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# Save Thousands of Lives Every Year: Resuscitate the Peer Review Privilege

Alan G. Williams
Florida Coastal School of Law

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# SAVE THOUSANDS OF LIVES EVERY YEAR: RESUSCITATE THE PEER REVIEW PRIVILEGE

### ALAN G. WILLIAMS\*

I. Introduction	221
II. PREVENTABLE HOSPITAL DEATHS	225
III. PEER REVIEW	227
A. Credentialing and Admitting "Privileges"	228
B. The Morbidity and Mortality Conference	
C. Immunity, Confidentiality, and Privilege	233
IV. EROSION OF THE PEER REVIEW PRIVILEGE	
A. Federal Courts	236
B. State Courts	237
C. State Legislatures	
V. THE PATIENT SAFETY AND QUALITY IMPROVEMENT ACT	
A. How the PSQIA Should Work	240
B. Why the PSQIA Hasn't Worked Yet	243
C. How to Reduce Injuries and Deaths	245
VI. CONCLUSION	

# I. INTRODUCTION

The needs of the many outweigh the needs of the few.<sup>1</sup>

Doctors make mistakes—preventable medical mistakes—that kill or seriously injure patients.<sup>2</sup> The best way to reduce these preventable errors is through a medical peer review process typically referred to as a "morbidity and mortality conference."<sup>3</sup>

<sup>\*</sup>Alan G. Williams, Professor of Law, Florida Coastal School of Law.

<sup>&</sup>lt;sup>1</sup> Paraphrasing Aristotle, Jeremy Bentham, and John 11:49-50.

<sup>&</sup>lt;sup>2</sup> The medical errors physicians commit are, of course, unintentional. This essay is intended neither as a criticism of physicians nor of the medical care they render.

<sup>&</sup>lt;sup>3</sup> Because morbidity and mortality conferences are historically confidential, few non-physicians ever attend. For readers unfamiliar with them, the following two links provide fictionalized dramatizations of what morbidity and mortality conferences are, how they are conducted, what is discussed, and what the remedial and corrective effects can be: <a href="http://www.youtube.com/watch?v=kT4KN0kG--A">http://www.youtube.com/watch?v=kT4KN0kG--A</a> and <a href="http://www.youtube.com/watch?v=MaiXSzZGr9Y">http://www.youtube.com/watch?v=MaiXSzZGr9Y</a>. Regarding M&Ms as the best means to reduce medical errors, see infra Part II Section B.

However, over the past twenty years, federal and state courts, state legislatures, and state voters have effectively gutted the morbidity and mortality conference ("M&M") as a remedial and preventative tool, resulting in tens of thousands of unnecessary deaths every year. Doctors need our help restoring the effectiveness of M&Ms. Congress has created the means to do so; now, all the courts need do is use it. Otherwise, what has been happening over the last two decades will continue—physicians will fear the M&M, will either not participate in M&Ms or not participate fully, medical errors will not be thoroughly investigated and corrected, and the same preventable medical mistakes will continue to occur because physicians are scared if they admit during an M&M that they committed an error then, in a subsequent medical malpractice lawsuit, their admission will be used against them to prove negligence and liability. Doctors aren't stupid—if we continue to punish them when they admit their mistakes then they'll simply stop admitting them . . . which is bad for everyone, especially patients.

For nearly half a century the law recognized—either via case law or statute—a peer review privilege designed to immunize physicians and physician peer review committees, including M&Ms, from liability, and protect certain peer review statements, information, and materials from admissibility or disclosure in any subsequent legal proceedings.<sup>7</sup> Then, beginning in the mid-1990s, decisions in both federal and state courts, along with statutes enacted by some state legislatures—and

<sup>&</sup>lt;sup>4</sup> See infra Part I.

<sup>&</sup>lt;sup>5</sup> See Patient Safety and Quality Improvement Act infra Part Error! Reference source not found.

<sup>&</sup>lt;sup>6</sup> See, e.g., Duncan MacCourt & Joseph Bernstein, Medical Error Reduction and Tort Reform Through Private, Contractually-Based Quality Medicine Societies, 35 Am. J.L. & MED. 505, 552 (2009) ("Physicians are scared that identification and remediation of medical error—whether of their own or of their colleagues'—will expose them to a lawsuit."); Kathryn Leaman, Let's Give Them Something to Talk About: How the PSQIA May Provide Federal Privilege and Confidentiality Protections to the Medical Peer Review Process, 11 MICH. ST. U. J. MED. & L. 177, 178 (2007) ("Over the years, physicians became more and more reluctant to participate in the peer review process because of their increased risk of civil liability as the committees' focus shifted from the possible negligent care provided by the hospital to the possible negligent care each individual physician provided, thus undercutting the ultimate goal of improving the quality of healthcare.").

<sup>&</sup>lt;sup>7</sup> The peer review privilege was, at least implicitly, first legally recognized in <u>Bredice v. Doctors Hospital</u>, 50 F.R.D. 249 (1970), *aff'd* 479 F.2d 920 (D.C. Cir. 1973), in which the court held that all communications during and records of a "staff meeting" conducted pursuant to guidelines promulgated by the Joint Commissions on Accreditation of Hospitals whose purpose was to review the medical care resulting in the patient's death were "entitled to a qualified privilege on the basis of [the] overwhelming public interest" in identifying medical errors so they can be prevented in the future. The court employed the "self-critical analysis" privilege in so ruling. Other jurisdictions created a peer review privilege based in part on the rationale behind the inadmissibility of subsequent remedial measures to prove liability (Federal Rule of Evidence 407). *See*, *e.g.*, Fox v. Kramer, 82 Cal. Rptr. 2d 513 (Cal. App. 1999), judgment affirmed, 22 Cal. 4th 531 (Cal. App. 2000).

even voter-initiated state constitutional changes—began to erode the peer review privilege.8

Consider, six-year-old Hannah arrives with her parents at the children's hospital for a scheduled tonsillectomy. Hannah's parents are worried but surgeon Dr. Gwande reassures them the procedure is routine and then introduces Hannah to the anesthesiologist, Dr. Stevens. Hannah gets prepped for surgery, is administered anesthesia by Dr. Stevens, and counts backward from one hundred until she becomes unconscious. Dr. Gwande successfully and without incident removes Hannah's tonsils, but Hannah never wakes up from the procedure.

Hannah's parents are devastated; they want answers regarding why their daughter died and assurances nothing like this will ever happen to someone else's child. The hospital summons Dr. Stevens and Dr. Gwande for a peer review morbidity and mortality conference to investigate what went wrong and how the hospital can ensure the mistake is not repeated. During the M&M, the two physicians candidly explain that they have investigated and identified the medical error that led to Hannah's death: the anesthesia dosage was mixed incorrectly, resulting in Hannah being administered 100 times the recommended amount. Unaware of the glitch in its procedures until this incident and subsequent investigative M&M, the hospital implements a new policy to ensure this type mistake never happens again.

A year later, Hannah's parents sue the hospital and the two physicians, alleging medical negligence in the death of their daughter, and during the discovery phase of the lawsuit demand all the information, documentation, and statements/admissions made by Drs. Stevens and Gwande, including everything done and said at the M&M. The defendants object, claiming the protections of the peer review privilege and arguing that if M&Ms are not privileged, confidential, and inadmissible in any subsequent legal proceedings, physicians have no incentive to admit and discuss mistakes in an effort to prevent future similar errors.<sup>11</sup> Depending upon what

<sup>&</sup>lt;sup>8</sup> Based on Supreme Court and circuit court of appeals precedent, nearly all federal districts courts have likewise declined to recognize a federal privilege for peer review. *See infra* Part III Section **Error! Reference source not found.** and note 81. For evidence of state courts eroding the peer review privilege *see infra* note 87. Some state legislatures have also limited the peer review privilege with in their state. *See infra* note 90.

<sup>&</sup>lt;sup>9</sup> Such a peer review meeting "has the goal of protecting future patients from medical error." Frederick Levy et al., *The Patient Safety and Quality Improvement Act of 2005*, 31 J. LEGAL MED. 399, 401 (2010).

<sup>&</sup>lt;sup>10</sup> Some hospitals, medical institutions, and state statutes do not employ the term "morbidity and mortality conference." In this essay, however, "morbidity and mortality conference" or "M&M" refers to any peer review meeting at which an adverse medical outcome in a specific patient or class of patients is discussed, reviewed, investigated, or analyzed by participating physicians.

<sup>&</sup>lt;sup>11</sup> Physicians "who engage in this self-scrutiny will have to generate highly sensitive data about their own performance, data that may reveal" negligent medical care. Alice G. Gosfield, "Patient Safety Organization Can Help Providers Improve Performance and Results," MEDICAL ECONOMICS (Jan. 23, 2014), <a href="http://medicaleconomics.modernmedicine.com/medicaleconomics/content/tags/data-collection/patient-safety-organizations-can-help-providers-impro?page=0.0">http://medicaleconomics.modernmedicine.com/medicaleconomics/content/tags/data-collection/patient-safety-organizations-can-help-providers-impro?page=0.0</a>.

jurisdiction Drs. Gwande and Stevens practice in, the M&M is either privileged and protected from admissibility or it is not.

The law recognizes numerous evidentiary privileges, and values some privileges more than others: the attorney-client communication privilege is considered more sacred than the attorney work-product privilege, the spousal communications privilege more important than the spousal testimonial privilege. 12 Unfortunately, even where it still exists, the peer review privilege is way down on the list. Although other privileges certainly must be valued for what they protect, how can shielding what a client communicates to his attorney be more important or deserve greater legal protection than saving tens of thousands of lives every year? If Congress and state legislatures which accept the premise that M&Ms result in improved medical care, fewer medical errors, and a reduction of preventable injuries and deaths—believe the peer review privilege affords physicians the best opportunity to maximize the benefits of M&Ms, shouldn't we value the peer review privilege at least as much as we value other evidentiary privileges? Shouldn't the peer review privilege—at a minimum—trump an individual medical malpractice plaintiff's attempt for monetary recovery? Weighing the needs of the many against the needs of the few, isn't saving tens of thousands of lives annually more important than a handful of medical malpractice plaintiffs improving their odds of being monetarily compensated? In this essay, I argue that it is.

By enacting the relatively obscure Patient Safety Improvement and Quality Care Act<sup>13</sup> in 2005 (which did not truly take effect until 2009<sup>14</sup>), Congress provided a tool that can be employed to resuscitate the peer review privilege, although no court has yet invoked the PSQIA and upheld the privilege.<sup>15</sup> In this essay, I argue that courts must employ the PSQIA and begin upholding the peer review privilege to protect M&Ms, which will ultimately result in an improved quality of medical care rendered, a reduction of medical errors, and fewer patient deaths.

Part I of this essay summarizes the extent of the problem—many call it a crisis—of preventable deaths plaguing U.S. hospitals. Part II explains peer review, both in the context of physician credentialing/hiring and M&Ms, and the legal protections afforded under the provisions of immunity, confidentiality, and privilege. Part III discusses how federal and state court decisions, state legislative enactments, and voter initiatives have weakened existing protections for peer review, especially regarding M&Ms. Part IV describes the PSQIA and how it can—and should—be the solution to preventable hospital deaths. Part V concludes with a summation of the argument that courts employ the PSQIA privilege to protect M&Ms, and that physicians and hospitals do their part by fulfilling the requirements of the PSQIA such that they may invoke the privilege therein contained.

<sup>&</sup>lt;sup>12</sup> Steven Walker, *The Attorney Client Privilege and Work Product - Navigating Recent Changes and How They Affect Your Technology Company*, <a href="https://apps.americanbar.org/litigation/committees/intellectual/roundtables/0308">https://apps.americanbar.org/litigation/committees/intellectual/roundtables/0308</a> outline.pdf.

<sup>&</sup>lt;sup>13</sup> 42 U.S.C. § 299b-21 to -26 (2006).

 $<sup>^{14}</sup>$  The Department of Health and Human Services did not issue final regulations until December of 2008 allowing for the creation of Patient Safety Organizations.

<sup>&</sup>lt;sup>15</sup> See infra note 115.

#### II. PREVENTABLE HOSPITAL DEATHS

Few truly understood the extent and severity of the national crisis of preventable hospital deaths until publication of the 1999 Institute of Medicine's comprehensive report estimating that as many as 98,000 patients die each year in America's hospitals from preventable medical errors, <sup>16</sup> a mortality figure three times as high as the number of annual deaths caused by vehicular accidents. <sup>17</sup> Fourteen years later, a separate study concluded that more than 400,000 preventable deaths occur nationally each year as a result of medical errors. <sup>18</sup> Other studies have concluded that nearly half of all patients experience a medical error at some point during treatment, <sup>19</sup> as many as 18% of hospital patients endure a medical injury caused by a healthcare provider, <sup>20</sup> and "some medical errors are not known by clinicians and only come to light during autopsies, which have found misdiagnoses in 20% to 40% of cases." <sup>21</sup>

A medical error is defined as "the failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning)."<sup>22</sup> All medical errors do not result in harm or death, and all preventable medical injuries/deaths are not necessarily caused by medical errors. As of 2009, Medicare and Medicaid no longer reimburse healthcare providers for care

<sup>&</sup>lt;sup>16</sup> Institute of Medicine, To ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM 26 (Kohn et al. eds., 2000). See, also, Carol Brass, *A Proposed Evidentiary Privilege for Medical Checklists*, 2010 COLUM. BUS. L. REV. 835, 851 (2010) ("One commentator described medical errors as the 'eighth leading cause of death in the United States. The number of deaths [every day] due to errors is equivalent to a jet airliner crashing every day.""), quoting, David Costa, *Human Error: An Inevitable Part of Healthcare, or a Better Future?*, RESPIRATORY THERAPY, JUNE-JULY 2008, at 9.

<sup>&</sup>lt;sup>17</sup> Tom Baker, The Medical Malpractice Myth 22, 23 (2005). Preventable medical errors were approximated to cost between \$17 billion and \$29 billion each year, when factoring in direct healthcare costs, disability, lost productivity, and lost wages/income. *See* IOM, To Err Is Human, *supra* note16, at 1-3. Empirical research suggests that medical errors committed in hospitals add approximately \$1,264 in costs per patient admission. Michelle M. Mello et al., *Who Pays for Medical Errors? An Analysis of Adverse Event Costs, the Medical Liability System, and Incentives for Patient Safety Improvement*, 4 J. Empirical Legal Stud. 838, 847 (2007).

<sup>&</sup>lt;sup>18</sup> John T. James, *A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care*, 9 J. Patient Safety 122 (2013). If the 400,000 figure is accurate, only cancer and heart disease kill more Americans annually than preventable medical harm/errors. Leah Binder, "Stunning News on Preventable Deaths in Hospitals," Forbes (September 23, 2013), accessed at: <a href="http://www.forbes.com/sites/leahbinder/2013/09/23/stunning-news-on-preventable-deaths-in-hospitals/">http://www.forbes.com/sites/leahbinder/2013/09/23/stunning-news-on-preventable-deaths-in-hospitals/</a>.

<sup>&</sup>lt;sup>19</sup> Lori Andrews, Studying Medical Error in Situ: Implications for Malpractice Law and Policy, 54 DEPAUL L. REV. 357, 370 (2005).

<sup>&</sup>lt;sup>20</sup> Jennifer Arlen, *Contracting over Liability: Medical Malpractice and the Cost of Choice*, 158 U. PA. L. REV. 957, 971 (2010) ("Studies have found that between four and eighteen percent of hospital patients are the victims of medical errors, many of which cause serious injuries.").

<sup>&</sup>lt;sup>21</sup> See James, Evidence-based Estimate, supra note 18 at 122, citing, Lucian Leape, Institute of Medicine Medical Error Figures Are Not Exaggerated, 284 JAMA 95 (2000).

<sup>&</sup>lt;sup>22</sup> See IOM, To ERR IS HUMAN, supra note 16 at 28.

rendered to rectify a "never event";<sup>23</sup> however, most preventable medical injuries would not be categorized as never events (which, thankfully, are quite rare<sup>24</sup>). Regardless, preventable medical injuries and deaths—whether caused by medical error or not—continue to occur far too frequently in U.S. hospitals. Therefore, corrective measures must be undertaken to address preventable hospital deaths. Most physicians agree that peer review and, more specifically, effective morbidity and mortality conferences, present the best means to reduce preventable hospital deaths.<sup>25</sup>

For example, on March 29, 2012, twelve-year-old Rory Staunton was discharged from the emergency room with a diagnosis of dehydration and nausea subsequent to a two-day-old cut on his arm.<sup>26</sup> Rory's pediatrician had sent him to the ER because Rory was complaining of pain and had vomited on the pediatrician. The ER physicians ordered lab tests, supplied Rory with I.V. fluids, determined Rory had improved, and sent him home. The lab tests, however, revealed Rory was producing neutrophils and bands (white blood cells) at abnormally high rates, suggesting a serious bacterial infection. Three days later, Rory was dead from streptococcus pyogenes, a normally-occurring bacteria that can turn deadly if it moves from the throat to penetrate blood or soft tissue. The ER physicians' failure to properly interpret the lab results, appreciate that Rory exhibited three symptoms of possible sepsis, and discharge of Rory with an incorrect diagnosis is a prime example of a preventable medical error resulting in death. This is the exact type of iatrogenic mistake the Institute of Medicine's report explained could be remedied by performing systemsbased evaluations of medical care. Instead of blaming an individual physician, the IOM report sought to engender a revolutionary approach to medical errors that focused on correcting systemic defects.<sup>27</sup> A system that somehow alerted Rory's ER physicians to check for streptococcus pyogenes based on a combination of the lab results and the exhibition of three sepsis indicators may have saved Rory's life.<sup>28</sup>

<sup>&</sup>lt;sup>23</sup> For a list of the 28 "never events" listed by Medicare/Medicaid, please see, U.S. Dept. Health and Human Services letter to state Medicare/Medicaid directors 7/31/08, <a href="http://www.medicaid.gov/Federal-Policy-Guidance/downloads/SMD073108.pdf">http://www.medicaid.gov/Federal-Policy-Guidance/downloads/SMD073108.pdf</a> (last accessed September 16, 2014).

 $<sup>^{24}</sup>$  Id. Although rare, studies show that when they do occur, "never events" are fatal in 71% of cases.

<sup>&</sup>lt;sup>25</sup> See, e.g., Steven J. Kravet, et al., Morbidity and Mortality Conference, Grand Rounds, and the ACGME's Core Competencies, 21 J. GEN. INTERN. MED. 1192 (2006); George E. Newton II, Maintaining the Balance: Reconciling the Social and Judicial Costs of Medical Peer Review Protection, 52 ALA. L. REV. 723, 724 (2001).

<sup>&</sup>lt;sup>26</sup> This incident was detailed in, "An Infection, Unnoticed, Turns Unstoppable," New YORK TIMES, July 11, 2012 at <a href="http://www.nytimes.com/2012/07/12/nyregion/in-rory-stauntons-fight-for-his-life-signs-that-went-unheeded.html?">http://www.nytimes.com/2012/07/12/nyregion/in-rory-stauntons-fight-for-his-life-signs-that-went-unheeded.html?</a> pagewanted=all (last accessed September 30, 2014).

 $<sup>^{27}</sup>$  Because they are specialized, highly-complex, and operate interdependently, hospitals and healthcare systems are particularly vulnerable to systemic error. *See* IOM, To Err IS HUMAN, *supra* note 16 at 58-59.

<sup>&</sup>lt;sup>28</sup> See, e.g., Levy, Patient Safety, supra note 9 at 400:

<sup>[</sup>A] systems-based approach prospectively seeks to correct and improve systemic sources of error. Through this approach, patient safety standards could constantly be evaluated, revised, and improved to maximize patient safety . . . [S]uch a systems-based

#### III. PEER REVIEW

The term "peer review" generally describes an array of review processes created by hospitals, medical groups, and other healthcare entities to verify that only competent physicians treat patients and that they continue to provide quality medical care.<sup>29</sup> The medical community created peer review "to decrease instances of medical malpractice and improve the condition of health care by allowing practicing physicians to recognize inadequacies in their peers' performances and discipline accordingly."<sup>30</sup> Initiated in the early 1900s,<sup>31</sup> hospitals began formalizing the peer review process in 1952 after the Joint Commission on Accreditation of Hospitals began requiring hospitals create peer review procedures in order to obtain accreditation.<sup>32</sup> For a hospital to participate in and receive reimbursement from Medicare or Medicaid it must establish a peer review committee, and most states include in their hospital licensure requirements the creation and maintenance of a peer review committee.<sup>33</sup> There are two distinct subsets within the concept of peer review: hospital credentialing/admitting privileges and M&Ms.<sup>34</sup>

approach would focus on prospective systemic safety remedies and prophylaxis, rather than on retrospective assessment of blame. The focus of a systems-based review of error would be to assess potential flaws so as to prevent future errors.

<sup>&</sup>lt;sup>29</sup> Ilene N. Moore, *Rethinking Peer Review: Detecting and Addressing Medical Malpractice Claims Risk*, 59 VAND. L. REV. 1175, 1177 (2006). *See also*, Susan O. Scheutzow, *State Medical Peer Review: High Cost But No Benefit—Is It Time for a Change?*, 25 AM. J.L. & MED. 7, 12 (1999) ("peer review is the generally accepted method of enhancing quality health care"); Daniel M. Mulholland III and Phil Zarone, *Waiver of the Peer Review Privilege: A Survey of the Law*, 49 S.D. L. REV. 424 (2004) (the "peer review system is the only meaningful, ongoing process by which medical care is monitored and evaluated and inferior care is dealt with through sanctions that prevent substandard practitioners from causing harm to patients").

<sup>&</sup>lt;sup>30</sup> See Newton, Maintaining the Balance, supra note 25 at 724.

<sup>&</sup>lt;sup>31</sup> In 1914, Dr. Ernest Codman at Massachusetts General Hospital attempted to create "End Results Cards" regarding patient diagnosis, treatment, and outcome, as well as to conduct conferences to evaluate physicians' competence; Mass. General considered Dr. Codman disruptive to the status quo and he was fired. Ultimately, Dr. Codman's "efforts were not in vain, however, as the wheels of progress had been set in motion. Dr. Codman's ideas contributed to the standardization of hospital practices—including a case report system that ascribed responsibility for outcomes—by the American College of Surgeons in 1916." THE SAGES MANUAL OF QUALITY, OUTCOMES AND PATIENT SAFETY: Chapter 18. Morbidity and Mortality by Chirag A. Dholakia and Kevin M. Reavis 162-164 (Tichansky, Morton, and Jones, eds. 2012).

<sup>&</sup>lt;sup>32</sup> See Scheutzow, State Medical Peer Review, supra note 29 at 13.

<sup>&</sup>lt;sup>33</sup> Eleanor D. Kinney, *Hospital Peer Review of Physicians: Does Statutory Immunity Increase Risk of Unwarranted Professional Injury?*, 13 MICH. ST. U. J. MED. & L. 57, 60 (2009). Similarly, Congress further recognized the benefits of a protected peer review process when it created such for both the Department of Defense and Department of Veteran Affairs medical programs. *See*, 10 U.S.C.A. §1102(a) (West 2012) and 38 U.S.C.A. §5705(a) (West 2012).

<sup>&</sup>lt;sup>34</sup> *Id*.

# A. Credentialing and Admitting "Privileges" 35

Prior to granting hospital admitting privileges to physicians to allow them to treat patients at its hospital or prior to hiring physicians as hospital employees, a panel of physicians at the hospital undertakes a review of the education, training, experience, and medical outcomes of the reviewed physician; this process falls under the general umbrella of peer review.<sup>36</sup> So vital to ensuring that hospitals only employ—or grant treatment/admitting privileges to—competent physicians, in 1986 Congress enacted the Health Care Quality Improvement Act<sup>37</sup> ("HCQIA") in part to promote quality peer review.<sup>38</sup> The HCQIA sets forth the standards for peer reviews but does not itself provide any legal protections—other than qualified immunity from suit, under certain circumstances—for those reviewing physicians participating in the peer review process.<sup>39</sup> The HCQIA established no legal protections for the reviewed physician and specifically rejected creating a federal evidentiary privilege to protect peer review.<sup>40</sup> Relying on Congress' failure to create a federal peer review privilege in the HCQIA and themselves declining to find a peer review privilege within federal common law,<sup>41</sup> federal courts have repeatedly held there is no federal peer review

<sup>&</sup>lt;sup>35</sup> The term hospital admitting "privileges" simply means that a physician who is not an employee of, or independent contractor for, a hospital nonetheless may admit to, and treat patients at, a particular hospital. I apologize for any confusion caused the reader, but in the legal context "privileges" means one thing but in the medical context it means something else entirely.

<sup>&</sup>lt;sup>36</sup> Lisa M. Nijm, Pitfalls of Peer Review, 24 J. LEGAL MED. 541, 543 (2003).

<sup>&</sup>lt;sup>37</sup> 42 U.S.C. §§ 11101-11152.

<sup>&</sup>lt;sup>38</sup> The second reason Congress enacted the HCQIA was to create the National Practitioner Data Bank, "a national clearinghouse of information, to prevent physicians who had their clinical privileges at a hospital limited due to quality problems from moving to other hospitals with impunity." *See* Scheutzow, *State Medical Peer Review, supra* note 29 at 8, <a href="https://a.next.westlaw.com/Document/I5d495061227711dbbab99dfb880c57ae/View/FullText.html?transitionType=UniqueDocItem&contextData=%28sc.Default%29&userEnteredCitation=25+Am.+J.L.+%26+Med.+7 - co\_footnote\_F20110783765.

<sup>&</sup>lt;sup>39</sup> Congress well-knew that physicians would be hesitant to serve as peer reviewers if they thought they could be sued personally for denying another physician admitting privileges at the hospital, rejecting a physician from employment at the hospital, or firing a physician from the hospital.

<sup>&</sup>lt;sup>40</sup> "Even with immunity for participating in peer review proceedings, [physicians] may still be reluctant to participate in the peer review process because they do not want their appraisals of a physician's competence to be disclosed later in court . . . during a malpractice or other action later brought against the reviewed physician." *See* Scheutzow, *State Medical Peer Review*, *supra* note 29 at 18.

<sup>&</sup>lt;sup>41</sup> Although the Supreme Court expressly held that "Rule 501 of the Federal Rules of Evidence authorizes federal courts to define new privileges by interpreting 'common law principles... in the light of reason and experience," <u>Jaffee v. Redmond</u>, 116 S.Ct. 1923, 1927 (1996), nearly all federal courts have declined to do so regarding a peer review privilege.

privilege protecting the statements made during, the information elicited within, or the documents generated by the peer review process.<sup>42</sup>

In the absence of a federal peer review privilege but recognizing that "[p]eer review confidentiality is rooted in public policy to support physicians in their self-regulatory efforts to monitor the competency and conduct of their peers," each of the 50 states and the District of Columbia enacted a statute or evidentiary rule to legally protect as privileged the peer review process. However, over the last two decades, state court decisions and state legislative enactments have resulted in states' statutory privileges either disappearing or being severely restricted in the protections provided, leaving physicians without an effective peer review privilege in either federal or state courts.

# B. The Morbidity and Mortality Conference<sup>47</sup>

<sup>&</sup>lt;sup>42</sup> See, e.g., <u>Allen v. Cuyahoga Co.</u>, 2014 WL 434558 (N.D. Ohio 2014) ("The weight of authority in the Sixth Circuit and elsewhere is that no medical peer review privilege exists under federal common law"); Charles G. Kels, *Odd Man Out? The Medical Peer Review Privilege in Federal Litigation*, 60-DEC FED. LAW. 52, 54 (2013) ("[p]eer review materials may be discoverable in connection with many federal causes of action").

<sup>&</sup>lt;sup>43</sup> Kenneth R. Kohlberg, *The Medical Peer Review Privilege: A Linchpin for Patient Safety Measures*, 86 MASS. L. REV. 157, 157-158 (2002). *See also*, <u>DeFrancesco v. Stamford Health</u>, 2013 WL 1189380 (Conn. Sup. Ct. 2013) (The "strong policy favoring free and open discussion in peer review proceedings represents a legislative choice between medical staff candor and a plaintiff's access to information.").

<sup>&</sup>lt;sup>44</sup> Am. Med. Ass'n, PEER REVIEW PRIVILEGES AND IMMUNITIES: A 50 STATE SURVEY AND ANALYSIS 4 (2006); see also, THE NEW WIGMORE § 7.8.2, at 1124; Adkins v. Christie, 488 F.3d 1324, 1330 (11th Cir. 2007) ("[w]e are mindful of the fact that a peer review privilege is recognized by all fifty states and the District of Columbia"). See, e.g., ARIZ. REV. STAT. ANN. §36-445.01 (WEST 2012) ("All proceedings, records and materials prepared in connection with [peer] reviews . . . including all peer reviews of individual health care providers practicing in and applying to practice in hospitals or outpatient surgical centers and the records of such reviews, are confidential and are not subject to discovery."); CAL EVID. CODE §1157(A) (WEST 2012) ("Neither the proceedings nor the records of organized . . . peer review bod[ies], or medical or dental review [bodies] . . . shall be subject to discovery."); CONN. GEN. STAT. §19A-17B(D) (WEST 2012) ("The proceedings of a medical review committee conducting a peer review shall not be subject to discovery or introduction into evidence in any civil action for or against a health care provider arising out of the matters which are subject to evaluation and review by such committee"); IND. CODE §34-30-15-2 (WEST 2012) ("[A] person who attends a peer review committee proceeding shall not be permitted or required to disclose:(1) any information acquired in connection with or in the course of a proceeding; (2) any opinion, recommendation, or evaluation of the committee; or (3) any opinion, recommendation, or evaluation of any committee member.").

<sup>&</sup>lt;sup>45</sup> See infra Part III, Section B.

<sup>&</sup>lt;sup>46</sup> See infra part III, Section C.

<sup>&</sup>lt;sup>47</sup> Some states specifically employ the term "morbidity and mortality conference" or "morbidity and mortality committee" while others use a hybrid of the term. For example,

Separate from a physician's credentialing and the granting of hospital admitting privileges, there exists a second subset of peer review designed to allow physicians to discuss in an open yet protected forum medical mistakes resulting in injury or death. Whether a resident physician at an academic medical center or an attending physician with thirty years' experience, either may be summoned before a morbidity and mortality conference. He M&M traces its roots to the origination of the peer review process itself, but only in 1983 did the Accreditation Council for Graduate Medical Education begin requiring all resident physician training programs to create and conduct regular M&Ms. So

During an M&M, "the errors made and resultant complications during the care of patients are scrutinized and discussed" by physicians with the goals being "to modify behavior and judgment based on previous experiences, and to prevent repetition of errors leading to further complications." Many institutions conduct M&Ms monthly,

Maryland calls it a "Morbidity and Quality Review Committee." Md. Code Ann. Health Gen.  $\S$  5-802(B).

<sup>&</sup>lt;sup>48</sup> In general, the five goals of an M&M are: (1) identify events resulting in adverse medical outcomes; (2) encourage discussion of adverse events; (3) identify and disseminate information and insights regarding patient care drawn from physicians' experiences; (4) reinforce accountability for providing high-quality patient care; and, (5) create a forum in which physicians acknowledge and address reasons for medical mistakes with the goal of reducing/eliminating similar errors. Jay D. Orlander, MD, MPH, Thomas W. Barber, MD, and Graeme Fincke, MD, *The Morbidity and Mortality Conference: The Delicate Nature of Learning from Error*, 77 ACAD. MED. 1001, 1004 (2002).

<sup>&</sup>lt;sup>49</sup> One study found that, of responding medical institutions, 90% conducted regular M&Ms—usually on a monthly basis—and that physician attendance was mandatory. The study concluded that M&Ms bring "doctors together to examine cases that have gone badly in an effort to increase their skill" and "learning from mistakes and confronting error are central to the medical profession and form the basis" of the belief in the importance of M&Ms. *Id.* at 1005.

<sup>&</sup>lt;sup>50</sup> ACGME Program Requirements for Graduate Medical Education in Surgery: Accreditation Council for Graduate Medical Education; 2014, available at <a href="https://www.acgme.org/acgmeweb/Portals/0/PFAssets/ProgramRequirements/">https://www.acgme.org/acgmeweb/Portals/0/PFAssets/ProgramRequirements/</a> 440 general <a href="https://www.acgme.org/acgmeweb/Portals/0/

<sup>&</sup>lt;sup>51</sup> See Dholokia, SAGES MANUAL, supra note 31 at 164. Hospitals in other countries similarly conduct M&Ms with the goal of reducing preventable deaths and injuries. See, e.g., Juliet Higginson, Rhiannon Walters, Naomi Fulop, Mortality and Morbidity Meetings: An Untapped Resource for Improving the Governance of Patient Safety?, 21 B.M.J. QUAL. SAF. 576 (2011) ("In regularly reviewing deaths and complications, these [M&M] meetings have the potential to provide accountability and the necessary improvement measures required for patient safety as well as professional learning") regarding M&Ms in the United Kingdom.

while others may have greater or less frequency;<sup>52</sup> all institutions conduct them differently. Some hospitals invite participation by physicians who desire to discuss a specific case, while others schedule a case for discussion at the M&M and require the treating physician to attend (and, usually, require that treating physician to discuss the care she rendered).<sup>53</sup>

As an example of the remedial benefits of M&Ms, over a two-year period at Vanderbilt's Monroe Carell, Jr. Children's Hospital, thirty-three action items were identified at monthly M&Ms as corrective measures to address system-based deficiencies where medical errors had occurred or could occur. <sup>54</sup> Most of the deficiencies were addressed by the corrective action items, all based on what was learned at the M&Ms. Although it is impossible to quantify how many patient lives were saved or patient injuries averted by these corrective measures, clearly the M&Ms and subsequent corrective actions have resulted in fewer preventable deaths and injuries at Vanderbilt. For purposes of this essay, I accept that M&Ms improve patient care and reduce preventable medical errors, just as Congress so accepted (based on empirical evidence) when it passed both the HCQIA and the PSQIA. <sup>55</sup>

Physicians firmly believe that "to provide high quality patient care, members of a multidisciplinary health care team must engage in objective, nonjudgmental review of adverse outcomes and commit systematic process change."<sup>56</sup> In a nutshell, that is the

<sup>&</sup>lt;sup>52</sup> "The ACGME . . . requires that surgery morbidity and mortality conferences present and discuss 'all deaths and complications that occur on a weekly basis.'" Edgar Perluissi, MD, et. al., *Discussion of Medical Errors in Morbidity and Mortality Conferences*, 290 J. AM. MED. Ass. 2838 (2003).

<sup>&</sup>lt;sup>53</sup> *Id*.

<sup>&</sup>lt;sup>54</sup> At Vanderbilt, physicians are assured that an M&M "discussion is considered privileged and confidential" and the M&Ms employ a multi-disciplinary and inter-disciplinary root cause analysis that "draws on the expertise and clinical opinion of all" M&M participants to ensure effective peer review. Jamie N. Deis, MD, et al., *Transforming the Morbidity and Mortality Conference into an Instrument for Systemwide Improvement*, APPROACHES IN PATIENT SAFETY: NEW DIRECTIONS AND ALTERNATIVE APPROACHES, Vol. 2 Culture and Redesign (K. Henrikson, et al., eds. 2008).

states 2841 ("Discussion of errors with the goal of learning how to prevent them underlies the tradition of the morbidity and mortality conference [citations omitted] and is supported by the principles of adult learning . . . Increased error reporting has led to safety improvements in other industries and is promoted by leaders in the fields of medicine and safety"). However, contrast, Charles R. Koepke, *Physician Peer Review Immunity: Time to Euthanize a Fatally Flawed Policy*, 22 J.L. & HEALTH 1 (2009) (arguing that physicians sometimes use the protections of peer review to shield themselves from retaliatory actions they commit against peers: "Accusatory physicians who are involved in the peer review process 'are easily able manipulate the process to achieve ulterior motives, such as eliminating the economic competition in a particular practice field"), quoting, Yann H.H. van Geertruyden, *The Fox Guarding the Henhouse: How the Health Care Quality Improvement Act of 1986 and State Peer Review Protection Statutes Have Helped Protect Bad Faith Peer Review in the Medical Community*, 18 J. CONTEMP. HEALTH L. & POL'Y 239, 246 (2001).

<sup>&</sup>lt;sup>56</sup> See Deis, Transforming the Morbidity, supra note 54. See also, Orlander, Morbidity and Mortality Conference, supra note 48 at 1004 ("Though the M&M[] conference may take a number of different forms, one can consider its defining characteristic to be that it is designed to identify medical errors in order to learn from them to improve medical practice.").

M&M. Hannah died unexpectedly, and to reduce the chances of the same thing happening to a future patient the hospital informs Drs. Gwande and Stevens that a confidential meeting will occur where the cause of Hannah's death will be investigated and discussed. To inspire candor, the two physicians are assured that the M&M is "privileged and confidential," that nothing the physicians say or do at the M&M will, or can, ever be used against them. If Dr. Stevens believes that admitting he committed an anesthesia mistake that cost Hannah her life could result in Hannah's parents successfully introducing into evidence during their medical malpractice lawsuit against Dr. Stevens his implicit admission of negligence, odds are he will never admit to the mistake during the M&M. Even though he knows other physicians could learn from his mistake and prevent future deaths by instituting revised anesthesia protocols to ensure the mistake does not recur, Dr. Stevens naturally would be quite reluctant to expose himself and his family to severe financial loss.

Of course, not only do physicians rightly fear whatever they admit in an M&M will be offered against them as an admission of negligence/liability in a subsequent medical malpractice lawsuit, but they also rightly fear that, if other physicians in attendance at the M&M criticize the care rendered by the defendant physician, those criticisms will be admissible during the medical malpractice case as evidence of the defendant physician's negligence. An expert hired by the plaintiff and paid to criticize the care rendered by the defendant physician is one thing, but how much more

Confidentiality is essential to effective functioning of these . . . meetings; and these meetings are essential to the continued improvement in the care and treatment of patients. Candid and conscientious evaluation of clinical practices is a *sine qua non* of adequate hospital care. To subject these discussions and deliberations to the discovery process, without a showing of exceptional necessity, would result in terminating such deliberations. Constructive professional criticism cannot occur in an atmosphere of apprehension that one doctor's suggestion will be used as a denunciation of a colleague's conduct in a malpractice suit. The purpose of these . . . meetings is the improvement, through self-analysis, of the efficiency of medical procedures and techniques.

Oviatt v. Archbishop of Bergan Mercy Hosp., 214 N.W.2d 490, 492 (Neb. 1974) (quoting Bredice, supra note 72).

59 See, e.g., Charles M. Key, The Role of PSQIA Privilege in Medical Error Reduction, 21 HEALTH LAW. 24 (2008) (Physicians "have historically been reluctant to report errors that occur in the course of healthcare service delivery, due to fear of liability, the risk of adverse actions against them by hospitals medical staffs, licensing boards, and other professional organizations, and the potential for injury to their professional reputations"); Paul J. Barringer, J.D., M.P.A. and Allen B. Kachalia, M.D., J.D., Error Reporting and Injury Compensation: Advancing Patient Safety Through a State Patient Safety Organization, 8 WYO. L. REV. 349, 352 (2008) ("fear of punitive sanctions or malpractice liability associated with reporting is likely to reduce . . . reporting . . . which in turn can lead to underreporting"); Kelly G. Dunberg, Just What the Doctor Ordered? How the Patient Safety and Quality Improvement Act May Cure Florida's Patients' Right to Know About Adverse Medical Incidents (Amendment 7), 64 Fl.A. L. REV. 513, 518 (2012) ("healthcare providers are less likely to engage in critical analysis of their fellow physicians during peer review because of a lack of confidentiality and privilege protections").

<sup>&</sup>lt;sup>57</sup> *Id. See also*, Dholokia, SAGES MANUAL, *supra* note 31 at 164 ("The conferences are designed to be nonpunitive and focus on the goal of improved patient care . . . [and] should facilitate open discussion of medical/surgical error, without . . . fear of punishment.").

 $<sup>^{58}</sup>$  The Nebraska Supreme Court summarized the protection from disclosure/admissibility provided to M&Ms thusly:

persuasive to a jury are the criticisms of the defendant physicians' friends, colleagues, and bosses. In fact, if admissible, the criticisms of reviewing physicians attending the M&M may obviate the typical legal requirement that the plaintiff hire an expert to criticize the standard of care rendered by the defendant physician.

#### C. Immunity, Confidentiality, and Privilege

Previously, each state's peer review privilege included one or more of the following protections: (1) individuals and entities participating in the peer review process are immune from liability and thus cannot be sued; (2) information obtained and documents reviewed during the peer review process remain confidential; and (3) documents generated by, and the conclusions reached during, the peer review process are privileged and thus inadmissible in any legal action. Typically, physicians are unaware there is a legal difference between the terms immunity and confidentiality and privilege. In speaking with doctors, they usually employ the terms interchangeably, so it's understandable that when physicians attempt to reassure each other that M&Ms are "confidential" what they really should say—if they want the M&M fully protected—is that everything said and done at the M&M is "privileged." Immunity protects someone from being held personally liable; confidentiality requires a participant not divulge what she heard, read, or was privy to; privilege protects material or statements from admission into evidence.

The HCQIA provides immunity from some legal actions. For example, a reviewing physician is immune from a defamation suit when it is based on something the reviewing physician allegedly said during peer review. However, the HCQIA confers neither confidentiality nor privilege for the peer review process, and specifically provides no protections of any kind in a medical malpractice suit.<sup>62</sup>

In states that protect as privileged whatever occurs in, is said during, or is generated by the peer review process, legislatures have recognized that disclosure, openness, and admissibility produce a chilling effect on both the peer review participants and process, which undermines the goals of peer review. A peer review privilege

<sup>&</sup>lt;sup>60</sup> Not privileged is any information, material, or evidence created independent of the peer review process (i.e., just because a document is reviewed or discussed during the peer review process does not necessarily equate to that document becoming privileged). For example, a patient's medical records—even though presented during an M&M—are not protected by the peer review privilege. *See, e.g.*, <u>Moretti v. Lowe</u>, 592 A.2d 855, 858 (R.I. 1991) ("information otherwise available from original sources even if the information was presented at a peer-review committee meeting" not protected by the peer review privilege); <u>Gauthreaux v. Frank</u>, 656 So.2d 634 (La. 1995).

<sup>&</sup>lt;sup>61</sup> See, e.g., Susan O. Scheutzow and Sylvia Lynn Gillis, Confidentiality and Privilege of Peer Review Information: More Imagined Than Real, 7 J.L. & HEALTH 169, 191 (1993) ("Confidentiality and privilege are two compatible, yet distinct, concepts. Privilege addresses a person's right not to have another testify as to certain matters as part of a judicial process, while confidentiality addresses the obligation to refrain from disclosing information to third parties other than as part of legal process.").

<sup>&</sup>lt;sup>62</sup> 42 U.S.C. § 11115 ("Nothing in this chapter shall be construed as affecting in any manner the rights and remedies afforded patients under any provision of Federal or State law to seek redress for any harm or injury suffered as a result of negligent treatment or care by any physician, health care practitioner, or health care entity").

protecting M&Ms encourages participants to be bone-scrapingly honest in an effort to determine what went wrong and how to prevent it in the future. 63 Without the privilege, there can be no full, open candor. 64

State privilege laws protecting peer review vary widely, with some states applying a broad privilege to protect virtually everything regarding peer review, 65 while others protect only materials generated by and discussions occurring during the actual peer review. 66 Most states appear to value more highly the peer review privilege as it applies to credentialing/hiring, as opposed to regarding what occurs at M&Ms. 67

Given the 'overwhelming public interest' in providing physicians with a confidential context in which to evaluate the effectiveness of life-saving techniques and procedures, the Court is compelled to recognize the self-critical analysis privilege in the context of morbidity and mortality conferences will apply in this case . . . Clearly the public good—saving lives and correcting life threatening errors by physicians resulting from preserving the confidentiality of morbidity and mortality conferences—outweighs the general preference for open discovery.

# Weekoty v. U.S., 30 F.Supp.2d 1343, 1347-1348 (D.N.M. 1998).

65 Texas physicians, for example, enjoy a fairly expansive privilege: "each proceeding or record of a medical peer review committee is confidential, and any communication made to a medical peer review committee is privileged . . . [t]he records and proceedings of a medical committee are confidential and are not subject to court subpoena." Tex. Occ. Code Ann. §160.007(a) and Tex. Health & Safety Code Ann. §161.032(a). In Massachusetts, a hospital "incident report" regarding a psychiatric patient jumping off the hospital roof was considered under the umbrella of peer review and thus privileged. Carr v. Howard, 689 N.E.2d 1304 (Mass. 1998). Illinois courts have interpreted the peer review privilege to include medical journal articles read and considered by the peer review committee because the articles would reveal the committee's decision-making process (which the peer review privilege protects). Anderson v. Rush-Copley Med. Ctr., Inc., 894 N.E.2d 827 (Ill. App. 2008).

<sup>&</sup>lt;sup>63</sup> "[T]he direct chilling effect on the institutional or individual self-analyst . . . operates to discourage the analyst from investigating thoroughly and frankly or even from investigating at all" and that is exactly what the privilege is designed to prevent. Note, *The Privilege of Self-Critical Analysis*, 96 HARV. L. REV. 1083, 1091-1092 (1983).

<sup>&</sup>lt;sup>64</sup> See, e.g., Robin Locke Nagele & Kathy L. Poppitt, *Is the Peer Review Privilege in Critical Condition?* Health Lawyers Organization website, <a href="http://www.healthlawyers.org/Events/Programs/Materials/">http://www.healthlawyers.org/Events/Programs/Materials/</a> Documents/AM13 /J nagele poppitt.pdf, last accessed October 4, 2014 ("The threat of litigation can prove a strong deterrent to candid discussion and evaluation of peers . . . If information generated during the peer review process can be discovered or introduced as evidence at trial, the effectiveness of peer review could be hampered because physicians will be reluctant to provide a complete and honest evaluation."). One federal district court summarized the importance of providing the protection of privilege to M&Ms thusly:

<sup>66</sup> Melissa Chiang, *Promoting Patient Safety: Creating a Workable Reporting System*, 18 YALE J. REG. 383, 388 (2001). For example, Ohio's peer review privilege does not extend to "unusual occurrence' reports. Ward v. Summa Health, 920 N.E.2d 421 (Ohio App. 2009). Nevada's peer review privilege does not protect "occurrence" reports. Columbia/HCA v. Eighth Judicial Dist. Nevada, 936 P.2d 844 (Nev. 1997).

<sup>67</sup> See Nagle, supra note 64.

#### IV. EROSION OF THE PEER REVIEW PRIVILEGE

Recognizing the value of peer review (both in credentialing/hiring and in M&Ms) as a vital tool in the prevention of medical errors, state legislatures enacted confidentiality and privilege protections for peer review to protect it from discovery and admissibility in subsequent legal actions, <sup>68</sup> chiefly medical malpractice cases; <sup>69</sup> in the absence of a federal peer review privilege, states supplied the needed protection. However, despite state statutes and evidentiary rules designed to protect peer review, state courts—and even some state legislatures—continue to weaken the peer review privilege. And, based on Congress intentionally declining to create a peer review privilege in the HCQIA, for over two decades federal courts have refused to recognize a federal peer review privilege, whether based on common law or other principles. <sup>70</sup> Of course, when adjudicating state medical malpractice claims that also involve a federal question, federal courts apply federal procedural rules and therefore decline to allow the state's peer review privilege to protect and exclude from admission into evidence statements and materials from an M&M.<sup>71</sup>

<sup>&</sup>lt;sup>68</sup> Without adequate legal protection for M&Ms, it was feared that effective peer review would simply cease. *See*, *e.g.*, *Dade County Medical Ass'n v. Hlis*, 372 So. 2d 117, 120 (Fla. App. 1979):

Confidentiality is essential to effective functioning of [M&M] meetings; and these meetings are essential to the continued improvement in the care and treatment of patients. Candid and conscientious evaluation of clinical practices is a *sine qua non* of adequate hospital care. To subject these discussions and deliberations to the discovery process, without a showing of exceptional necessity, would result in terminating such deliberations.

<sup>&</sup>lt;sup>69</sup> See Nagele, Is the Peer Review Privilege, supra note 64 at 2 ("Medical Malpractice and related cases in the state courts have been the impetus for most peer review confidentiality and privilege protections").

<sup>&</sup>lt;sup>70</sup> Congress "spoke loudly with its silence in not including a privilege against discovery of peer review material in the HCQIA." Alissa Marie Bassler, *Federal Law Should Keep Pace with States and Recognize a Medical Peer Review Privilege*, 39 IDAHO L. REV. 689, 704 (2003), quoting, <u>U.S. v. QHG of Ind., Inc.</u>, 1998 WL 1756728 at \*7 (N.D. Ind. 1998).

<sup>71</sup> Thus, plaintiffs are encouraged to create a means to have their state medical malpractice case heard in federal court, resulting in subsequent—perhaps collateral—federal governmental hospitals or healthcare clinics being added as defendants to invoke liability against the federal government and thus create a federal question (via a claim under the Emergency Medical Treatment and Active Labor Act, Federal Torts Claim Act, Americans with Disabilities Act, or perhaps even under the Sherman Act). Hancock v. Dodson, 958 F.2d 1367, 1373 (6th Cir. 1992) (holding that "where there are both federal and supplemental state law claims at issue, the federal common law of privileges controls as to the entire case"); see also, Schlegel v. Kaiser Foundation Health, 2008 WL 4570619 (E.D. Cal. 2008); Rodney H. Lawson et al., Credentialing and Peer Review of Health Care Providers: The Process and Protections, Am. LAW INST. ABA 7 (2012) ("plaintiffs will sometimes join medical malpractice claims with [federal] claims in order to obtain federal question jurisdiction . . . the majority position seems to be that state privilege law does not apply in a case with federal question jurisdiction and supplemental state claims"); See also Bassler, Federal Law Should Keep Pace, supra note 70 at 691 ("federal courts in these cases are not applying the [state's peer review] privilege to either the federal claims or the state claims . . . [thus] plaintiffs have an incentive to look for a federal question as a device for forcing disclosure in a federal court").

#### A. Federal Courts

The HCQIA specifically does not create a federal peer review privilege, <sup>72</sup> but federal courts were faced with the question whether to recognize a new federal peer review privilege, as physicians and medical institutions requested courts find an implicit privilege within the Act or based on federal common law. <sup>73</sup> The HCQIA does specifically exclude from the qualified immunity it created to protect reviewing physicians in peer review actions any information, documents, or materials sought from the peer review process by litigants in a federal civil rights action. <sup>74</sup> So, federal courts have ruled that in medical malpractice actions physicians cannot look to the HCQIA for privilege protection from disclosure, discover, and admissibility anything done, said, or generated during morbidity and mortality conferences. <sup>75</sup>

Historically, the Supreme Court of the United States has disfavored evidentiary privileges<sup>76</sup> and has "expressly declined to create a federal common law privilege against disclosure" of peer review materials in employment discrimination cases.<sup>77</sup> Although the Supreme Court has never ruled on the existence of a peer review privilege for morbidity and mortality conferences in the context of a medical malpractice action,<sup>78</sup> the federal circuit courts of appeal have noted that "a medical peer review privilege was not among the nine specific privileges recommended by the Advisory Committee in its proposed privileges rule"<sup>79</sup> and that federal common law never adopted a peer review privilege, and thus have ruled no such privilege exists.<sup>80</sup> Based on Supreme Court and circuit court of appeals precedent, nearly all federal districts courts have likewise declined to recognize a federal privilege for peer review.<sup>81</sup>

<sup>&</sup>lt;sup>72</sup> "'Congress spoke loudly with its silence' in not enacting a broad privilege against discovery of peer review materials." <u>KD Ex Rel. Dieffenbach</u>, 715 F.S.2d 587, 594-595 (D.Del. 2010), quoting, in part, <u>Teasdale v. Marin Gen. Hosp.</u>, 138 F.R.D. 691, 694 (N.D. Cal. 1991).

<sup>&</sup>lt;sup>73</sup> Federal Rule of Evidence 501.

<sup>&</sup>lt;sup>74</sup> See, e.g., <u>Johnson v. Spohn</u>, 334 Fed.Appx. 673, 684 (5<sup>th</sup> Cir. 2009) ("The HCQIA specifically excludes civil rights claims from immunity" under 42 U.S.C. § 11111(a)).

<sup>&</sup>lt;sup>75</sup> *Id*.

<sup>&</sup>lt;sup>76</sup> See, e.g., <u>U.S. v. Nixon</u>, 418 U.S. 683, 710 (1974) (evidentiary privileges "are not lightly created nor expansively construed, for they are in derogation of the search for truth").

<sup>&</sup>lt;sup>77</sup> Univ. of Pa. v. E.E.O.C., 493 U.S. 182, 189 (1990).

<sup>&</sup>lt;sup>78</sup> Francis v. U.S., 2011 WL 2224509 (S.D.N.Y. 2011).

<sup>&</sup>lt;sup>79</sup> See <u>Allen</u>, supra note 42; see also, <u>Jenkins v. DeKalb Co.</u>, 242 F.R.D. 652, 655 (N.D. Ga. 2007) (the "Supreme Court has never recognized a federal medical peer review privilege and there are no circuit court cases recognizing such a privilege").

<sup>&</sup>lt;sup>80</sup> See, e.g., Virmani v. Novant Health, Inc., 259 F.3d 284 (4th Cir. 2001); Memorial Hosp. McHenry Co. v. Shadur, 664 F.2d 1058 (7th Cir. 1981).

<sup>&</sup>lt;sup>81</sup> See, e.g., Nilavar v. Mercy Health, 210 F.R.D. 597, 609 (S.D. Ohio 2002) ("the Court finds that the federal common law has never adopted a physician peer review privilege, and that the great weight of authority . . . militate[s] against doing so in this case"); Leon v. County of San Diego, 202 F.R.D. 631 (S.D. Cal. 2001): Krolikowski v. Univ. Mass., 150 F.Supp.2d 246

#### B. State Courts

Unlike federal courts that decide whether a federal common law privilege for medical peer review exists or should be recognized under the facts of a particular case, state courts determine privilege based on state statutes regarding peer review. As all 50 states enacted some form of law or evidentiary rule to provide some protection for peer review, disparate case law exists in every state regarding a peer review privilege. Although state courts review the relevant peer review statute or evidentiary rule when deciding such cases, in general the courts narrowly interpret the privilege and thus order production, disclosure, and admissibility when the evidence does not fit squarely within the protections provided by statute. Some state courts appear to be extending the parameters of what constitutes waiver of the peer review privilege, resulting in the physician or hospital losing protection. Even in cases where there was no intent to waive the peer review privilege, courts have ruled there was a waiver and thus have denied privilege.

The focus of this essay is the peer review privilege as it applies to M&Ms and the goal of medical error reduction and, therefore, state court decisions regarding the interpretation of the peer review privilege as it applies to M&Ms are most persuasive. A prime example of the manner in which state courts are weakening the peer review privilege protecting M&Ms is the Supreme Court of Kentucky's decision in <u>Sisters of Charity Health System v. Raikes.</u> There, in three medical malpractice suits consolidated for purposes of answering the legal question of the extent of the privilege, the court held that Kentucky's peer review privilege did not protect peer review in

<sup>(</sup>D.Mass. 2001). However, a handful of federal districts have recognized a federal peer review privilege specific to the facts of that case. *See, e.g.*, <u>Francis, supra</u> note 78 ("The Court is persuaded that a privilege protecting peer review records from disclosure in medical or dental malpractice actions would promote the interests of health care practitioners, health care facilities and the public, by encouraging self-evaluation and improving the quality of care."); <u>Veith v. Portage County</u>, 2012 WL 4850197 (N.D. Ohio 2012) ("The public interest lies strongly in favor of recognizing a privilege for these materials in medical malpractice actions.").

<sup>&</sup>lt;sup>82</sup> *Id*.

<sup>&</sup>lt;sup>83</sup> *Id*.

<sup>84</sup> See, e.g., Pastore v. Samson, 900 A.2d 1067 (R.I. 2006) (court must strictly and narrowly construe peer review privilege statute); Claypool v. Mladineo, 724 So.2d 373 (Miss. 1998) (peer review privilege statute does not protect all materials and statements from peer review); Ward v. Summa Health Sys., 920 N.E.2d 421 (Ohio App. 2009) (peer review privilege does not extend to unusual medical occurrences); Pietro v. Marriott, 810 N.E.2d 217 (Ill. App. 2004) (peer review privilege does not extend to statements of, and documents generated by, nurses at assisted living facility); Valley Health v. Eighth Jud. Dist. Ct. Nevada, 252 P.3d 676 (Nev. 2011); Adams v. St. Francis Med. Ctr., 955 P.2d 1169 (Kan. 1998); Hosp. Auth. Valdosta v. Meeks, 678 S.E.2d 71 (Ga. 2009); DeSantis v. Simon, 209 P.3d 1069 (Colo. 2009); Phelps v. Physicians Ins. Co., 698 N.W.2d 643 (Wis. 2005); Fellows v. Moynihan, 285 P.3d 864 (Wash. 2012); Riverside Hosp. v. Johnson, 636 S.E.2d 416 (Va. 2006).

<sup>85</sup> See Mulholland, Waiver of the Peer Review Privilege, supra note 29.

<sup>86</sup> See, e.g., State ex rel. Brooks v. Zakaib, 588 S.E.2d 418 (W. Va. 2003).

<sup>87 984</sup> So.2d 464 (Ky. 1998).

medical malpractice cases.<sup>88</sup> In other words, the exact type of legal action—an accusation of negligent medical care resulting in harm or death—physicians fear the most and that has the most chilling effect on physician candor during M&Ms, is what Kentucky does not protect with its peer review privilege. In so ruling, instead of recognizing that the needs of the many outweigh the needs of the few, the court instead found that the needs of a few injured plaintiffs in proving a case for damages outweigh the need for Kentucky's medical patients to receive the best care possible while risking the smallest chance of suffering a preventable hospital injury or death: apparently, in enacting a peer review privilege statute, the Kentucky legislature's "intent and purpose was *not* to hinder an aggrieved patient's search for the truth in a medical malpractice suit against a negligent physician or hospital."<sup>89</sup>

# C. State Legislatures

Although all 50 states at one time created a peer review privilege, some state legislatures have since weakened the privilege or reduced the scope of protection. For example, the Ohio legislature revised its peer review statute in 2002, eliminating the privilege it originally created and substituting limited immunity instead. Washington's state legislature subsequently revised its original 1971 and 1986 peer review protection statutes, resulting in denial of the privilege when seeking to protect peer review materials and statements regarding a hospital's credentialing of, and granting of admitting privileges to, a physician in a case alleging medical negligence

<sup>88</sup> Id.

<sup>&</sup>lt;sup>89</sup> *Id.* at 469. The Supreme Court of Kentucky subsequently affirmed in two other cases that, with regards to M&Ms, Kentucky's peer review privilege does not apply to medical malpractice actions. McFall v. Peace, Inc., 15 S.W.3d 724 (Ky. 2000); Saleba v. Schrand, 300 S.W.3d 177 (Ky. 2009). Other states have similarly ruled. *See, e.g.*, Winters v. Lutheran Medical Ctr., 539 N.E.2d 715 (Ohio App. 1989) (a "hospital's surgical department's morbidity and mortality conference records may be discoverable and not privileged from disclosure"); Romero v. Cohen, 679 N.Y.S.2d 264 (N.Y. App. 1998) (physician's account of adverse medical incident communicated to M&M not protected by peer review privilege); Robinson v. Springfield Hosp., 2010 WL 503096 (D. Ver. 2010) (Vermont's peer review privilege only protects statements explaining adverse medical incident when made at a formal M&M, not when made to members of M&M in an office setting); Anderson v. Rush-Copley Med. Ctr., Inc., 894 N.E.2d 827 (Ill. App. 2008) (remedial changes to hospital policies and procedures subsequent to M&M investigating cause of adverse medical incident not protected by peer privilege and must be disclosed).

<sup>&</sup>lt;sup>90</sup> The previous version of Ohio's peer review statute provided that, "[p]roceedings and records of all review committees . . . shall be held in confidence and shall not be subject to discovery or introduction in evidence in any civil action against a health care professional . . . [and] no person . . . shall be permitted or required to testify in any civil action as to any evidence or other matters produced or presented during the [peer review] proceedings," but the current version provides only that, "[n]o individual who is a member of or works for or on behalf of a peer review committee of a health care entity shall be liable in damages to any person for any acts, omissions, decisions, or other conduct within the scope of the functions of the peer review committee." Ohio Stat. § 2305.251 (2012).

against the physician and hospital.<sup>91</sup> The Virginia legislature revised its peer review privilege statute to exempt from protection hospital incident reports because, although they are utilized in the peer review and/or M&M process, the reports also serve another purpose.<sup>92</sup>

In one instance, it was not the state legislature but state voters—spurred on by the plaintiffs bar—that simply eviscerated the peer review privilege regarding M&Ms. Originally, Florida possessed one of the strongest, most comprehensive peer review privileges. However, in 2004 Florida voters overwhelmingly approved a state constitutional amendment called "The Patient's Right to Know" that was presented as common sense legislation allowing patients access to any and all records regarding adverse medical incidents but in reality was a thinly veiled attempt by medical malpractice plaintiffs lawyers to gain access to admissions/inculpatory evidence to prove their cases. So shocking to physicians, hospitals, defense attorneys, and state legislators was this development, for a four-year court and legislative battle ensued to prevent, limit, or delay application; finally, in 2008, the amendment took effect and, according to Florida physicians, full and effective M&Ms simply ceased.

<sup>&</sup>lt;sup>91</sup> See, e.g., Fellows v. Moynihan, 285 P.3d 864, 872 (Wash. 2012) ("We hold that the peer review privilege and quality improvement privilege do not apply to records documenting a hospital's initial credentialing and privileging of a" physician).

<sup>&</sup>lt;sup>92</sup> Va. Code § 8.01-581.17(C) (2014); <u>Riverside Hosp., Inc. v. Johnson</u>, 636 S.E.2d 416 (Va. 2006).

<sup>&</sup>lt;sup>93</sup> Fla. Stat. § 395.0191, § 395.0193, § 395.0197, § 766.1015, § 459.016, § 400.118 (West 2007). See also, Holly v. Auld, 450 So.2d 217 (Fla. 1984); Cruger v. Love, 599 So.2d 111 (Fla. 1992); Brown v. Graham, 2005 WL 900722 (Fla. Cir. Ct. 2005) ("Florida courts have consistently upheld the privileges, even in circumstances beyond the literal reach of the statutory language.").

 $<sup>^{94}</sup>$  Art. X,  $\S$  25(a), Fla. Const. The constitutional amendment is commonly referred to as "Amendment 7."

<sup>&</sup>lt;sup>95</sup> See, e.g., James C. Sawran & Robert C. Weill, Amendment 7: Will the Patient's Right to Know Come at Too High A Price?, 24 No. 2 TRIAL ADVOC. Q. 7 (2005).

<sup>&</sup>lt;sup>96</sup> Melissa Morgan Hawkins, *Amendments 7 and 8 Update: Legislation Enabling the Patients' Right to Know Act and Three Strike Rule*, 25 No. 2 TRIAL ADVOC. Q. 7 (2006).

<sup>97</sup> Florida Hospital Waterman v. Buster, 984 So.2d 478 (Fla. 2008).

<sup>&</sup>lt;sup>98</sup> No physician or hospital administrator would go on the record admitting they are no longer conducting candid M&Ms because Florida and federal law continue to require peer review activity, but many informed me privately that they simply "go through the motions" because they know if they admit medical mistakes during an M&M then their liability in a subsequent medical malpractice lawsuit is assured. *See also*, Laura V. Yeager, *Amendment 7: Medical Tradition v. the Will of the People: Has Florida's Peer Review Privilege Vanished?*, 13 MICH. St. U. J. MED. & L. 123, 148 (2009) ("since the passage of Amendment 7 peer review [in Florida] has come to a screeching halt"); Sawran, *Amendment 7, supra* note 95 at 7 ("with the loss of confidentiality will come a decrease in the quality of care to patients . . . health care providers will now think twice about reporting incidents since they know such information will not be protected . . . health care facilities may be unable to identify trends or track results . . . the health care industry [now] fears that a lower quality peer review process may decrease the quality of physician services").

Thus, no peer review privilege protecting M&Ms exists in federal court, and the patchwork of state peer review privileges as a whole does not provide sufficient protection for M&Ms.<sup>99</sup> Physicians simply will not candidly participate in peer review if there are no privilege protections; and the prevalence of medical errors killing America's patients can only be explained by physicians' refusal to identify, investigate, and discuss medical errors due to their fear that such disclosures will be used against them in a medical malpractice case.<sup>100</sup> Something had to be done, and believe it or not Congress did it. Unfortunately, physicians, hospitals and most importantly the courts are not using it.

## V. THE PATIENT SAFETY AND QUALITY IMPROVEMENT ACT

Immediately after publication of the IOM report detailing the extent of preventable hospital deaths caused by medical error, members of Congress began working on bipartisan legislation to address the problem. Specifically, Congress desired to incorporate many of the IOM's recommendations regarding disclosure, investigation, and information-sharing of medical errors. The result was the PSQIA, passed unanimously in the Senate and with only three dissenting votes in the House. The administrative rule implementing the PSQIA became effective in 2009, so, basically, the PSQIA has been around for over seven years; however, as yet no federal or state court has held that a physician's statements, documents, or materials produced during an M&M is privileged under the PSQIA.

#### A. How the PSQIA Should Work

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<sup>&</sup>lt;sup>99</sup> Congress believed that "State peer review protections are inadequate to allow the sharing of information to promote patient safety." S. Rep. No. 109-544, at 3 (2005). *See also*, Levy, *Patient Safety*, *supra* note 9 at 403 ("state protections are not able to promote a wide-scale system of disclosure and analysis of medical errors").

<sup>&</sup>lt;sup>100</sup> See IOM, To ERR IS HUMAN, supra note 16 at 109-112.

<sup>&</sup>lt;sup>101</sup> The IOM report "pinpointed among underlying issues the tendency to place undue focus on individual blame, while ignoring the reality of broader systematic failure as a core issue affecting patient safety." Key, *The Role of the PSQIA*, supra note 59; Chiang, *Promoting Patient Safety*, *supra* note 66 at 4.

<sup>102</sup> The PSQIA was enacted and signed into law in 2005, less than a year after Floridians voted to allow unfettered access to M&M records by approving Amendment 7. Although members of Congress began working on the PSQIA years prior to Florida's Amendment 7 being voted in, it certainly does not seem coincidental that the PSQIA—which provides the privilege protection for M&Ms that Amendment 7 eviscerated—came so quickly on the heels of Amendment 7.

<sup>&</sup>lt;sup>103</sup> Final Vote Results for Roll Call 434, at <a href="http://clerk.house.gov/evs/2005/roll434.xml">http://clerk.house.gov/evs/2005/roll434.xml</a> (last accessed Sept. 30, 2014).

<sup>&</sup>lt;sup>104</sup> Patient Safety and Quality Improvement, 73 Fed. Reg. 70031, 70732 (Nov. 21, 2008) (codified at 42 C.F.R. Part 3).

<sup>&</sup>lt;sup>105</sup> See infra note 115.

Nowhere in the PSQIA does the term "peer review privilege," or even the term "peer review," appear. 106 Instead, the PSQIA calls for establishing "Patient Safety Organizations" ("PSOs") intended to serve as the umbrella for conducting M&Ms. The PSQIA contemplates that a company or group, or a hospital or other medical institution, will create a separate PSO entity to which medical error information is transmitted. The goal of the PSO is to collect and analyze medical error information so that corrective actions and changes to policies and procedures can be enacted to remediated errors. Local PSOs then provide their error data to the larger Network of Patient Safety Databases that analyzes error trends both regionally and nationally and recommends strategies to prevent future errors. Under the PSQIA, the medical error information is termed "Patient Safety Work Product" ("PSWP") and prior to being sent to a PSO this PSWP is communicated/transmitted by the involved physicians to the individual hospital's Patient Safety Evaluation System ("PSES"). In essence, the PSES becomes the M&M. The PSES does many things—generates, collects, archives, and maintains PSWP-but also serves as the forum where everything that used to occur at an M&M should now take place.

For example, the <u>Florida Hospital Association</u> and the <u>South Florida Hospital & Healthcare Association</u> partnered to create the Patient Safety Organization of Florida ("PSOF"). <sup>107</sup> If they so choose, Florida hospitals may join the PSOF—or any other

106 However, Congress' purpose in creating the PSQIA was clear, according to the House of Representatives report:

The IOM report offered several recommendations to improve patient safety and reduce medical error, including that Congress pass legislation to extend peer review protections to data related to patient safety and quality improvement that are developed and analyzed by health care organizations for internal use or shared with others solely for the purpose of improving safety and quality . . . This bill's intended purpose is to encourage the reporting and analysis of medical errors and health care systems by providing peer review protection of information reported to patient safety organizations for the purposes of quality improvement and patient safety. These protections will facilitate an environment in which health care providers are able to discuss errors openly and learn from them. The protections apply to certain categories of documents and communications termed "patient safety work product" that are developed in connection with newly created patient safety organizations. This patient safety work product is considered privileged and, therefore, cannot be subject to disclosure.

H.R. Rep. No. 109–197 (2005) (emphasis added). See also, Dieffenbach, supra note 72 at 595 (the PSQIA "announces a more general approval of the medical peer review process and more sweeping evidentiary protections for materials used therein"). It is possible Congress intentionally declined to employ the term "peer review" in an effort to protect an even broader category of information qualifying for privilege than typically encompassed by traditional peer review. See, e.g., Levy, Patient Safety, supra note 9 at 414.

<sup>107</sup> Patient Safety Organization of Florida website, <a href="http://www.psoflorida.org/about.html">http://www.psoflorida.org/about.html</a>, last accessed September 30, 2014. It is important to note that the PSQIA commercialized M&Ms in a manner not previously seen; traditionally hospitals conducted M&Ms, but the PSQIA requires a separate PSO entity be created as a clearinghouse for the hospital's PSWP and PSES analysis (i.e., no privilege protects PSWP or PSES analysis if the hospital does not contract with a PSO with the intention of transmitting PSWP to the PSO). Most PSOs charge a per-bed fee to hospitals to serve as the hospital's PSO, which turns the PSO system into a potentially profitable business. <a href="https://www.arkansas.business.com/print/article/33574">See, e.g.</a>, Mark Friedman, "Hospital Safety System Slow to Take Off in Arkansas," Arkansas Business, Sept. 12, 2011, at <a href="http://www.arkansas.business.com/print/article/33574">http://www.arkansas.business.com/print/article/33574</a> ("The price to use [PSO] American Data Network's system

PSO in Florida—and employ it as their PSO.<sup>108</sup> The Mayo Clinic of Jacksonville may decide it wants to join the PSOF and does so. The Mayo Clinic establishes its own PSES at its facility. A medical error occurs at Mayo and the patient dies. The involved physicians meet with other physicians within the context of Mayo's PSES and discuss the error—just as they would at an M&M—and determine the cause of the error. The physicians make full, open, candid statements about the care they rendered and admit their mistakes. The PSWP records and PSES analysis are transmitted to the PSOF. The PSOF analyzes the PSWP information, and also sends it on to the Network of Patient Safety Database. From the information, investigation, and analysis provided through its PSES, Mayo is able to determine a system failure that led to the errors made by the physicians; Mayo implements a new policy to ensure the mistake does not occur again. The PSOF identifies other hospitals that it serves as incurring the same medical error that Mayo encountered; the PSOF analyzes the PSWP of all the hospitals it serves and makes a recommendation for remedial action at all its hospitals.<sup>109</sup> The Network of Patient Safety Database analyzes the PSWP and data sent from the PSOF and identifies a regional or national trend of the same error May encountered; the Network of Patient Safety database makes a regional or national recommendation to all the hospitals it serves. The specific medical error that resulted in a death at the Mayo Clinic in Jacksonville, Florida is never repeated again at any hospital in the United States. 110 This is exactly how Congress envisioned the PSOIA working.

To encourage hospitals and physicians to participate in this system, the PSQIA establishes a broad privilege protecting PSWP. A patient who becomes a medical malpractice plaintiff alleging negligent care certainly may discover and admit into evidence her own medical records, <sup>111</sup> but if the alleged negligent care was discussed

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ranges from \$25,000 to less than \$30,000 for a hospital with about 200 beds."). This new financial aspect of peer review may be considered one of the drawbacks of the PSQIA, and one reason not all hospitals have contracted with a PSO.

<sup>&</sup>lt;sup>108</sup> There is no requirement mandating hospitals create or join a PSO.

<sup>&</sup>lt;sup>109</sup> The American Medical Association encourages physicians to join a PSO, touting that "PSO participation enables physicians to learn from the experiences of others, participate in redesigning systems that enhance care delivery, and develop resources and processes needed to enhance safer care, mitigate patient harm and increase care efficiency." AMA, "The Physician's Guide to Patient Safety Organizations," 3 (2009). *See also*, Gosfield, *Patient Safety, supra* note 11 ("Here are five steps physicians should take to protect themselves while also working to improve the quality of care they provide . . . 1. Develop a [PSES] . . . 2. Identify and contract with a PSO").

<sup>110</sup> Although no court has yet ruled on the issue, in all likelihood Florida's Amendment 7 is trumped by the PSQIA—"[n]otwithstanding any other provision of Federal, State, or local law . . . patient safety work product shall be privileged," 42 U.S.C.A. § 299b-22—so even where a state's voters have effectively abolished the peer review privilege, so long as the requirements of the PSQIA are met, what under the state scheme is discoverable and admissible nonetheless becomes privileged and inadmissible under the PSQIA. This is the exact opposite effect of what plaintiffs lawyers previously accomplished by adding a federal claim to defeat a state's peer review privilege. See supra note 71.

 $<sup>^{111}\,</sup>$  42 U.S.C. § 299b-21 (7)(B)(ii) (2010). The PSQIA also exempts from privilege discharge records and medical bills, as these records are maintained for a purpose other than patient safety, even though they ultimately may be transmitted through a PSES or to a PSO. Because patients who become medical malpractice plaintiffs may still discover and seek admissibility of original

and analyzed within the PSES with the goal of improving future patient care and safety, nothing regarding that discussion or analysis is discoverable or admissible, and no one in attendance at any PSES meeting (i.e., M&M) may divulge what occurred or was said. As long as the PSWP is collected or created for the purpose of reporting it to a PSO or simply "constitute the deliberations or analysis of" 112 a PSES, it is privileged, confidential, not subject to discovery, and protected from any subpoena. 113

So, the PSQIA provides physicians that level of protection they have long sought.<sup>114</sup> If their hospital is a member of a PSO and establishes a PSES, physicians may conduct candid M&Ms under the blanket of a PSES to properly investigate, discuss, analyze, and remediate medical errors, and even fully admit mistakes during the M&M without fear the admission will later be used to prove negligence/liability. But, seven years after its effective date, the PSQIA system isn't working—or, isn't working fully yet—at least in the context of published case opinions.

# B. Why the PSQIA Hasn't Worked Yet

If the PSQIA protects M&Ms in a comprehensive way no state peer review privilege does, then why is there not at least one reported federal or state case holding that PSWP from an M&M (or, to use the PSQIA term, a PSES) is privileged under the PSQIA and thus inadmissible against a physician accused of medical negligence? Dozens of reported cases involve the question whether the PSQIA operates to protect

medical records to prove their claim, the PSQIA does not "alter any existing rights or remedies available to injured patients." 151 Cong. Rec. S8744, 555 (2005).

<sup>&</sup>lt;sup>112</sup> 42 U.S.C. § 299b-21 (7)(A)(ii) (2006). It is vital to note that PSWP need not actually be transmitted to a PSO for privilege to attach. *See*, 73 Fed. Reg. 70741; however, some courts have erroneously held that PSWP was not privileged because it was not transmitted to a PSO. *See*, *e.g.*, <u>Lee Medical, Inc. v. Beecher</u>, 312 S.W.3d 515, 535 (Tenn. 2010) (stating that the "PSQIA creates a tightly crafted federal privilege for 'patient safety work product' actually reported to a" PSO).

<sup>113 42</sup> U.S.C. § 299b-22 (a)(2). The PSQIA also addresses the issue of waiver of the privilege (see supra Part III Sec. B); under the PSQIA, sharing of PSWP with PSOs does not result in waiver. Similarly, under the PSQIA, state medical malpractice plaintiffs no longer need simply file a federal claim to pierce any state peer review privilege. However, there are a handful of limitations on the privilege. For example, in criminal proceedings PSWP may be disclosed if it contains evidence of a criminal act and such information cannot be reasonably obtained through other means. Id. § 299b-22 (c)(2)(G).

<sup>114</sup> Levy, *Patient Safety*, *supra* note 9 at 408 ("Congress created this system so that safety information could be processed without fear of discovery."). The PSQIA also provides another protection for physicians: if a physician alleges her employer retaliated against her because she revealed a medical error, the physician may successfully request PSWP be disclosed to prove her case of retaliation. 42 U.S.C. § 299b-22 (c)(1)(B) (2010). Clearly, Congress desired to do all it could to ensure medical errors are reported. Additionally, the PSQIA may provide a higher level of protection in peer review credentialing/hiring actions than the HCQIA does. The HCQIA merely grants qualified immunity for the peer review process; although the PSQIA does not specifically address credentialing/hiring, it does define "patient safety activities" to include "the utilization of qualified staff," which could be read as encompassing credentialing/hiring if PSWP regarding such is created and transmitted to a PSO. Levy, *Patient Safety*, *supra* note 9 at 413.

as privileged certain peer review documents or statements, but not one court has ruled that—in the case of a medical malpractice action against a physician or hospital—it does. 115

Some of this can be explained by the supposition that, although the effective date of the PSQIA was 2009, it took hospitals and medical institutions time to set up a PSES, create or join a PSO, incur a medical error involving harm or death, conduct an M&M regarding that medical error, have the patient commence a medical malpractice action and request documents or information from the M&M, and then for a court to hear and decide upon the legal question resulting in a published decision. However, courts have ruled against the PSQIA privilege in cases, <sup>116</sup> so, obviously there has been sufficient time for cases to progress to the stage where a decision has been reported and published.

The most glaring decision denying the PSQIA privilege came from the Supreme Court of Kentucky on August 21, 2014. In <u>Tibbs v. Bunnell</u>, <sup>117</sup> the 4-2 majority held that, in a medical malpractice action against a physician and hospital, the PSQIA did not protect as privileged a PSES record regarding plaintiff's surgical death that was transmitted to the hospital's PSO. <sup>118</sup> The plaintiff's interrogatory at issue posed "whether any investigation, including but not limited to peer review and/or incident reports, has been conducted upon the medical treatment, surgery or care rendered to the Plaintiff," and the plaintiff's request for production asked for "any and all documents generated by any investigation, including but not limited to peer review and/or incident reports of the events." <sup>119</sup> The lengthy dissent explained that this information and material was exactly what the PSQIA was enacted to protect, <sup>120</sup> but the majority concluded that the PSQIA created a narrow privilege and that, because Kentucky law mandated that hospitals establish and maintain administrative reports—

<sup>&</sup>lt;sup>115</sup> One state appellate court held that, in a case where a state agency sought records from a pharmacy regarding possible medication errors by three of its pharmacists, the PSQIA protected as privileged medication error reports made to an internal reporting system that were then transmitted to the pharmacy's PSO. <u>Dept. Financial & Professional Reg. v. Walgreen, Co.</u>, 970 N.E.2d 552 (Ill. App. 2012). As yet, this is the only reported case wherein a court has upheld the privilege created in the PSOIA.

<sup>116</sup> See, e.g., Venosh v. Henzes, 2013 WL 3725157 at \*12 (Pa. Com. Pl. 2013) (materials not privileged under PSQIA because not reported to PSO); Schlegel v. Kaiser Foundation Health Plan, 2008 WL 4570619 at \*2-3 (E.D. Cal. 2008) (the PSQIA does not create a broad federal peer review privilege but rather "carves out a narrow peer review privilege"); Gulley v. LaPaglia, 2014 WL 223646 (E.D. Tenn. 2014) (declining to rule the PSQIA privilege protects the requested information and documents); Francis, supra note 78 at \*6 ("The quality assurance review documents at issue in this [FTCA] action are not protected under the PSQIA, since they were not provided to a PSO."); Lee Memorial Health Sys. v. Guillermo, 2011 WL 5826672 (M.D. Fla. 2011) (declining to take jurisdiction and decide whether the PSQIA privilege preempts Florida's Amendment 7 requiring M&M disclosure); Lee Memorial Health Sys. v. Ranieri, 2012 WL 1565366 (M.D. Fla. 2012) (declining to take jurisdiction and decide whether the PSQIA privilege pre-empts Florida's Amendment 7 requiring M&M disclosure).

<sup>117</sup> Tibbs v. Bunnell, 2014 WL 4115912 (Ky. 2014).

<sup>&</sup>lt;sup>118</sup> *Id*.

<sup>&</sup>lt;sup>119</sup> *Id.* at \*1.

<sup>120</sup> Id. at \*11-16.

including incident reports—the PSES investigation (i.e., M&M) of the surgical death and resulting report were not privileged under the PSQIA. <sup>121</sup> Under this logic, because Kentucky law requires collection and maintenance of most of the records and reports the PSQIA seeks to protect, the PSQIA effectively protects very little PSWP in Kentucky, subverting the goal of the PSQIA.

So, the courts are not helping, not employing the PSQIA privilege to protect M&M statements, information, and documents. But physicians and hospitals are not doing all they can to avail themselves of the PSQIA privilege. Currently, there are only 81 PSOs in the entire country, located in 30 states; there are only two PSOs west of Texas. <sup>122</sup> Nearly 50 companies that originally filed applications for PSO approval have since abandoned their PSO listing. <sup>123</sup> As no federal law requires hospitals contract with a PSO, many simply do not. <sup>124</sup>

Perhaps there are scores of PSQIA cases working their way through the courts; or, medical malpractice plaintiffs lawyers simply are no longer requesting statements, information, and documents from M&Ms because they know the hospital has a PSES and is a member of a PSO... but I doubt it. Likely, no court desires to take the plunge and be the first in the nation to hold that the PSQIA protects M&M materials and statements in a medical malpractice case against a physician or hospital. I hope, however, that by the time this essay is published, some court has so ruled.

#### C. How to Reduce Injuries and Deaths

The needs of the many outweigh the needs of the few. When faced with the question whether to rule that the PSQIA privilege protects M&M materials and statements from disclosure and admissibility, a court must hold that it does. The PSQIA privilege—what traditionally was termed the peer review privilege—should be valued at least as much as, say, the spousal communications privilege. If the Supreme Court has found that the spousal communications privilege is to be "regarded as so essential to the preservation of the marriage relationship as to outweigh the disadvantages to the administration of justice," then shouldn't saving lives by reducing preventable hospital deaths similarly outweigh the disadvantage of depriving medical malpractice plaintiffs of one—or a few—items of additional evidence to prove their cases?

<sup>&</sup>lt;sup>121</sup> *Id.* at \*6. The court cited as authority its previous decision in <u>Saleba</u>, *supra* note 89 (Kentucky's peer review privilege does not extend to medical malpractice cases), which predates the effective date of the PSQIA. The Tibbs majority relied on the exception to privilege in the PSQIA for "a provider's recording-keeping obligation" under State law. 42 U.S.C. § 299b-21 (7)(B)(iii)(III) (2006).

<sup>122</sup> Some have no clients, and simply have been approved by the DHHS to serve as a PSO.

<sup>&</sup>lt;sup>123</sup> Alan G Williams, *Congress Saved Peer Review: Who Knew?*, 149 JAMA Surgery 317, 318 (2012).

<sup>&</sup>lt;sup>124</sup> However, if a healthcare insurance company wants to have its products/services included in the state or federal healthcare insurance exchanges under the Affordable Care Act, Pub. L. 111-148 (2010), its products/services may only be used at/with hospitals that have a contract with a PSO.

<sup>125</sup> Wolfle v. U.S., 54 S. Ct. 279 (1934).

Courts must interpret the PSQIA as Congress intended and find a broad privilege protecting statements physicians make and materials hospitals create that further the goal of improving patient safety. Instead of employing the majority's approach in Kentucky's <u>Tibbs</u> case, courts must consider the privilege as the dissent did, with the goal of protecting M&M statements and materials, if possible, because doing so results in lives saved and injuries averted. Odds are, medical malpractice plaintiffs seeking to discover M&M statements and materials would far prefer that the same alleged error they argue harmed/killed them was corrected prior to their hospital stay; the best way to do that is to protect M&Ms with the privilege the PSQIA provides.

#### VI. CONCLUSION

The medical community has long known that the peer review process—specifically M&Ms—works best to improve patient care and reduce preventable injuries and death. <sup>126</sup> The legal community began assisting the medical community in their efforts when the law began recognizing a peer review privilege. Because federal courts declined to provide privilege protections for M&Ms, state courts did not adequately protect M&Ms via privilege, and state legislatures did not explicitly step in to correct holes in state privileges, Congress created the ultimate remedy for the problem when it enacted the PSQIA. The PSQIA privilege is the best available tool to provide physicians the protection they need to embark on their quest to reduce preventable medical errors.

Now that Congress has done its job, state and federal courts must do their jobs and boldly uphold the peer review privilege established in the PSQIA when the facts allow for a legal interpretation that the privilege may apply. And the medical community must do its job by: (1) creating more than 81 PSOs in 30 states; (2) ensuring every hospital contracts with a PSO; and, (3) fully utilizing M&Ms for candid investigation, discussion, analysis, and remediation of medical errors. If the courts and the medical community now do their jobs, medical errors will decrease: every year, tens of thousands of injuries will be prevented, tens of thousands of lives will be saved.

<sup>&</sup>lt;sup>126</sup> Abraham <u>Lichtmacher</u>, *Quality Assessment Tools: ACOG Voluntary Review of Quality of Care Program, Peer Review Reporting System*, 35 <u>Obstet Gynecol Clin North Am.</u> 147, 147-62 (2008).