371, 374 (2002) (describing case where disclosure of an error easily hidden resulted in a protracted lawsuit).

<sup>67</sup> Recall, even lack of document admissibility in the ultimate adjudication does not support any document privilege exclusion. The court may still order production of the documents as "[i]t is not grounds for objection that the information may be inadmissible at trial, if the information sought appears reasonably calculated to lead to the discovery of admissible evidence." *Missouri, ex rel. Dixon v. Darnold*, 939 S.W.2d 66, 70 (Mo. App. 1997).

<sup>68</sup> See FED. R. CIV. P. 26(a)(1)(B).

<sup>69</sup> See Elise Brennan, *Peer Review Confidentiality*, 1999 AMERICAN HEALTH LAWYERS ASSOCIATION ANNUAL MEETING. In a related matter, staff privilege application documents are also discoverable. For example, in *Harper v. Cadenhead*, 926 S.W.2d 588, 588 (Tex. App. 1995), the plaintiffs in a medical malpractice action requested discovery from a hospital of "[a]ll documents (including applications, inquiries and recommendations) concerning the credentialing committee's consideration of [defendant physician's] being given staff privileges" at the hospital. *Id.* The hospital refused, claiming that the peer review privilege rendered these documents undiscoverable. *Id.* However, the appellate court rejected this argument, indicating that because these documents are kept within the regular course of the hospital's business, the credentialing committee was not acting as a peer review committee, and since the committee was only assessing whether the physician is qualified to practice at the hospital, the peer information was not immune from discovery and was thus discoverable by plaintiffs. *Id.*

mation required for error detection and analysis, while some statutes appear to provide such documents with some protection.<sup>70</sup> Overall, although there may be limited protection, state PR/QA privilege alone may not protect sensitive safety information from being used for unintended litigation support.<sup>71</sup>

<sup>70</sup> This variation problem becomes magnified by the lack of case law interpreting state statutes as they apply to safety materials. However, preliminary results are not encouraging; See Liang, *A System of Medical Error*, *supra* note 7, at n.25. In addition, corrective action plans and memoranda in nursing homes have not been protected by PR/QA privilege. See, e.g., *Hale v. Odd Fellow & Rebekah Health Care Facility*, 728 N.Y.S.2d 649 (N.Y. Sup. Ct. 2001). These holdings are of great concern, since the very basis of the activities performed was for quality improvement purposes; by allowing for discovery, and thus allowing for quality information to be used against the facility, such quality activities will be severely discouraged.

<sup>71</sup> Other weaknesses attend state PR/QA privilege laws. Despite most states protecting at least some information generated by a PR/QA committee, these statutes generally decline to extend the privilege to information obtainable from an "original source." See, e.g., HAW. REV. STAT. ANN. § 624-25.5(b) (Michie 1997); 745 ILL. COMP. STAT. ANN. 55/4 (West 1998); LA. REV. STAT. ANN. § 13:3715.3 (West 1997); TENN. CODE ANN. § 63-6-219(e) (1997); D.C. CODE ANN. § 32-505(b) (1997); FLA. STAT. ANN. § 766.101(5) (West 1997); IOWA CODE ANN. § 147.135(2) (West 1997); MASS. GEN. LAWS ANN. CH. 111, § 204(b) (West 1997); MO. ANN. STAT. § 537.035(4) (West 1997). Possession of the information by the relevant committee therefore does not create immunity for the information itself. This is highly problematic. Although in theory, facts and analysis are distinguishable, in practice, the use of either can result in a distorted picture of the circumstance so described and analyzed. But "[b]ecause quality of care review reports may gather into one comprehensive document many of the most egregious quality problems at the provider's facilities, the facts in the report alone could be quite damaging to the provider if disclosed to prosecutors or third parties. Without the analysis, these facts can lose their context, allowing for varied interpretations to support unlikely conclusions." Healy et al., *supra* note 60, at 630.

Hence, merely presenting materials to the peer review committee will not afford the materials legal protection from discovery. Further, even in the states with the highly protective statutes, these statutes generally do not shield what is deemed administrative information, including incident reports, occurrence reports, or reports made in the normal course of business. See, e.g., HAW. REV. STAT. ANN. § 624-25.5(b) (Michie 1997), TENN. CODE ANN. § 63-6-219(e) (1997). Information that has been held discoverable include: "[incident] reports . . . completed by the staff person(s) involved in or observing the incident," *Cochran v. St. Paul Fire and Marine Ins. Co.*, 909 F. Supp. 641, 644 (W.D. Ark. 1995); "antecedent reports memorializing bare facts . . . collected from percipient witnesses," *Columbia/HCA Healthcare Corp. v. Daily*, 936 P.2d 844, 850 (Nev. 1997); "information or data provided to a [peer review/quality assurance] committee or collected for the committee's review," *Trinity Med. Ctr. v. Holum*, 544 N.W.2d 148, 157 (N.D. 1996); "routine accumulative information despite the fact that these documents may eventually serve as evidence in [peer review/quality assurance] committee deliberations," *McAllen Methodist Hosp. v. Ramirez*, 855 S.W.2d 195, 198 (Tex. - Corpus Christi 1993), (citing *Barnes v. Whittington*, 751 S.W.2d 493, 496 (Tex. 1988)); "information originat[ing] outside the peer review process," *Humana Hosp. Desert Valley v. Edison*, 742 P.2d 1382, 1385 (Ariz. Ct. App. 1987); "personnel, administrative, and other hospital records . . . which do not contain reference to proceedings [before medical investigative committees]," *Schulz v. Stavig*, 136 Cal.Rptr. 67, 71 (Cal. Ct. App. 1977); "the effect of [peer review/quality assurance] proceedings," *Anderson v. Breda*, 700 P.2d 737, 741 (Wash. 1985); "investigation [reports] . . . by hospital



administration," *Marsh v. Lake Forest Hosp.*, 519 N.E.2d 504, 509 (Ill. Ct. App. 1988); "investigation [documents] generated by the [hospital] Board or its agents as part of its investigation of a complaint [against a provider]," *Adams v. St. Francis Regional Med. Ctr.*, 955 P.2d 1169, 1183 (Kan. 1998); "[d]ocuments in the possession of and information known to the hospital's board and [CEO]," *Shelton v. Morehead Mem. Hosp.*, 347 S.E.2d 824, 830 (N.C. 1986); "information contained in peer review records . . . available from another source," *Garber v. Abington Mem. Hosp.*, 1993 WL 209542 (E.D. Pa. 1993), at \*2; "document[s] . . . created in the ordinary course of the hospital's medical business, or for the purpose of rendering legal opinions, or to weigh potential liability risk, or for later corrective action." *Chicago Trust Co. v. Cook Cty. Hosp.*, 698 N.E.2d 641, 649 (Ill. App. 1998).

Discoverability of incident and occurrence reports is very discouraging for patient safety efforts. For example, in *Columbia/HCA Healthcare Corp. v. Eighth Judicial District Court*, 936 P.2d 844, 846 (Nev. 1997), the parents of a child who died after being treated for an arachnoid cyst filed a medical malpractice action against the hospital and physicians involved in the care. The parents-plaintiffs requested discovery of "[a]ny incident report arising out of the treatment of [the child] . . . [and] [t]ranscriptions of oral statements about or written statements about any Hospital employee or from any physician with staff privileges at Hospital involved in the care of [the child]." *Id.* at 846.

The defendant hospital claimed that these reports were protected from discovery under the peer review privilege. However, the court rejected this argument, indicating that since the reports were prepared in the ordinary course of business, i.e., the hospital required incident and occurrence reports to be filed, it was not protected by the privilege, even though these reports were prepared "to improve 'the quality of care given'" at the hospital. *Id.* at 848. The court noted that only formal proceedings by peer review committees, not documents submitted or generated without the peer review committee's impetus, were privileged. *Id.* at 849. Unfortunately, this result bodes poorly for error research efforts because reports of error as represented by incident reports are precisely the type of information that is required to begin and build systemic patient safety efforts. Treatment of incident reports at law as discoverable will provide little impetus for providers to engage in this reporting.

Thus, if a court, in fact, does recognize error reports and/or analysis as an occurrence report or a report made in the normal course of business (which is likely considering that, for example, JCAHO and state authorities mandate the creation of these documents under accreditation and licensing rules), it is generally not protected by PR/QA privilege.

This result may also be obtained when providers attempt to invoke another privilege: the attorney-client privilege. For example, in *State of West Virginia, ex rel., United Hospital Center, Inc. v. Bedell*, 484 S.E.2d 199 (W.Va. 1997), a deceased patient brought a personal injury action against a hospital emergency room. The patient had fallen in the emergency room and requested discovery of the incident report that described the event. *Id.* at 204. The hospital refused to supply the report, arguing that the incident report was within the attorney-client privilege because it was submitted to the hospital's general counsel. *Id.* at 205. The court again disagreed. *Id.* at 209. First, the court noted that incident reports were filed in "[a]ny event that occurs during the hospital stay of a patient, visitor or volunteer which is non-routine (i.e., an accident or mistake). . . [and that] the purpose of incident reporting is not to place blame on individuals. [Reporting] is designed to enhance the care provided and to assist in providing a safe environment." *Id.* at 204.

This recognition of the document's specific patient safety use notwithstanding, the court held that the information was not privileged. The court noted that the attorney-client privilege is to be narrowly construed like other privileges. The court then held that the incident reports at issue were not protected since the hospital neither showed that the nurse who filed the report with the hospital's general counsel believed that an attorney-client privilege existed, nor did the nurse seek legal advice from the general counsel. Thus, in this case of direct assessment of safety reporting issues, the court indicated that

#### D. PR/QA Privilege: State-Federal Interface

To add insult to injury against those interested in promoting error reports and patient safety communications and discussions, the PR/QA privilege has a significant and gaping weakness: its authority is derived from state law.<sup>72</sup> Here is where the federal-state interaction creates highly undesirable results for the privilege and any ability to keep safety information protected.

Causes of action involving federal law heard in a federal court will generally not be subject to state law privileges. Only if the federal court elects to adopt state law privileges will any such privilege apply to the case.<sup>73</sup> However, as a general matter in relation to PR/QA privilege, in strictly federal causes of action, federal courts have virtually always refused to adopt state law PR/QA privilege due to the Supreme Court jurisprudence that strongly disfavors discovery limitations through peer review privilege.<sup>74</sup>

But beyond claims involving federal law alone, because state law claims such as patient injury suits may be pled with federal claims, the federal court may exercise pendent jurisdiction over them.<sup>75</sup> Yet, in that case, the federal privilege approach will then generally apply to the state law claims in the proceeding—that is, no privilege at all.<sup>76</sup> Thus, beyond simple federal cause of action suits and rejection of PR/QA privilege, federal courts across the country have been amazingly consistent in holding that when at least one federal claim is extant, including antitrust law,<sup>77</sup> the Amer-

the materials were discoverable by plaintiffs. *Id.* Again, this result would have a tendency to chill substantive participation in reporting medical error.

<sup>72</sup> Exacerbating the issue is that this is not a problem that can be settled by the interpretation or ruling of a single court. It bears emphasizing that every jurisdiction in every state can rule and interpret for itself how far the applicable state statute should go to protect error and safety documents, if at all, which will only increase the variation in law and uncertainty as to what will and will not be protected.

<sup>73</sup> FED. R. EVID. 501.

<sup>74</sup> *Univ. of Penn. v. E.E.O.C.*, 493 U.S. 182 (1990); See also Liang, *Risks of Reporting*, *supra* note 30.

<sup>75</sup> 28 U.S.C. § 1367; *LeMasters v. Christ Hosp.*, 791 F. Supp. 188, 191 (S.D. Ohio 1991); *Hansen v. Allen Mem. Hosp.*, 141 F.R.D. 115, 121 (S.D. Iowa 1992) (asserting that federal privilege law governs even pendent state claims).

<sup>76</sup> *Wm. T. Thompson Co. v. Gen. Nutrition Corp.*, 671 F.2d 100, 104 (3d Cir. 1982); *Pagano v. Oroville Hosp.*, 145 F.R.D. 683, 687 (E.D. Cal. 1993). See also Liang, *Risks of Reporting*, *supra* note 30, at 114.

<sup>77</sup> See, e.g., *Teasdale v. Marin Gen. Hosp.*, 138 F.R.D. 691, 699 (N.D. Cal. 1991); *Purgess v. Sharrock*, 33 F.3d 134 (2d Cir. 1994); *Pudlo v. Adamski*, No. 91C 7474 1992 WL 27002, at 3 (N.D. Ill. Feb. 12, 1992); *Sarthmore Radiation Oncology, Inc. v. Lapes*, No. Civ. A. 92-3055 1992 WL 517722, at 3 (E.D. Pa. Dec. 1, 1993); See also Liang, *Risks of Reporting*, *supra* note 30.



icans with Disabilities Act,<sup>78</sup> Title VII civil rights actions,<sup>79</sup> the Federal Torts Claims Act,<sup>80</sup> racial discrimination claims,<sup>81</sup> gender discrimination claims,<sup>82</sup> and the Emergency Medical Treatment and Active Labor Act,<sup>83</sup> the state PR/QA privilege is inapplicable and cannot prevent discovery of PR/QA information.<sup>84</sup> Thus, joining a federal claim to a patient injury suit involving an adverse event effectively emasculates state PR/QA privilege protection of safety materials—even if the same case in the same state in state court without the federal claim would have held that the PR/QA privilege applied to these very same materials.

The federal Health Care Quality Improvement Act of 1986 (HCQIA)<sup>85</sup> further solidifies this position. The HCQIA provides for qualified immunity to *participants* in peer review, but does not include a privilege preventing discovery of peer review *materials*.<sup>86</sup>

<sup>78</sup> See, e.g., *Marshall v. Spectrum Medical Group*, 198 F.R.D. 1 (D. Me. 2000); *Robertson v. Neuromedical Center*, 169 F.R.D. 80 (M.D. La. 1996); *Johnson v. Nyack Hosp.*, 169 F.R.D. 550 (S.D.N.Y. 1996). See also Liang, *Risks of Reporting*, *supra* note 30.

<sup>79</sup> See, e.g., *Holland v. Muscatine Gen. Hosp.*, 971 F. Supp. 385 (S.D. Iowa 1997); *Mem. Hosp. v. Shadur*, 664 F.2d 1058, 1061 (7th Cir. 1981). See also Liang, *Risks of Reporting*, *supra* note 30.

<sup>80</sup> See, e.g., *Syposs v. U.S.*, 179 F.R.D. 406 (W.D.N.Y. 1998). See also Liang, *Risks of Reporting*, *supra* note 30.

<sup>81</sup> See, e.g., *Virmani v. Novant Health, Inc.*, 259 F.3d 284 (4th Cir. 2001); *Johnson v. Nyack Hosp.*, 169 F.R.D. 550 (S.D.N.Y. 1996); *King v. Conde*, 121 F.R.D. 180, 187 (E.D.N.Y. 1988). See also Liang, *Risks of Reporting*, *supra* note 30.

<sup>82</sup> See *LeMasters v. Christ Hosp.*, 791 F. Supp. 188, 189 (S.D. Ohio 1991).

<sup>83</sup> See, e.g., *Burrows v. Redbud Comm. Hosp.*, 187 F.R.D. 606, 607 (N.D. Cal. 1998); see also Susan Webster, *Doctor Cleared of Murder Charges, But Case Raises Big Question on Peer Review Immunity*, 7 BNA HEALTH LAW REP. 470 (1998); and Liang, *Risks of Reporting*, *supra* note 30.

<sup>84</sup> See also *Mem. Hosp. v. Shaddur*, 664 F.2d 1058 (7th Cir. 1981) (declining explicitly to recognize peer review privilege) (*quoted in Virmani*, 259 F.3d at 292). Note also that other federal laws serve as disincentives and barriers to improve quality due to the potential for its use against the provider. The False Claims Act may do the same:

the ubiquity of false claims actions and other fraud and abuse litigation against health care providers has provided a disincentive for providers to conduct thorough internal reviews of their quality of care practices because of the legitimate fear that documents pertaining to those reviews will be used against them in the courtroom.

Healy et al., *supra* note 60, at 607.

<sup>85</sup> See 42 U.S.C.A. §§ 11101, 11111-11152 (2003).

<sup>86</sup> *Id.*; but see *Davenport v. Northeast Ga. Med. Ctr., Inc.*, 237 Ga. App. 252 (Ct. App. 1999) (denying immunity to hospital peer review board because it did not provide adequate notice to terminated physician); *Szczerbaniuk v. Mem. Hosp. for McHenry Cty.*, 536 N.E.2d 138 (Ill. App. 1989) (peer review immunity not applicable to CEO of hospital who made unilateral decision to terminate physician because physician contract required CEO to consult with hospital governing body).

Since PR/QA information will only be protected if federal law expressly delineates some discovery limitation specifically noted by statute,<sup>87</sup> it is clear that HCQIA does not extend any federally-based protection to any documents included or created in the PR/QA process.

In addition, notwithstanding the level of protection an individual state's PR/QA statute may provide, information may be obtained through the federal Freedom of Information Act (FOIA).<sup>88</sup> Federal regulation related to hospitals accredited by JCAHO mandates that the hospital permit the JCAHO to release, both to the state and the federal Centers for Medicare and Medicaid Services (CMS), a copy of the most current accreditation survey. Such information could include anything related to the survey, including error reports and safety information. Thus, allowing CMS access to this information is extremely problematic for disclosure of the informa-

<sup>87</sup> See, e.g., *Todd v. South Jersey Hosp. System*, 152 F.R.D. 676 (D.N.J. 1993); see also *Armstrong v. Dwyer*, 155 F.3d 211 (3d Cir. 1998).

<sup>88</sup> See 5 U.S.C.A. § 552. Note other federal statutes may result in disclosure that may trump state PR/QA privilege. A common scenario involves state survey's to determine if a facility has met the Medicare program's conditions of participation:

For example, within ninety days after a survey is completed by a state agency to determine a facility's compliance with the federal conditions of participation [for the Medicare program], the following items may be made publicly available at the local Social Security office or public health assistance office: the official Medicare report of the survey; any statements of Medicare deficiencies that were conveyed to the provider after the survey; any plans of correction; and other comments of the provider in response to the deficiencies cited. Official reports by the United States Department of Health and Human Services, Center for Medicare and Medicaid Services ("CMS") on provider performance may be obtained by any member of the public upon written request, although information identifying individuals, patients, physicians, and other practitioners is excluded. Medicare reports of provider audits may also be disclosed to the public and the press. . . . HHS . . . may publicly disclose . . . accreditation surveys and any related information to the extent it relates to an agency enforcement action. Healy et al., *supra* note 60, at 614-15 (footnotes omitted). Further, the aftermath of a federal fraud and abuse investigation can result in a "corporate integrity agreement" or CIA. However, under a CIA, providers are generally mandated to conduct quality reviews, with little protection given for these reviews. See *United States ex rel. McCarthy v. Straub Clinic and Hosp.*, 140 F. Supp.2d 1062 (D. Haw. 2001). Providers are usually mandated to submit documents generated from those reviews to the federal government investigatory bodies (such as the DOJ and OIG). The implication of this is that "[w]ithout adequate legal protections for th[is] [quality of care] information at the federal level, the Straub case has allowed qui tam relators [pursuing cases against providers under the False Claims Act] to obtain quality of care documents through Freedom of Information Act ("FOIA") requests or discovery for use against providers operating under a CIA. The inevitable result will be that those providers will conduct less thorough and effective quality of care reviews to avoid the litigation risks associated with accumulating and generating quality of care documentation." Healy, et al., *supra* note 60, at 617-18.

tion because, pursuant to FOIA, CMS is authorized—indeed, mandated—to release the information in direct response to a request from the public. Thus, even if a particular state's PR/QA statute is protective and a court holds in favor of protection, through the FOIA-CMS mechanism, it is feasible that a plaintiff's attorney may still obtain error and safety information.<sup>89</sup> The state of the problem can be described as follows:

Whether a plaintiff's firm obtains a provider's quality of care documents during civil discovery or through FOIA requests as a method of "fishing" for a case, such documents are accessible because of the lack of adequate legal protections. In this way, plaintiffs' firms have been able to extract large judgments or out-of-court settlements from providers using the providers' own self-critical quality of care information.<sup>90</sup>

Overall, due to the limited state-based protection for PR/QA error and safety discussions, when combined with federal rules and court assessments, additional incentives are created to avoid error reporting and safety discussions.

### III. MEDIATION: GETTING THE PATIENT AND PROVIDER TALKING

#### A. Mediation and A Partnership of Patient and Provider

Part of the process of partnership between patient and provider to reduce errors and promote safety requires that, as a component of mutual respect and partnership, providers maintain an active communicative relationship with patients and vice versa.<sup>91</sup> One part of this effort includes disclosing errors to patients if and

<sup>89</sup> See Fay A. Rozovsky et al., *The JCAHO Sentinel Event Policy: Concerns and Alternatives*, 26 HEALTH LAW DIGEST 3-10 (1998). See also Liang, *Risks of Reporting*, *supra* note 30. Of course, beyond federal FOIA requests, state FOIA statutes may also allow for access to information that is required to be reported under state mandates for healthcare provider reporting, including the dozen or so adverse event state reporting statutes. See IOM REPORT, *supra* note 3, at 78; see also *Public Health: Clinton Orders Task Force to Issue Report on Patient Safety, Previews New Measures*, BNA HEALTH CARE DAILY REP., Dec. 8, 1999, at 1.

<sup>90</sup> Healy et al., *supra* note 60 at 618-19. Such actions are not costless to society. Insurance access has been at crisis proportions recently, with providers without losses having premiums raised 30-70% and those with losses 100-200%, assuming insurance is available. *Id.* at 619. Undoubtedly these resources will be unavailable to good faith providers attempting to improve patient care through safety efforts.

<sup>91</sup> Note that patients and their families also have responsibilities in a true partnership, and these responsibilities should include reporting and discussing issues regarding the system of delivery and their own medical histories and information. Their role should be active, rather than the traditional passive role often espoused or implied by traditional medical ethics and ethicists. See Liang, *Error Disclosure*, *supra* note 13.

when they occur and cause injury.<sup>92</sup> To facilitate this part of involving the patient in the health delivery system, mediation should be an essential part of working with patients who are injured. Through mediation, valuable system information can be unearthed for corrective action. Such corrective action would be applicable to the facility and possibly to other organizational entities. Further, mediation provides critical social and emotional benefits for patients unavailable—indeed, discouraged—through litigation.

However, at present such efforts may not be possible or desirable. Federal-state issues may result in difficult determinations as to whether information purportedly confidential may or will be disclosed, similar to PR/QA safety efforts. As such, again like PR/QA efforts in safety, mediation privilege may provide little if any protection for sensitive information. Its potential disclosure may chill efforts to engage in open and fruitful discussions between providers and patients to promote safety.

#### B. A Brief Primer on Mediation

Mediation is a facilitative process whereby a neutral third party attempts to assist parties in a dispute to negotiate a mutually agreeable resolution.<sup>93</sup> One tremendous value of this process is the quality and quantity of information that may be available for a settlement effort, particularly with a skilled third party assisting, even when the information is only disclosed to the mediator.<sup>94</sup> Thus, mediation provides significant potential for promoting communications and information exchange.

Effective mediation requires trust between the parties and the mediator.<sup>95</sup> Part of this trust relationship requires that information discussed during mediation remain confidential like PR/QA information; otherwise, there will be little if any incentive to be forthright

<sup>92</sup> Errors that do not cause injury should still be disclosed to patients to obtain important insights as to system function. See Barach & Small, *supra* note 48; see also Liang, *A System of Medical Error*, *supra* note 7; and Liang, *Risks of Reporting*, *supra* note 30.

<sup>93</sup> Bryan A. Liang, *ADR in Health Care: An Overview of the ADR Landscape*, HEALTH CARE DISPUTE RESOLUTION MANUAL 3:1-3:43 (2000) [hereinafter Liang, *ADR in Health Care*].

<sup>94</sup> Ellen E. Deason, *Predictable Mediation Confidentiality in the U.S. Federal System*, 17 OHIO ST. J. DISPUTE RESOLUTION 239, 245 (2002) (stating "that a skilled neutral can enhance the quality and quantity of information brought to bear in a settlement attempt").

<sup>95</sup> Indeed, part of the importance of mediation is to keep the mediator neutral. If the mediator may be called to testify in court about the substantive aspects of the mediation, such testimony will of course tend to support one party or the other, and be seen as the "tiebreaker," which may compromise the perception of neutrality for future mediations. *Id.* at 246.



in communications and discussions.<sup>96</sup> As noted in the context of attorney-client privilege, the U.S. Supreme Court observed that:

if the purpose of the attorney-client privilege is to be served, the attorney and client must be able to predict with some degree of certainty whether particular discussions will be protected. An uncertain privilege, or one which purports to be certain but results in widely varying applications by the courts, is little better than no privilege at all.<sup>97</sup>

Similarly, if the parties believe that the mediator or opposing party will disclose or be compelled to disclose statements made in mediation, there will be significant dampening of the communication necessary to promote useful information flow.<sup>98</sup>

Indeed, since mediation often occurs with parties who are adversaries, confidentiality assumes an even greater importance to promote effective communications: "[w]ithout such protection, parties will rationally anticipate that their statements in mediation will be turned against them by the opposing party if there are subsequent legal proceedings."<sup>99</sup> Parties in a mediation will often reveal personal and business secrets, disclose and discuss sensitive feelings about others, and make legal and factual admissions; as such, without the protection of confidentiality, "a participant's candor in mediation might be rewarded by a discovery request, the revelation of mediation information at trial, or worse."<sup>100</sup>

In the mediation process, the neutral third party mediator is often selected by the parties jointly. The process of mediation is usually informal, with no rigid or set rules except those agreed to by the parties or requested by the mediator to promote useful communications (for example, no interruptions when one party is speaking). In addition, parties themselves usually represent themselves and communicate in the mediation proceeding; attorneys are much less common as agents of the parties than in more formal dispute resolution mechanisms such as litigation.

Since informal communications in mediation are common, these communications may extend to statements of the parties' per-

<sup>96</sup> "[M]ediation is dependent upon trust among the participants." Anne M. Burr, *Confidentiality in Mediation Communications: A Privilege Worth Protecting*, 57 DISP. RESOL. J. 64, 64 (Feb.-Apr. 2002).

<sup>97</sup> *Upjohn Co. v. United States*, 449 U.S. 383, 393 (1981).

<sup>98</sup> Deason, *supra* note 94, at 245 ("A skilled mediator can often use this sensitive information to advance the negotiations even without conveying it to the adverse party. Confidentiality is a key element in encouraging this three-way communication process.")

<sup>99</sup> *Id.* at 246.

<sup>100</sup> Burr, *supra* note 96, at 65.

ceptions of the dispute in a joint session, and/or may involve the mediator meeting each party separately to understand each party's goals and concerns, goals that might be shared by both, as well as proposed resolutions which could be acceptable to both. Several joint and separate sessions usually occur to fully delineate the critical claims and necessary characteristics of any resolution. The mediator may take this information and identify areas of joint interest to help the parties fashion a mutually beneficial agreement between them.<sup>101</sup>

Critically, it should be emphasized that this process is premised upon and can only be successful if communications between the parties is promoted. By improving communications, the interests, goals, and needs of each are identified to the other. This improvement may be especially important in situations where the parties have an ongoing relationship and will need to engage in activities together in the future.<sup>102</sup>

In addition, when the parties control the process without rigid legal rules (and sometimes without attorneys) constraining them,<sup>103</sup> the availability of solutions beyond mere pecuniary transfer allow for more creative and flexible solutions to be proposed and implemented.<sup>104</sup> Mediation can therefore provide more responsive results that specifically address the parties' concerns regarding their dispute rather than hammering the form of communications and potential solutions into the somewhat artificial and arcane shape of the formal litigation rubric.

The mediation process provides the parties "an opportunity to show and express a productive amount of emotion, within or outside the presence of the other party."<sup>105</sup> Additionally, it provides parties an opportunity to tell their story and have their suffering acknowledged.<sup>106</sup> Mediation may also allow providers a chance to apologize and show empathy for the patient and/or his or her fam-

<sup>101</sup> Liang, *ADR in Health Care*, *supra* note 93, at 3:7.

<sup>102</sup> *Id.*

<sup>103</sup> *Id.* at 3:8.

<sup>104</sup> Patients have been reported strongly to desire other actions by providers than simply the payment of money. This includes facilitation of communication, resolution of uncertainty, allowance for venting and to be heard, acknowledgment of suffering, and creation of a dynamic that allows for a future relationship, healing, and flexibility. See Liang, *A System of Medical Error*, *supra* note 7, at 67 (citations omitted).

<sup>105</sup> Liang, *ADR in Health Care*, *supra* note 93, at 3:8.

<sup>106</sup> Liang, *A System of Medical Error*, *supra* note 7, at 67.

ily.<sup>107</sup> These activities provide catharsis regarding the dispute and may contribute positively to a resolution,<sup>108</sup> rather than having communication battle lines drawn for litigation.

The focus of mediation also shifts discussion and context of the conflict from the past to the future. Such a focus provides a productive sense of what needs to be done to help both parties regain control of their lives after the dispute is resolved. Focusing on the future also allows each party to discuss a broader scope of interests that each may be reluctant to disclose to the other in the litigation context.<sup>109</sup>

### C. The Mediation Privilege—Problems and Conflicts

#### 1. Overview

As might be discerned from above, mediation provides significant potential to promote communication between patients and providers regarding important systems issues as well as provide a forum that is responsive to patient needs. However, it is critical to ensure confidentiality in mediation activities to ensure and encourage the full and frank discussion between the parties and the mediator that is a necessary component to obtain these benefits.<sup>110</sup> Hence, mediation communications must be protected from forced disclosure.<sup>111</sup>

<sup>107</sup> *Id.*

<sup>108</sup> *Id.*

<sup>109</sup> For example, some non-pecuniary interests may indicate or allow traditional legal argument to increase or reduce damages.

<sup>110</sup> Further, in recognizing the importance of this tenet, there are ethical codes for professionals in dispute resolution to maintain confidentiality. For example:

Confidentiality. Maintaining confidentiality is critical to the dispute resolution process. Confidentiality encourages candor, a full exploration of the issues, and a neutral's acceptability. There may be some types of cases, however, in which confidentiality is not protected. In such cases, the neutral must advise the parties, when appropriate in the dispute resolution process, that the confidentiality of the proceedings cannot necessarily be maintained. Except in such instances, the neutral must resist all attempts to cause him or her to reveal any information outside the process. A commitment by the neutral to hold information in confidence within the process also must be honored.

Society of Professionals in Dispute Resolution. Ethical Standards of Professional Responsibility § 3, 6, available at: <http://www.acresolution.org/research.nsf/key-print/EthSta?OpenDocument> (last visited Sept. 20, 2003).

<sup>111</sup> Alan Kirtly, *The Mediation Privilege's Transition from Theory to Implementation: Designing a Mediation Privilege Standard to Protect Mediation Participants, the Process and the Public Interest*, J. DISP. RESOL. 1 (1995); See also Joshua P. Rosenberg, *Keeping the Lid on Confidentiality: Mediation Privilege and Conflict of Laws*, 10 OHIO ST. J. DISP. RESOL. 157 (1994) (arguing for a

However, the protection of mediation communications from disclosure is far from certain:

Currently, it is not an overstatement to say that no mediator or counsel in the country can, with confidence, predict the extent to which it will be possible to maintain the confidentiality of a mediation . . . Discrepancies in confidentiality protection from state to state and court to court send confusing and contradictory messages on the extent to which parties can reasonably expect their statements in mediation to remain confidential.<sup>112</sup>

"[T]he reality is that given current law, a mediator may not be able to keep the mediation proceedings confidential."<sup>113</sup>

This circumstance stems generally from the fact that there are vastly different applications for and involving mediation across the United States. Perhaps a victim of its own success, there is a plethora of mediation statutes encouraging and mandating its use, with an average of five state statutes per state as well as hundreds of federal laws intersecting, interacting, and interfering with all and each other,<sup>114</sup> each covering a different conflict (e.g., labor disputes; child custody; farm disputes) and using different rules. Further, it is

consistent application of the mediation). See also Deason, *supra* note 94, at 240 ("confidentiality is axiomatic in mediation"). As Deason also points out, confidentiality is central to the mediation process itself, Ellen E. Deason, *The Quest for Uniformity in Mediation Confidentiality: Foolish Consistency or Crucial Predictability?*, 85 MARQ. L. REV. 79 (2001), and even its critics acknowledge the need for confidentiality, Deason, *supra* note 94, at n.12.

<sup>112</sup> Deason, *supra* note 94, at 241-42.

<sup>113</sup> Rosenberg, *supra* note 111, at 162.

<sup>114</sup> Burr, *supra* note 96, at n.27; *Developments in the Law—The Paths of Civil Litigation*, 113 HARV. L. REV. 1851, 1866-67 (2000); SARAH R. COLE et al., *MEDIATION: LAW, POLICY, PRACTICE* Appendix C (2d ed. 1994 & Supp. 2001). Note that the source of confidentiality provisions also creates significant variability, with statutes and federal common law delineating (or not) the scope and extent of mediation privilege. For example, while the Administrative Dispute Resolution Act provides for confidentiality of agency mediations from discovery or disclosure, under this statute, communications made by a party during a joint session are not so protected. 5 U.S.C. § 574(b)(7); see also *In re Grand Jury Subpoena Dated Dec. 17, 1996*, 148 F.3d 487, 492 (5th Cir. 1998) (stating statute did not create a privilege against disclosure in grand jury proceedings relating to communications made in state agricultural loan mediation program even if confidential). Further, the Alternative Dispute Resolution Act requires all federal courts to adopt their own local rule for mediation communication confidentiality but does not define it. 28 U.S.C. § 652(d). Unfortunately, this adds tremendous variation to efforts at confidentiality rules and predictability. Compare *FDIC v. White*, 76 F. Supp. 2d 736, 738 (N.D. Tex. 1999; *Datapoint Corp. v. Picturatel Corp.*, 1998 U.S. Dist. LEXIS 1145 (N.D. Tex. Jan. 23, 1998) (District Court ordered disclosure despite statute-based court rule ensuring confidentiality); *contra* *Olam v. Cong. Mort. Co.*, 68 F. Supp. 2d 1110, 1125 (N.D. Cal. 1999) (statute's local rule requirement for confidentiality enforceable as privilege, prohibiting disclosure of and preventing others from disclosing protected communications). As well, some states have expressly formulated offices for dispute resolution that encourage use of mediation (with their accompanying rules), while others have not. *Id.* at 1124.



difficult to ascertain the specific court that would even hear the confidentiality dispute<sup>115</sup> or even whether confidentiality for mediation communications will be kept when performed under the auspices of a federal court.<sup>116</sup>

## 2. *Claims that Mediation Privilege Unnecessary: The Weakness of Contract and Evidence Rules*

There have been claims that there is no need for a mediation privilege to keep mediation communications confidential due to both contractual and evidentiary protections. Contract protections are generally founded upon private agreements to keep information regarding the mediation and conflict resolution discussions private and to prohibit service of a subpoena on the mediator.<sup>117</sup>

However, private arrangements to suppress relevant evidence are generally frowned upon by the courts.<sup>118</sup> As well, such agreements do not prevent non-parties from seeking or disclosing sensitive mediation-sourced information because they are not bound by the confidentiality agreement.<sup>119</sup> Finally, a difficult issue for a breach of confidentiality suit against the party who inappropriately violated the confidentiality provision is contractual damages; there may be significant thorny issues of proof and valuation imbued in such a case that will burden the nondisclosing party and result in a reduced set of incentives to adhere to the nondisclosure requirement.<sup>120</sup>

Evidence law is also claimed to obviate the need for a mediation privilege,<sup>121</sup> particularly under Federal Rules of Evidence Rule 408. This evidence rule purports to protect communications related to offers at compromise and settlement.<sup>122</sup> On its face, the rule

<sup>115</sup> Deason, *supra* note 94, at 252.

<sup>116</sup> *Id.* at 239.

<sup>117</sup> Burr, *supra* note 96, at 66-67. Note also that if the parties happen to choose a particular forum and that forum actually has a lower degree of confidentiality, a court may consider such a choice of forum a waiver of mediation confidentiality agreement. *Id.*

<sup>118</sup> *Id.* at 67; Kirtley, *supra* note 111, at 10-11.

<sup>119</sup> Rosenberg, *supra* note 111, at 165. See also *Grumman Aerospace Corp. v. Titanium Metals Corp.*, 91 F.R.D. 84, 87-88 (E.D.N.Y. 1981) (confidentiality agreements are valid only against the parties who signed the agreement).

<sup>120</sup> See Rosenberg, *supra* note 111, at 166.

<sup>121</sup> See, e.g., Eric D. Green, *A Heretical View of the Mediation Privilege*, 2 OHIO ST. J. ON DISPUTE RESOL. 1, 15 (1986) (arguing "the traditional rule of evidence excludes offers of compromise and statements made in connection with offers").

<sup>122</sup> FED. R. EVID. 408. The rule states:

would seem to indicate that mediation communications should be covered. However, like other evidence rules,<sup>123</sup> this rule is substantively weak. The rule does not prevent the same evidence to be introduced for some *other* purpose beyond evidence of validity or amount of a claim that is required for the rule's application, such as showing control of the facility or motive;<sup>124</sup> and the rule does not prevent a party in mediation from disclosing the information. Indeed, the rule does not exclude the evidence if it is introduced for other, related claims that arose during the mediation, or in fact for collateral use in future litigation.<sup>125</sup> As well, the rule may be read to include only those matters directly related to settlement—thus potentially allowing parties to disclose other sensitive matters that arose during their mediation discussion.<sup>126</sup>

Finally, the rule does not concern itself with other types of proceedings, such as administrative, legislative, or criminal hearings.<sup>127</sup> Thus, a broad array of communications and information can pass through the holes of this evidentiary rule.

In addition, Federal Rule of Evidence Rule 501 is also claimed to obviate the need for a mediation privilege. This evidence rule discusses the application of privilege, particularly as it relates to

Evidence of (1) furnishing or offering or promising to furnish, or (2) accepting or offering or promising to accept, a valuable consideration in compromising or attempting to compromise a claim which was disputed as to either the validity or amount, is not admissible to prove liability for or invalidity of the claim or its amount. Evidence of conduct or statements made in compromise negotiations is likewise not admissible. This rule does not require the exclusion of any evidence otherwise discoverable merely because it is presented in the course of compromise negotiations. This rule also does not require exclusion when the evidence is offered for another purpose, such as proving bias or prejudice of a witness, negating a contention of undue delay, or proving an effort to obstruct a criminal investigation or prosecution.

<sup>123</sup> Bryan A. Liang & Anita C. Liang, *Lies on the Lips: Dying Declarations, Western Legal Bias, and Unreliability as Reported Speech*, 5 LAW/TEXT/CULTURE 113 (2002) (discussing linguistic and medical objections to evidence rule of dying declarations).

<sup>124</sup> Or for other purposes. See, e.g., *In re Marriage of Bidwell*, 21 P.3d 161, 165 (Or. App. 2001) (Oregon Evidence Rule 408 does not preclude admission of mediation communications in attorney fee case).

<sup>125</sup> Rosenberg, *supra* note 111, at 164-65.

<sup>126</sup> Deason, *supra* note 94, at 273.

<sup>127</sup> Burr, *supra* note 96, at 67. Indeed, this is quite troublesome for discussions such as those that occur on the state medical board level, which are for the most part public and information therein held to be discoverable. See also Bryan A. Liang, *Promoting Patient Safety through Reducing Medical Error: A Paradigm of Cooperation Between Patient, Physician, and Attorney*, 24 S. ILL. U. L.J. 541, 557 n. 59 (2000) (discussing medical board access and disclosure of sensitive information despite PR/QA privilege).



federal diversity cases, and notes that when state law supplies the rule of decision, the privilege of a person is determined by "[s]tate law."<sup>128</sup> Regarding mediation,<sup>129</sup> with federal and state laws covering some (and not other) areas of mediation confidentiality, the difficulty with such a rule resides first in the rule's text: even if the "[s]tate law" applies, which state's law governs?<sup>130</sup> Another similar issue under the rule that leads to uncertainty is the need for application of "the common law" to determinations of privilege; but which "common law"? There are federal issue civil cases, diversity cases with claims or defenses based on state law, diversity cases where a claim or defense is based on federal law, federal courts that have applied state privilege law and thus created federal common law, and federal courts that have applied state privilege law under jurisdictional bases but have not adopted the law as federal common law.<sup>131</sup>

Hence, reliance on contract and evidence rules to maintain mediation confidentiality is laden with difficulty. Varying interpretations and exceptions provide little security for mediation communications, and the mediators and parties who desire confidentiality.

### 3. *More Problems with Confidentiality: Venue Variations and the Choice of Law*

Reviewing contract law and evidentiary rules yields a myriad of potential results, which provides a good segue into related issues of venue and choice of law that also plague the efforts at mediation confidentiality. In concert with the general vagaries of contract and evidence law, the difficulties associated with predicting confidenti-

<sup>128</sup> FED. R. EVID. 501 states that:

Except as otherwise required by the Constitution of the United States or provided by Act of Congress or in rules prescribed by the Supreme Court pursuant to statutory authority, the privilege of a witness, person, government, State, or political subdivision thereof shall be governed by the principles of the common law as they may be interpreted by the courts of the United States in light of reason and experience. However, in civil actions and proceedings, with respect to an element of a claim or defense as to which State law supplies the rule of decision, the privilege of a witness, person, government, State, or political subdivision thereof shall be determined in accordance with State law.

<sup>129</sup> The rulings of federal courts regarding state PR/QA privilege application in the face of this rule is clear—no state PR/QA privilege applies. See *supra* notes 60-92 and accompanying text.

<sup>130</sup> Rosenberg, *supra* note 111, at 166.

<sup>131</sup> *Id.* at 167-168.

ality in mediation arise from the significant variations of laws associated with mediation—in coverage, in application, as well as in interpretation of courts on the state and federal levels.<sup>132</sup> Because of what one might call the "splattered and scattered" nature of mediation statutes and interpretations, there is little guidance as to how issues of confidentiality of mediation communications will be treated.

This variation and conflict is closely associated with issues involving choice of law.<sup>133</sup> Challenges to confidentiality will likely be heard in some court,<sup>134</sup> which of course directly influences the law to be applied as well as the choice of law.<sup>135</sup> The court could be a state one at the site of the parties, or at a specified site in the agreement; or it could be a federal court if federal issues are involved, or if diversity of citizenship of the litigants is extant. Additionally, the dispute regarding confidentiality may be heard in some court at a distant locale that will adjudicate issues associated with confidentiality or the mediation itself, but has nothing to do with the initial dispute and indeed, may not even include the same parties.<sup>136</sup> There may also be choice of law issues that arise if and when media-

<sup>132</sup> *Id.* at 157-58. Note that the relative degree of coverage of a mediation privilege, even if recognized, increases variability. *Id.*

<sup>133</sup> It is somewhat interesting, but frustrating in the mediation privilege context, that choice of law issues generally do not conflict with evidentiary privilege law. See, e.g., Donald W. Price, *A Choice of Law Analysis of Evidentiary Privileges*, 50 LA. L. REV. 157 (1991). Unfortunately, when assessing the mediation privilege, they run a "collision course." Rosenberg, *supra* note 111, at 163.

<sup>134</sup> Such a hearing regarding mediation confidentiality may very well be an issue of first impression for many courts, further adding to potential confusion. Courts have been known to misinterpret rules, statutes, and even their own jurisdiction in important cases; see, e.g., Bryan A. Liang, *Patient Injury Incentives in Law*, 17 YALE LAW & POL'Y REV. 1, 35-49 (1998) [hereinafter Liang, *Patient Injury*] (discussing misinterpretation of ERISA preemption and jurisdictional confusion in state and federal courts). Further, in the mediation context, courts have misinterpreted or ignored applicable law in their assessments; see, e.g., *Hudgins v. Second Bank of Whitesboro*, 188 B.R. 938 (Bankr. E.D. Tex 1995); *McEnany v. W. Del. Cty. Comm. School Dist.*, 844 F. Supp. 523 (N.D. Iowa 1994).

<sup>135</sup> Deason, *supra* note 94, at 252-53. Note also that there may be issues associated with court-sponsored mediation that may influence choice of law. *Id.* at 253.

<sup>136</sup> *Id.* at 253-54. Note also that if the dispute arises and is under court-sponsored mediation, another court may in fact decide confidentiality issues associated with the mediation, such as a state trial court considering mediation confidentiality relating to a negotiated settlement on the state appellate level, or federal class actions require federal district court assessment and approval under a fairness standard. *Id.*

tion results in a settlement under, for example, a federal cause of action but enforcement must be performed under state law.<sup>137</sup>

Adding to the confusion are provisions of the RESTATEMENT (SECOND) OF CONFLICT OF LAW. In section 139(2), the Restatement indicates that:

Evidence that is privileged under the local law of the state which has the most significant relationship with the communication but which is not privileged under the local law of the forum will be admitted unless there is some special reason why the forum policy favoring admission should not be given effect.<sup>138</sup>

This provision first invalidates the privilege of the state with the admitted "most significant relationship with the communication."<sup>139</sup> Second, the "special reason" as such represents something akin to a "loaded weapon ready for the hand of any authority that can bring forward a plausible claim of an urgent need."<sup>140</sup> Consequently, parties could have their communications divulged in court even when they agreed at the time of the arrangement/contract to follow the rules of the state—the ephemeral "meeting of the minds" moment in contract—to limit any such action. Thus, the interest of the parties to the agreement, the foundational principles of contract, and the interest of the forum state and their citizens where the agreement was made can be ignored under this Restatement provision.

In addition, there are difficulties associated with evidence rules versus the concept of privilege that further complicate these choice-of-law difficulties. Although evidentiary rules purportedly deal with issues of elicitation of facts, whereas privilege rules block such access for acknowledged policy reasons, the idea that evidence rules are "procedural" while privilege law is a "rule of decision" cannot easily be reconciled when assessing court interpretation of media-

<sup>137</sup> *Id.* at 253-54. See also *Morris v. City of Hobart*, 39 F.3d 1105 (10th Cir. 1994) (breach of Title VII agreement results in state cause of action and thus federal courts lack jurisdiction); Darryl R. Marsch, *Postdismissal Enforcement of Settlement Agreements in Federal Court and the Problem of Subject Matter Jurisdiction*, 9 REV. LITIG. 249 (1990) (discussing issues associated with judicial enforcement of settled case originating in federal court). These jurisdictional issues are important concerns, since lack of jurisdiction would make any adjudications thereunder—including, for example, adjudications of confidentiality—void. See Liang, *Patient Injury*, *supra* note 134, at 37-40 nn. 177-183 (discussing implications of court adjudications without jurisdiction).

<sup>138</sup> RESTATEMENT (SECOND) CONFLICTS OF LAW § 139(2).

<sup>139</sup> *Id.*

<sup>140</sup> BRYAN A. LIANG, A ZONE OF TWILIGHT: EXECUTIVE ORDERS IN THE MODERN POLICY STATE n. 80 (National Legal Center for the Public Interest 1999) (quoting *Korematsu v. United States*, 323 U.S. 214, 246 (1944) (Jackson J., dissenting)).

tion privilege. Because so many jurisdictions have an interest in application of their own laws (or their own choice of law methodologies), some forums may necessarily accept or reject another forum's evidence and privilege rules (particularly between states and state and federal circumstances) and/or may expand or contract these rules, while other forums may also be legitimately interested in the application of its rules to the case (e.g., states of one or another party's domicile, the state where the dispute actions occurred, the state specified by contract for disputes between the parties).<sup>141</sup> As such, the distinction between "procedural" and "rule[s] of decision" becomes blurred indeed.<sup>142</sup>

Further, beyond the dizzying number of federal and state courts that may hear mediation confidentiality disputes, the choice of law methodology, and the procedural/rule of decision issue, and even assuming the law to be applied associated with that forum is clear and consistent (a dubious assumption at best), like the PR/QA privilege, some courts have in fact rejected other courts' holding of mediation privilege. This circumstance is particularly true when federal courts assess some state court mediation rules.<sup>143</sup> As well,

<sup>141</sup> Rosenberg, *supra* note 111, at 163, 163 n.50.

<sup>142</sup> As well, choice of whether assessment of mediation privilege is substantive or procedural also confuses matters further. In one particularly important area relevant to patient safety, under the Federal Tort Claims Act, 28 U.S.C. § 1346(b)(1) (2000), courts contradict each other as to the source of privilege, with some courts indicating that the state law provides the rule of decision and thus privilege even though jurisdiction is based on a federal statute, *see, e.g., Ellis v. United States*, 922 F. Supp. 539, 540 (D. Utah 1996); *Huzjak v. United States*, 118 F.R.D. 61, 63 (N.D. Ohio 1987), while other courts indicate that state law is incorporated within the federal statute itself, and therefore mandates under FED. R. EVID. 501 to utilize state law of tort to determine liability are precluded, and federal common law should govern privilege, *see, e.g., Galarza v. United States*, 179 F.R.D. 291, 293 (S.D. Cal. 1998); *Young v. United States*, 149 F.R.D. 199, 201-02 (S.D. Cal. 1993). Other courts have taken a different tack, indicating state law of privilege was simply inapplicable due to federal question jurisdiction under the Federal Tort Claims Act, *see, e.g., Syposs v. United States*, 179 F.R.D. 406, 409 (W.D.N.Y. 1998), *on reconsid'n*, 63 F. Supp.2d 301 (W.D.N.Y. 1999).

<sup>143</sup> *See, e.g., In re March 1994—Special Grand Jury*, 897 F. Supp. 1170, 1173 (S.D. Ind. 1995) (refusing to quash a subpoena requiring a mediator to testify about a mediation heard under the state mediation program). *Smith v. Smith*, 154 F.R.D. 661, 670-71 (N.D. Tex. 1994) (federal law held to supersede Texas rule of confidentiality for state alternative dispute resolution proceedings); *cf. Omaha Indem. Co. v. Royal Am. Managers, Inc.*, 140 F.R.D. 398, 400 (W.D. Mo. 1991) (confidentiality order in civil case did apply to prospective prosecution, but redacted portions of transcripts would be opened if a witness testifies in a criminal case and access to sworn testimony would determine whether portions could be used for impeachment purposes); *cf. United States v. Gullo*, 672 F. Supp. 99, 104 (W.D. N.Y. 1987) (government failed to make adequate showing of need for disclosure of statements made during dispute resolution process that were purportedly confidential under state law); *see Folb v. Motion Picture Industry Pension and Health Plans*, 16 F. Supp.2d



even federal courts that have recognized a mediation privilege may limit it to actual discussions between parties and the mediator, which "is inconsistent with every current form of state protection for mediation confidentiality."<sup>144</sup> Finally, this situation is compli-

1164, 1175 (C.D. Cal. 1998) (adopting state mediation rules precluding discovery of mediation information and communications). *But see* *Royal Caribbean Corp. v. Modesto*, 614 So.2d 517, 518 (Fla. App. 1992) (holding that state mediation privilege governs even though "[t]he enforceability and validity of settlement agreements [here are] determined by federal law"). Generally, this on-off possible application of privilege can be stated as follows: "[w]here Congress has declared a substantive federal policy by enacting specific legislation, the weight of authority holds that the federal courts should resolve questions of privilege under federal law, not state law. There are, however, several cases which hold that federal courts may consider and adopt state law where there is a substantial state interest." Rosenberg, *supra* note 111, at 173. However, it must be added that state courts also do the same. *Id.*

It should also be noted that similar difficulties arise when federal claims are mixed with pendent state law claims. In general, like PR/QA privilege holdings, federal courts have concluded that the federal common law of privilege should govern all claims in the litigation. *See* *Pearson v. Miller*, 211 F.3d 57, 66 (3d Cir. 2000); *Hancock v. Dodson*, 958 F.2d 1367, 1372-73 (6th Cir. 1992); *Religious Tech. Center v. Wollersheim*, 971 F.2d 364, 367-69 (9th Cir. 1992); *Hancock v. Hobbs*, 967 F.2d 462, 466 (11th Cir. 1992); *von Bulow v. von Bulow*, 811 F.2d 136, 141 (2d Cir. 1987); *William T. Thompson Co. v. General Nutrition Corp.*, 671 F.2d 100, 104 (3d Cir. 1982); *Memorial Hosp. v. Shadur*, 664 F.2d 1058, 1061 (7th Cir. 1981); *Iron Workers Local Union No. 17 Ins. Fund v. Philip Morris, Inc.*, 35 F.Supp.2d 582, 589 (N.D. Ohio 1999). As perhaps may be expected, other courts have disagreed or distinguished the cases. *See, e.g.,* *Platypus Wear v. K.D. Co.*, 905 F. Supp. 808, 812 (S.D. Cal. 1995) (state privilege applies to state claims even in presence of federal counterclaim); *Scott v. McDonald*, 70 F.R.D. 568, 572 (N.D. Ga. 1976) (state privilege applies in diversity case even with claims based on federal law). Other methods have also been used. Deason, *supra* note 94, at 287-88. In one more variant, even when the mediation is through federal court rules, state law of privilege may apply to mediation communications, providing less protection:

[E]ven though uncertainty can induce more conservatism (at least in lawyers) than statistical probabilities, we cannot conclude that the remote possibility of disclosure [of mediation communications] during enforcement proceedings is likely to have a substantial adverse impact on freedom of communication in mediations.

But even if we believed that continuing to apply the proviso of F.R.E. 501 in settings like this posed a more substantial threat, we would be most reluctant to use pre-emption doctrine to support a conclusion that federal courts should not apply state confidentiality or privilege law when the rule of decision is supplied by state law.

Having considered and rejected the arguments that might support a contrary result, we conclude that even when a local rule adopted by a federal district court . . . offers more protection to mediation communications than would be offered by the law of the state where the district court sits, the federal court must apply state privilege law when state substantive law is the source of the rule of decision on the claim to which the proffered evidence from the mediation is relevant.

*Olam v. Congress Mort. Co.*, 68 F. Supp. 2d 1110, 1125 (N.D. Cal. 1999).

<sup>144</sup> Deason, *supra* note 94, at 268. Note that here, too, the courts diverge: *See* *Folb v. Motion Picture Industry Pension & Health Plans*, 16 F. Supp.2d 1164, 1180 (C.D. Cal. 1998), *aff'd*

cated by a significant omission—that approximately half of the states have not addressed confidentiality in mediation rules or statutes, while some states have narrow statutes applying to specialized subject areas, and others conflict on basic definitions.<sup>145</sup> Further, some courts are "mandated" and have created court-annexed ADR/mediation programs, others are mandated, but have not, while others are under no such mandate but require mediation before the case may enter traditional litigation proceedings.<sup>146</sup>

Thus, the state or federal statute relating to the matter, the federal and/or state court in question, the jurisdiction of that court, the federal and/or state choice of law statutes available, the subject matter of the dispute, the specific type and source of evidentiary protection potentially available for the mediation communications, and the deciding choice of law all create significant variation, confusion, and unpredictability as to the confidentiality of mediation dis-

*mem.*, 216 F.3d 1082 (9th Cir. 2000) (holding local rule privilege only extends to sessions with the mediator); *cf. Sheldone v. Penn. Turnpike Comm.*, 104 F. Supp.2d 511 (W.D. Pa. 2000) (confidentiality provisions cover all communications "in connection with" a mediation).

<sup>145</sup> Indeed, some state statutes disagree even on the definition of mediation; while others have no definition; some states use privilege law to define confidentiality provisions; others use testimonial capacity, or a broad evidentiary exclusion, or a narrow settlement negotiation exclusion; and efforts to use a federal mediation privilege are limited by the need to either develop from federal common law or are limited by the specific nature of disputes covered by federal law. Other variations include the party that holds the privilege, exceptions to the mediation privilege, methods to assess the exceptions, and substantive content of exceptions within the statutes. *See, e.g.,* Rosenberg, *supra* note 111, at 159-60 nn.16-26 and accompanying text. Of course, the topics covered by each of these rules vary (e.g., general conflicts versus conflicts relating to human rights, employment, farmer-creditor disputes, civil rights, gas pipeline disputes, family court). Deason, *supra* note 94, at 255, 257, 260. Note also that courts have imposed additional variation by creating exceptions to mediation privilege, *see, e.g., In re Young*, 253 F.3d 926, 927 (7th Cir. 2001) (indicating appellate mediations are confidential in general but may be disclosed in misconduct circumstances); *In re Waller*, 573 A.2d 780 (D.C. App. 1990) (confidentiality provisions not applicable with regard to reporting potential violations of disciplinary rules to judge); *Doe v. Nebraska*, 971 F. Supp. 1305, 1308 (D. Neb. 1997) (allowing confidentiality to be breached to assess motion for sanctions from mediation in district court program). *But see* *Lawson v. Brown's Day Care Center, Inc.*, 776 A.2d 390, 393 (Vt. 2001) (mediation information confidential and revealing it in matter of professional misconduct sanctionable if done in bad faith); MONT. CODE ANN. § 41-3-437(5) (mediation privilege applies in child abuse proceedings). *See also* Charles W. Ehrhardt, *Confidentiality, Privilege and Rule 408: The Protection of Mediation Proceedings in Federal Court*, 60 LA. L. REV. 91 (1999) (discussing federal court variability in local rules regarding mediation confidentiality); Kirtly, *supra* note 111 (discussing state court variability of mediation communication information); Erin L. Kuester, *Confidentiality in Mediation: A Trail of Broken Promises*, 16 HAMLINE J. PUB. L. & POL'Y 573 (1995).

<sup>146</sup> Rosenberg, *supra* note 111, at 158 n.10.

cussions and information on, in, and between state and federal courts.<sup>147</sup>

#### IV. A PROPOSED STATUTE

##### A. Addressing the Problems of Confidentiality

To address the significant impediments to provider and patient discussions regarding medical error and patient safety, federal legislation should be passed to provide protections for safety communications and discussions.<sup>148</sup> Critically, such legislation should deal directly with the confidentiality provisions of peer review to ensure such information is not available to support lawsuits<sup>149</sup> and

<sup>147</sup> Thus, for example, if a federal court is assessing confidentiality of mediation proceedings, it must determine whether federal or state law governs; whether the confidentiality is protected by a privilege or testimonial incapacity (which then requires application, respectively, of Federal Rules of Evidence Rule 501 or 601); but if the protection is deemed an evidentiary exclusion, then the Erie doctrine is instead used to determine the choice of law; settlements may necessarily have to be evaluated under the law governing the settlement; and if any of the foregoing implicates state law, additional uncertainties arise in determining the law, analysis, and standards to evaluate mediation confidentiality. Deason, *supra* note 94, at 280-81. Note also that even when federal courts agree that FED. RULES OF EVID. 501 is the relevant rule to apply, they have conflicted in determining whether the state mediation law applies or federal law of privilege. See, e.g., *FDIC v. White*, 76 F. Supp.2d 736, 737 (N.D. Tex. 1999) (federal law applies under FRE 501); cf. *Haghighi v. Russian-American Broad. Co.*, 945 F. Supp. 1233 (D. Minn. 1996), *rev'd on other grounds*, 173 F.3d 1086 (8th Cir. 1999) (state law applies under FRE 501).

<sup>148</sup> Federal legislation is needed not only to provide a single, national legal regime clarifying the conditions for this work as well as what is most efficient in terms of implementing policy as compared with the common law. See, e.g., Richard A. Epstein, *The Social Consequences of Common Law Rules*, 95 HARV. L. REV. 1717 (1982). Note also that other commentators have expressed their perspective on a federal resolution to some of the issues noted herein:

Congress could enact statutes declaring federal choice of law rules for categories of disputes that arise frequently in multi-state disputes. These rules could determine which state's law would apply to a dispute when a conflict arises. Congress has the constitutional power to enact such rules, but has failed to do so. Although a large undertaking, this solution would prove most effective in guaranteeing uniformity when dealing with conflicts of laws cases involving state privileges. The benefits of a federal statute, which would provide a uniform national rule and a single interpreter of this rule, would mark a substantial improvement over the status quo.

Rosenberg, *supra* note 111, at 181 (citations omitted). As well, Michael H. Gottesman, *Draining the Dismal Swamp: The Case for Federal Choice of Law Statutes*, 80 GEO. L.J. 1, 2 (1991) notes that "a national solution imposed 'from above,' by a tribunal in which the states are fairly represented, can bring order back to this important area of the law. Congress is that tribunal." *Id.*

<sup>149</sup> Note, however, that this conception does not eliminate plaintiffs from utilizing other, original source materials such as medical charts if they wish to sue. Although it would be

should provide parties and mediators with assurance that mediation discussions will not and cannot be disclosed in order to promote full candor in communications.

The proposed federal statute below is based upon key provisions of the Patient Safety and Quality Improvement Act<sup>150</sup> and the Uniform Mediation Act<sup>151</sup> and could serve as the basis to fulfill the goals of encouraging safety activities and mediation.

##### B. The Bill

#### IN THE SENATE OF THE UNITED STATES A BILL

To amend title IX of the Public Health Service Act to provide for the improvement of patient safety and to reduce the incidence of events that adversely affect patient safety through encouraging providers to engage in safety research and integrating patient observations into the safety effort.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

##### SEC. 1. SHORT TITLE.

This Act may be cited as the "Promotion of Health Care Quality and Patient Partnership Act."

##### SEC. 2. FINDINGS AND PURPOSES.

- (a) FINDINGS.—Congress makes the following findings:
- (1) In 1999, the Institute of Medicine released a report entitled "To Err Is Human" that described medical errors as the eighth leading cause of death in the United States, with as many as 98,000 patients dying as a result of medical errors each year.
  - (2) To address these deaths and injuries due to medical errors, the health care system must identify and learn from such errors so that systems of care can be improved.
  - (3) In its report, the Institute of Medicine called upon Congress to provide legal protections with respect to information reported for the purposes of quality improvement and patient safety.
  - (4) The Health, Education, Labor, and Pensions Committee of the Senate held four hearings in the 106th Congress and one hearing in the 107th Congress on patient safety where experts in the field supported the recommendations of the Institute of Medicine for congressional action.
  - (5) Some public and private patient safety initiatives have begun.

preferable if a partnership between patient and provider and the use of mediation would be the primary means of resolving any disputes, this legislation would not preclude such suit.

<sup>150</sup> See generally, S. 2590, 107th Congress, 2d Sess. (2002).

<sup>151</sup> See generally, Nat'l Conference of Comm'rs on Unif. State Laws, Uniform Mediation Act (2001), available at: <http://www.pon.harvard.edu/guests/uma> (last visited Oct. 16, 2002).



(6) The research on patient safety unequivocally calls for a learning environment, rather than a punitive environment, in order to improve patient safety.

(7) Voluntary data gathering systems are more supportive than mandatory systems in creating the learning environment referred to in paragraph (6) and as stated in the Institute of Medicine report.

(8) There have been some efforts to promote study of patient safety reporting systems, largely through projects funded by the Agency for Healthcare Research and Quality.

(9) Many organizations currently attempting to collect patient safety data have expressed a need for legal protections that will allow them to review protected information so that they may collaborate in the development and implementation of patient safety improvement strategies for present and future patients. Currently, State peer review protections provide inadequate conditions to allow for the collection and sharing of information to promote patient safety.

(10) Many organizations desire to promote a partnership between providers and patients in an effort to improve patient safety.

(11) Virtually all healthcare organizations have mission statements that indicate respect for the patient and the treatment of the patient as a partner in the health delivery enterprise.

(12) Mediation fosters the early resolution of disputes and results in conflict resolution that is specifically tailored to the parties' needs and interests, and party participation and control over the result has been shown to lead to greater satisfaction and reduced disruption in the lives of those affected by the conflict.

(13) Mediation diminishes the unnecessary expenditure of personal, organizational, and societal resources for conflict resolution, promotes a more civil society, and often leads to settlement earlier because of the expression of emotions and exchange of information that occur as part of the mediation process; this has led to thousands of State and Federal statutes establishing mediation applicable to a wide array of contexts.

(14) Litigation is often a long and expensive means of providing only a few patients injured in the health delivery system with compensation and does not provide systems information necessary to improve health delivery outcomes, improved patient safety, and enhanced health care quality.

(15) Confidential mediation has been shown to be desirable in the health care context from both provider and patient perspectives to resolve patient injury disputes, foster communications that may result in important system information to be unearthed for quality improvement purposes, fulfill patient needs to obtain compensation quickly, allow providers to express empathy and apologize, and empower patients to participate in the quality improvement process while also providing closure and preserving provider-patient relationships.

(16) Confidentiality of mediation communications is currently governed by a wide array of overlapping State and Federal laws, and parties have significant difficulty in predicting whether mediation communications will be kept confidential, impeding the free flow of communication and information.

(17) Confidentiality of mediation communications is critical to encourage a culture of open and honest communication and candor

between parties to resolve health care conflicts and to provide important information regarding the system of health care delivery, patient safety, and health care quality.

(b) PURPOSES.—It is the purpose of this Act to—

(1) encourage a culture of safety and quality in the United States health care system by providing for legal protections of information reported voluntarily for the purposes of quality improvement and patient safety; and

(2) encourage a culture of partnership in safety and quality efforts in the United States health care system by providing for legal protections of communications made in mediation for the purpose of quality improvement, patient safety, patient compensation, and resolution of health care disputes.

These sections indicate the importance of a culture of safety, the need for a partnership between patient and provider, the important delivery system benefits that can derive from a systems approach, and the high level of benefits that mediation can bring to resolving medical error conflicts. These sections also describe the impediments that efforts attempting to address medical error and patient safety face, including state-based PR/QA privilege may not effectively protect medical error and patient safety discussions, and that the presence and scope of mediation privilege is difficult if not impossible to predict.

### SEC. 3. AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT.

Title IX of the Public Health Service Act (42 U.S.C. §299 et seq.) is amended—

(1) in section 912(c), by inserting “, in accordance with part C,” after “The Director shall”;

(2) by redesignating part C as part D;

(3) by redesignating sections 921 through 928.

(4) in section 938(1) (as so redesignated), by striking “921” and inserting “931”; and

(5) by inserting after part B the following:

#### “PART C—PATIENT SAFETY IMPROVEMENT”

##### “SEC. 921. DEFINITIONS.

“In this part:

“(1) NON-IDENTIFIABLE INFORMATION.—The term ‘non-identifiable information’ means information that is presented in a form and manner that prevents the identification of any provider, patient, and the reporter of patient safety data, including aggregated data.

“(2) PATIENT SAFETY DATA.—The term ‘patient safety data’ means—

“(A) any data, reports, records, memoranda, analyses, deliberative work, statements, root cause analyses, corrective action plans, or quality improvement processes that could result in improved patient safety or health care quality, that are—

“(i) collected or developed by a provider for the purpose of reporting to a patient safety organization;

“(ii) reported to a patient safety organization for patient safety or quality improvement purposes;



"(iii) requested by a patient safety organization (including the contents of such request);

"(iv) reported to a provider by a patient safety organization;

"(v) collected or developed by a patient safety organization;

or

"(vi) reported among patient safety organizations, after obtaining authorization; or

"(B) information related to any corrective actions taken in response to patient safety data; for the purpose of improving patient safety, health care quality, or health care outcomes.

"(3) PATIENT SAFETY ORGANIZATION.—The term 'patient safety organization' means a private or public organization, or component thereof including but not limited to subsidiaries, committees, and third party provider contractees, that performs the following activities, which are deemed to be necessary for the proper management and administration of such organization or component thereof:

"(A) The conduct, as its primary activity, of efforts to improve patient safety and the quality of health care delivery.

"(B) The collection and analysis of patient safety data that are voluntarily submitted by a provider.

"(C) The development and dissemination of information to providers, including those providers within the provider organization, with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices.

"(D) The utilization of patient safety data to carry out activities under this paragraph and for the purposes of encouraging a culture of safety and of providing direct feedback and assistance to providers, including those providers within the provider organization, to effectively minimize patient risk.

"(E) The maintenance of confidentiality with respect to individually identifiable health information with relation to those parties not involved in improvement of patient safety and the quality of health care delivery.

"(F) The provision of appropriate security measures with respect to patient safety data with relation to those parties not involved in improvement of patient safety and the quality of health care delivery.

"(G) The certification to the Agency that the patient safety organization satisfies the criteria of this paragraph for the period in which the organization is carrying out such duties.

"(4) PROVIDER.—The term 'provider' means—

"(A) a provider of services (as defined in section 1861(u) of the Social Security Act) and a person furnishing any medical or other health care services (as defined in section 1861(s)(1) and (2) of such Act) through, or under the authority of, such a provider of services;

"(B) a physician (as defined in section 1861(r) of such Act);

"(C) any other person, including but not limited to a pharmacist, audiologist, technician, nurse, physician's assistant, and nurse practitioner, who is engaged in the delivery of medical or other health services (as defined in section 1861(s)(1) and (2) of such Act) in a State and who is required by State law or regulation to be licensed or certified by the State to engage in the delivery of such services in the State;

"(D) a renal dialysis facility, ambulatory surgical center, pharmacy, physician or health care practitioner's office, long-term care facility, behavioral health residential facility, hospital, or clinical laboratory; or

"(E) any other person or entity specified in regulations by the Secretary after public notice and comment.

"(5) PATIENT SAFETY ORGANIZATION AND PROVIDER.—The term 'patient safety organization' and 'provider' shall not preclude a provider, or relevant components thereof, to also be a patient safety organization.

"(6) MEDIATION.—The term 'mediation' means a process in which a mediator facilitates communication and negotiation between parties to assist them in reaching a voluntary agreement regarding their dispute.

"(7) MEDIATION COMMUNICATION.—The term 'mediation communication' means a statement, whether oral or in a record, or verbal or nonverbal, that occurs during a mediation or is made for the purpose of considering, conducting, participating in, initiating, continuing, or reconvening a mediation or retaining a mediator in any health care dispute or conflict.

"(8) MEDIATOR.—The term 'mediator' means an individual who conducts a mediation.

"(9) NONPARTY PARTICIPANT.—The term 'nonparty participant' means a person that participates in a mediation and whose agreement is not necessary to resolve the dispute.

"(10) PERSON.—The term 'person' means an individual, corporation, business trust, estate, trust, partnership, limited liability company, association, joint venture, government, governmental subdivision, agency, or instrumentality, public corporation, or any other legal or commercial entity.

"(11) PROCEEDING.—The term 'proceeding' means—

"(A) a judicial, administrative, arbitral, or other adjudicative process, including related pre-hearing and post-hearing motions, conferences, and discovery; or

"(B) a legislative hearing or similar process.

"(12) RECORD.—The term 'record' means information that is inscribed on a tangible medium or that is stored in an electronic form or other medium and is retrievable in perceivable form.

"(13) SIGN.—The term 'sign' means—

"(A) to execute or adopt a tangible symbol with the present intent to authenticate a record; or

"(B) to attach or logically associate an electronic symbol, sound, or process to or with a record with the present intent to authenticate a record.

These provisions indicate the key definitions regarding discussions of medical error to promote patient safety. They define the kinds of reports and communications that are the subject of the statute, and the entities that are eligible for protections enumerated by the statute. Critically, it should be noted that providers may also be patient safety organizations, thus allowing internal as well as external reporting and error discussions to promote safety and not limit-

ing efforts to promote safety simply to individual providers reporting to external agencies/organizations to obtain protections.

"SEC. 922. CONFIDENTIALITY AND PEER REVIEW PROTECTIONS.

"(a) IN GENERAL.—Notwithstanding any other provision of law, and subject to this section, patient safety data shall be privileged and confidential.

"(b) SCOPE OF PRIVILEGE.—Subject to the provisions of subsection (c), patient safety data to which subsection (a) applies shall not be—

"(1) subject to a civil, criminal, or administrative subpoena;

"(2) subject to discovery in connection with a civil, criminal, or administrative proceeding;

"(3) disclosed pursuant to section 552 of title 5, United States Code (commonly known as the Freedom of Information Act) or any other similar Federal or State law;

"(4) admitted as evidence or otherwise disclosed in any civil, criminal, or administrative proceeding; or

"(5) utilized in an adverse employment action or in the evaluation of decisions made in relation to accreditation, certification, credentialing, or licensing of an individual or entity, that is based on such individual or entity's participation in the development, collection, reporting, or storage of patient safety data in accordance with this part.

"(c) DISCLOSURE.—Nothing in this section shall be construed to prohibit one or more of the following disclosures, which are deemed to be necessary for the proper management and administration of the patient safety organization:

"(1) Disclosures by a provider in complying with authorized requests for the provision of information to which subsection (a) applies (such as a patient's medical record) that is in the control of such a provider and that has been developed, maintained, or exists separately from the process by which the provider collects or develops information for reporting to a patient safety organization.

"(2) Disclosures by a provider or patient safety organization of patient safety data as part of a disciplinary proceeding relating to a provider, or a criminal proceeding, only if such disclosure of such patient safety data or information is—

"(A) not available from any other source;

"(B) in the public interest;

"(C) material to the proceeding; and

"(D) not utilized to—

"(i) show purported poor quality of care or criminal activity of a provider by noting provider provision of a patient safety data to a patient safety organization as defined in paragraph (2)(A) and (3), respectively, of section 921; or

"(ii) show purported poor quality of care or criminal activity of a provider by reference to information within a report of patient safety data to a patient safety organization as defined in paragraph (2)(A) and (3), respectively, of section 921.

"(3) Disclosures by a provider or patient safety organization of relevant information to the Food and Drug Administration, or to a person or entity that is subject to the jurisdiction of such Administration, with respect to an Administration-regulated product, device, or activity for which that entity has responsibility, for the

purposes of activities related to the quality, safety, or effectiveness of such Administration-regulated product, device, or activity, subject to section 520(c) of the Federal Food, Drug, and Cosmetic Act.

"(4) Disclosures by a provider or patient safety organization of relevant information to State public health departments, or to a person or entity that is subject to the jurisdiction of such public health departments, with respect to a public health department-regulated product, device, or activity for which that entity has responsibility, for the purposes of activities related to the quality, safety, or effectiveness of such public health department-regulated product, device, or activity.

"(5) Disclosures by a provider or patient safety organization of information to which subsection (a) applies to carry out activities described in paragraph (2)(A)(i) through (vi) or (3) of section 921.

"(6) Nothing in this section shall preclude disclosures relating to fraud, deception, and/or violation of the provisions of this Act, or use of patient safety data or patient safety organizations for purposes of fraud, deception, or violations of the provisions of this Act.

"(7) In the event that patient safety data is provided in error or otherwise to individuals or entities that are not authorized to view or receive such materials, such materials shall still be subject to the prohibitions of use, confidentiality, and peer review protections as indicated in section 922.

"(d) TRANSFER OF INFORMATION.—The transfer of any patient safety data by a provider to a patient safety organization, or between providers for the purpose of improving patient safety, health care quality, or health care outcomes, shall not be treated as a waiver of any privilege, confidentiality, or protection established under this part or established under State law.

"(e) PENALTY.—Except as provided in subsection (c) and as otherwise provided for in this section, it shall be unlawful for any person to disclose any patient safety data described in subsection (a). Any person violating the provisions of this section shall, upon conviction, be fined in accordance with section 934(d).

"(f) NO LIMITATION OF OTHER PRIVILEGES.—Nothing in this section shall be construed to limit other privileges that are available under Federal or State laws that provide greater peer review or confidentiality protections than the peer review and confidentiality protections provided for in this section.

"(g) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to alter or affect the implementation of any provision of section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191, 110 Stat. 2033) or any regulation promulgated thereunder, except that the provisions of the Health Insurance Portability and Accountability Act of 1996 shall be construed to permit the use by providers and patient safety organizations of patient-identifiable health care information without patient authorization for the purpose of improving patient safety, health care quality, or health care outcomes.

These provisions outline the important protections associated with error reports, analysis, and conclusions. The provisions generally protect all patient safety and medical error assessments, including corrective action, from discoverability; they may be seen to



create a federal PR/QA privilege for safety and error materials, removing significant barriers to engaging in safety activities. Further, of special note, this section also clarifies the recent federal medical privacy rule that may also provide significant disincentives to engage in safety work.<sup>152</sup>

"SEC. 923. NATIONAL DATABASE.

"(a) AUTHORITY.—

"(1) IN GENERAL.—In conducting activities under this part, the Secretary may provide for the establishment and maintenance of a database to receive relevant non-identifiable patient safety data, or may designate entities to collect relevant non-identifiable patient safety data, that is voluntarily reported by patients safety organizations upon the request of the Secretary.

"(2) USE OF DATA.—Data reported to any database established or designated under paragraph (1) shall be used to analyze variations and national statistics related to patient safety and health care quality. The information resulting from such analyses may be included in the annual quality reports prepared under section 913(b)(2).

"(3) STANDARDS.—In developing or designating a database under subsection (a)(1), the Secretary may determine common formats for the voluntary reporting of non-identifiable patient safety data, including necessary data elements, common and consistent definitions, and a standardized computer interface for the processing of such data. To the extent practical, such standards shall be consistent with the administrative simplification provisions under part C of title IX of the Social Security Act.

"(c) CONFIDENTIALITY.—Any non-identifiable patient safety data that is transferred to the database under this section shall be privileged and confidential.

"SEC. 924. TECHNICAL ASSISTANCE.

"The Secretary, acting through the Director, may provide technical assistance to patient safety organizations. Such assistance shall include annual meetings for patient safety organizations to discuss methodology, communication, data collection, confidentiality, peer review privilege, or privacy concerns.

"SEC. 925. PROMOTING THE INTEGRATION OF HEALTH CARE INFORMATION AND TECHNOLOGY SYSTEMS.

"(a) DEVELOPMENT.—Not later than thirty-six months after the date of enactment of the Promotion of Health Care Quality and Patient Partnership Act, the Secretary shall develop or adopt voluntary national standards that promote the integration of health care information technology systems.

"(b) UPDATES.—The Secretary shall provide for the ongoing review and periodic updating of the standards developed under subsection (a).

"(c) DISSEMINATION.—The Secretary shall provide for the dissemination of the standards developed and updated under this section.

<sup>152</sup> Liang, *A System of Medical Error*, *supra* note 7, at 353-57. See Bryan A. Liang, *Patient Information Privacy: HIPAA Provisions and Patient Safety Issues*, 38(7) HOSP. PHYS. 43 (2002).

These sections provide for a national database by which analysis of errors and safety information can be performed on a larger scale, providing more robust and statistically valid analyses and information that may be provided back to providers for application to their own facilities. In addition, these sections clarify that data should be standardized for effective compilation and analysis, and that information used to create this database is also privileged and confidential. Also included is a section expressly allowing for the Secretary of DHHS to provide technical assistance for providers using the system, including assistance and feedback regarding practical issues of methodology, communication, confidentiality, peer review privilege application, and/or privacy issues, and a defined time limit for creating standards to allow for effective integration of patient safety data and information.

"SEC. 926. CONFIDENTIALITY AND MEDIATION COMMUNICATION PROTECTIONS.

"(a) IN GENERAL.—Notwithstanding any other provision of law, and subject to this section, mediation communications shall be privileged and confidential.

"(b) SCOPE OF PRIVILEGE.—Subject to the provisions of subsection (c), mediation communications to which subsection (a) applies shall not be—

"(1) subject to a civil, criminal, or administrative subpoena;

"(2) subject to discovery in connection with a civil, criminal, or administrative proceeding; and in a proceeding, the following privileges apply—

"(A) A mediation party may refuse to disclose, and may prevent any other person from disclosing, a mediation communication;

"(B) A mediator may refuse to disclose a mediation communication, and may prevent any other person from disclosing a mediation communication of the mediator.

"(C) A nonparty participant may refuse to disclose, and may prevent any other person from disclosing, a mediation communication of the nonparty participant;

"(3) disclosed pursuant to section 552 of title 5, United States Code (commonly known as the Freedom of Information Act) or any other similar Federal or State law;

"(4) admitted as evidence or otherwise disclosed in any civil, criminal, or administrative proceeding; or

"(5) utilized in an adverse employment action or in the evaluation of decisions made in relation to accreditation, certification, credentialing, or licensing of an individual or entity, that is based on such individual or entity's participation in the mediation.

This section provides the key bases for maintaining mediation confidentiality. Critically, a broad array of communications and parties are noted and included within the confidentiality provisions, and the privilege is extended to civil and criminal proceedings as well as administrative actions. As well, the section indicates that "end run"

efforts to obtain mediation communications and information will not be permitted under the Freedom of Information Act, and that such information is also precluded from use in hearings against a provider if it is based upon participation in mediation.

"(c) DISCLOSURE, WAIVER, AND PRECLUSION OF PRIVILEGE USE.—In this section—

"(1) Evidence or information that is otherwise admissible or subject to discovery does not become inadmissible or protected from discovery solely by reason of its disclosure or use in a mediation; and  
 "(2) A privilege under subsection (b) may be waived in a record or orally during a proceeding if it is expressly waived by all parties to the mediation and—

"(A) in the case of the privilege of the mediator, it is expressly waived by the mediator; and

"(B) in the case of the privilege of a nonparty participant, it is expressly waived by the nonparty participant.

"(3) A privilege under subsection (b) may be precluded from use under the following circumstances—

"(A) a person that discloses or makes a representation about a mediation communication which prejudices another person in a proceeding is precluded from asserting a privilege under subsection (b), but only to the extent necessary for the person prejudiced to respond to the representation or disclosure; and

"(B) a person that intentionally uses mediation to plan, attempt to commit or commit a crime, or to conceal an ongoing crime or ongoing criminal activity is precluded from asserting a privilege under subsection (b).

"(d) EXCEPTIONS TO PRIVILEGE.—There is no privilege under subsection (b) for a mediation communication that is—

"(1) in an agreement evidenced by a record signed by all parties to the agreement;

"(2) a threat or statement of a plan to inflict bodily injury or commit a crime of violence;

"(3) intentionally used to plan a crime, attempt to commit or commit a crime, or to conceal an ongoing crime or ongoing criminal activity;

"(4) sought or offered to prove or disprove a claim or complaint of professional misconduct or malpractice filed against a mediator;

"(5) sought or offered to provide or disprove a claim or complaint of professional misconduct or malpractice filed against a mediation party, nonparty participant, or representative of a party based on conduct during a mediation, except that a mediator may not be compelled to provide evidence of a mediation communication.

"(e) LIMIT OF EXCEPTIONS TO PRIVILEGE.—If a mediation communication is not privileged under subsection (b) as described in subsection (d), only the portion of the communication necessary for the application of the exception from nondisclosure may be admitted. Admission of evidence under subsection (d) does not render the evidence, or any other mediation communication, discoverable or admissible for any other purpose.

"(f) PRECLUDED USE.—A communication made in violation of subsection (b) may not be considered by a court, administrative agency, arbiter, or other person.

These provisions indicate important exceptions to the mediation privilege, and the relevant limitations to these exceptions. In general, these exceptions relate to voluntarily waivers of privilege as granted in the statute or in situations of professional misconduct or criminal activity.<sup>153</sup> Importantly, subsection (e) indicates that mediation communications disclosed do not then render all mediation communications accessible by a party or nonparty, and the limitation of use of the disclosed mediation communication to the forum at hand.

"SEC. 927. AUTHORIZATION OF APPROPRIATIONS.

"There is authorized to be appropriated such sums as may be necessary to carry out this Act."

SEC 4. STUDIES AND REPORTS.

(a) STATE LAWS RELATING TO PATIENT SAFETY PEER REVIEW SYSTEMS AND MEDIATION ACTIVITIES.—

(1) SURVEY.—The Attorney General shall conduct a survey of State laws that relate to patient safety data peer review systems and mediation confidentiality, including laws that establish an evidentiary privilege applicable to data developed by such systems and mediation discussions relating to health care, and shall review the manner in which such laws have been interpreted by the courts.

(2) REPORT.—Not later than nine months after the date of enactment of this Act, the Attorney General, or his or her designee, shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report concerning the results of the survey conducted under paragraph (1).

These sections provide what is often ignored but critical in legal policy—a provision for funding of the infrastructure necessary to implement its provisions, and a provision to assess the effectiveness and challenges relating to implementation of the statute as public policy.

<sup>153</sup> These provisions thus ensure that critical areas noted by commentators not be excluded for relevant public policy purposes. See, e.g., Pamela A. Kentra, *Hear No Evil, See No Evil, Speak No Evil: The Intolerable Conflict for Attorney-Mediators between the Duty to Maintain Mediation Confidentiality and the Duty to Report Fellow Attorney Misconduct*, 1997 BYU L. REV. 715 (1997) (providing for exceptions to mediation privilege for attorney misconduct); Mori Irvine, *Serving Two Masters: The Moral Obligation under the Rules of Professional Conduct to Report Attorney Misconduct in a Confidential Mediation*, 26 RUTGERS L.J. 155 (1994); Kevin Gibson, *Confidentiality in Mediation: A Moral Reassessment*, 1992 J. DISP. RESOL. 25 (1992) (providing for reporting threats, crime, or abuse and neglect circumstances); Lynne H. Rambo, *Impeaching Lying Parties with Their Statements During Negotiation: Demysticizing the Public Policy Rationale behind Evidence Rule 408 and the Mediation Privilege Statutes*, 75 WASH. L. REV. 1037 (2000) (providing for the purpose of impeaching prior inconsistent statements).



## V. CONCLUSION

At some point or another, all of us will be patients in the delivery system, and thus patient safety affects us all. Key systems approaches outside medicine and within it have shown the effectiveness of these methods. However, these methods require open, honest, and frank communications, discussions, and corrective actions. Currently, providers and patients rely on precisely the wrong methods to "improve" safety—shame and blame of individuals and a legal system that thwarts effective communication of safety data and issues. As well, federal-state issue analysis indicate PR/QA privilege may not be applicable to safety and error discussions, and mediation communications may be used for other, inappropriate activities that were never intended by the parties.

To improve safety, safe, confidential communications must be allowed, promoted, and rewarded. To obtain this goal, and to clarify the need for protected communications, federal legislation should be passed to protect PR/QA and mediation communications as they relate to safety. This piece proposes such a statute.

Overall, the conflicts between federal and state laws regarding PR/QA and mediation communications must be addressed. The vagaries of conflict of laws, privilege, jurisdiction, and choice of laws may be of great interest to the attorney; however, to an injured patient or provider caught in a system which discourages open discussion of safety, they represent only a source of angst that limits what can and will be discussed—and corrected. We must do better; for our lives, and the lives of our families and future generations, depend upon it.

## AN ASSESSMENT OF MEDICAID PLANNING

Alison Barnes\*

### INTRODUCTION

Access to long-term care in the United States, like health care, is allocated primarily on the basis of ability to pay. For a substantial segment of the population, health care costs are covered by insurance; however, long-term care insurance is far less common and may cover an unpredictably low portion of actual costs.<sup>1</sup> Therefore, premiums are high due to actuarial unpredictability and prevailing price strategies that determine premiums based on the insured's age at the time of purchase or that increase premiums with the advancing age of the insured.<sup>2</sup> Thus, older people who have such insurance must be quite affluent in order to afford the premiums.<sup>3</sup>

Long-term care policy and finance is intertwined with health care policy, in that long-term care in the second half of the twentieth century is defined as physical care that is *not* health care.<sup>4</sup> Long-term care policy is also closely aligned with government benefits for the poor.<sup>5</sup> In the past, one who could be self-supporting presumably could pay for long-term care, including non-medical physical assistance to offset incapacities due largely to the natural process of aging. As a result, social policy has yet to determine with certainty whether long-term care assistance is a legitimate need for those who are not clearly determined to be poor. Thus, policy makers in the United States are uncertain how and by what type of benefit long-term care should be available to elders. A persistent theme is that many elders can and should provide for their own long-term care

\* Professor of Law, Marquette University Law School; M. Phil. in Law, Cambridge University, England; J.D. University of Florida.

<sup>1</sup> See ALISON BARNES ET AL., COUNSELING OLDER CLIENTS 16-1 (1997).

<sup>2</sup> See *id.* at 16-4.

<sup>3</sup> See *id.* (citing LONG-TERM CARE POLICIES AVAILABLE IN WISCONSIN, Office of the Commissioner of Insurance (Jan. 1994)).

<sup>4</sup> See *id.* at V-3.

<sup>5</sup> See *id.* at V-4.