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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)

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NOTE

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)

*Kelly G. Dunberg**

Abstract

This Note addresses the impact of Florida's Patients' Right to Know About Adverse Medical Incidents (commonly known as Amendment 7) on the peer review process and the quality of healthcare in Florida. Enacted in 2004 as an amendment to the Florida Constitution, Amendment 7 provides citizens access to records and reports of past adverse medical incidents involving doctors, hospitals, and healthcare providers. Critics of Amendment 7 argue that peer review privilege protections are necessary to maintain high-quality healthcare in Florida, pointing to the need to encourage candid and vigorous evaluations by physicians of their colleagues. In contrast, Amendment 7 supporters argue that it provides Florida patients with valuable information to aid in their choice of physicians.

While it is still too early to determine Amendment 7's impact on the peer review system, and thus on the quality of healthcare systems statewide, any possible solution to counteract Amendment 7 would be beneficial to Florida patients. Under Amendment 7, healthcare providers likely will not critically analyze fellow physicians during peer review because of a lack of confidentiality and privilege protections. Peer review will no longer feature the full disclosure by specialized healthcare practitioners that is necessary for its maximum effectiveness. As a result, patients likely will suffer a decline in the quality of healthcare.

Congress enacted the Patient Safety and Quality Improvement Act (PSQIA) in response to a startling finding in 1999 by the Institute of Medicine that between 44,000 and 98,000 patients die annually in American hospitals due to medical errors. The PSQIA creates patient safety organizations (PSO) and the Network of Patient Safety Databases (NPSD), which enable healthcare providers to share reports of adverse medical incidents with the assurance of confidentiality and privilege protections. Joining a PSO may alleviate providers' fear of participation in

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the peer review process.

Through the PSQIA, Florida healthcare providers will not only improve the quality of healthcare by protecting peer review, but also by analyzing and aggregating PSO-submitted information. PSOs foster an environment in which providers can learn from their mistakes and the mistakes of others. Through the sharing of patient safety event information within PSOs and the NSPD, Florida healthcare providers will be able to counteract Amendment 7 and guarantee the exchange of medical information and data. Therefore, while the interplay between Florida’s Amendment 7 and Congress’s PSQIA has yet to be determined, the impact of the PSQIA is that adverse medical incidents will likely be reduced overall, despite the interference of Amendment 7 with full and frank peer review in Florida.

INTRODUCTION..... 515

I. THE PEER REVIEW PROCESS 519

II. AMENDMENT 7: PATIENTS’ RIGHT TO KNOW ABOUT ADVERSE MEDICAL INCIDENTS 521

 A. *Florida’s Peer Review Protections Before Amendment 7* 521

 B. *The Enactment of Amendment 7* 523

 C. *The Legislative and Judicial Responses to Amendment 7* 526

 D. *The Current Landscape Under Amendment 7* 530

III. THE PATIENT SAFETY AND QUALITY IMPROVEMENT ACT (PSQIA)..... 532

 A. *History and Enactment* 532

 B. *The Creation of Patient Safety Organizations and the Network of Patient Safety Databases* 534

 C. *Patient Safety Work Product and Patient Safety Evaluation System: Privilege and Confidentiality Protections*..... 537

 D. *The Judicial Response to and the Future of the PSQIA* 539

IV. WILL THE PSQIA BE THE CURE TO AMENDMENT 7? 541

 A. *Amendment 7 and the PSQIA* 541

 B. *How to Become a Patient Safety Organization in Florida*..... 542

 C. *Why Florida Healthcare Providers Should Join Patient Safety Organizations* 543

CONCLUSION.....546

INTRODUCTION

In 1999, the Institute of Medicine's *To Err Is Human* report (IOM Report) found that between 44,000 and 98,000 patients die annually in American hospitals due to medical errors, an estimate that caused medical error to exceed the then-eighth leading cause of death—suicide.¹ The startling findings of the prevalence of medical errors thrust the national healthcare system into the spotlight,² with the staggering estimates also exceeding the number of deaths caused by vehicle accidents and breast cancer.³ Yet the IOM Report asserted that these estimates were perhaps just the “tip of the iceberg.”⁴ It additionally stated that adverse medical incidents result in at least \$17 billion in total national costs.⁵ Implementing the IOM Report's recommendations,⁶ the Patient Safety and Quality Improvement Act (PSQIA) was enacted on July 29, 2005,⁷ to assist and encourage healthcare providers to develop and participate in voluntary

1. INST. OF MED., *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* 26 (Linda T. Kohn et al. eds., 2000) [hereinafter *TO ERR IS HUMAN*] (citing Donna L. Hoyert et al., *Deaths: Final Data for 1997*, NAT'L VITAL STAT. REP., June 30, 1999, at 1, 27, available at http://www.cdc.gov/nchs/data/nvsr/nvsr47/nvs47_19.pdf). The report defines “medical error” as the incorrect administration of care or the occurrence of an unplanned result. *Id.* at 4. Injury caused by healthcare providers—known as iatrogenesis—is considered the opposite of quality care. BARRY R. FURROW ET AL., *LIABILITY AND QUALITY ISSUES IN HEALTH CARE* 41 (6th ed. 2008).

2. See *TO ERR IS HUMAN*, *supra* note 1, at 4.

3. *Id.* at 26 (citing Joyce A. Martin et al., *Births and Deaths: Preliminary Data for 1998*, NAT'L VITAL STAT. REP., Oct. 5, 1999, at 1, 6, available at http://www.cdc.gov/nchs/data/nvsr/nvsr47/nvs47_25.pdf). While the current mortality by medical error rates vary, reports indicate that they have increased since 1999. See *infra* notes 259–64 and accompanying text. For instance, one report found that medical error deaths in 2007 were the fifth leading cause of death in the U.S., reaching 98,000 deaths annually. Press Release, Millennium Research Group, *Medical Error Is the Fifth-Leading Cause of Death in the U.S.* (Sept. 22, 2006) (citing MILLENNIUM RESEARCH GRP., *US MARKETS FOR ACUTE CARE CLINICAL INFORMATION SYSTEMS 2006* (2006), available at <http://mrg.net/News-and-Events/Press-Releases/MEDICAL-ERROR-IS-THE-FIFTH-LEADING-CAUSE-OF-DEATH.aspx>). Meanwhile, for comparison, the mortality rates for vehicle accidents and breast cancer have remained relatively stable. Jiaquan Xu et al., *Deaths: Final Data for 2007*, NAT'L VITAL STAT. REP., May 20, 2010, at 1, 32–35 tbl.10, available at http://www.cdc.gov/NCHS/data/nvsr/nvsr58/nvsr58_19.pdf.

4. *TO ERR IS HUMAN*, *supra* note 1, at 87 (internal quotation marks omitted).

5. *Id.* at 1–2 (citing Eric J. Thomas et al., *Costs of Medical Injuries in Utah and Colorado*, 36 *INQUIRY* 255, 260 (1999)). These total national costs include “lost income, lost household production, disability and health care costs.” *Id.* at 1 (citing Thomas et al., *supra*, at 355–64).

6. INST. OF MED., *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM—SUMMARY* 3–4 (1999) [hereinafter *TO ERR IS HUMAN SUMMARY*], <http://www.iom.edu/~media/Files/Report%20Files/1999/To-Err-is-Human/To%20Err%20is%20Human%201999%20report%20brief.pdf>.

7. Pub. L. No. 109-41 (2005) (codified at 42 U.S.C. §§ 299b-21 to -26); see also Charles M. Key, *The Role of PSQIA Privilege in Medical Error Reduction*, *HEALTH L.*, Oct. 2008, at 24.

reporting systems concerning patient safety events.⁸ The IOM Report stated that preventable medical errors from healthcare providers' systematic flaws could be determined, analyzed, and addressed through the creation of a network of shared patient safety data and information.⁹ Thus, the PSQIA enables healthcare providers to share their records and reports of medical errors and "near misses" to other providers by joining a patient safety organization (PSO).¹⁰ The PSQIA ensures that information shared within PSOs is privileged and confidential¹¹ to encourage providers' participation without the fear of liability.¹² The PSQIA took effect on January 19, 2009.¹³ Now there are approximately eighty listed PSOs across the nation¹⁴ sharing information to address the prevalence of medical errors and to improve the quality of healthcare.

More than ten years after the publication of the IOM Report, the healthcare system was again brought into the national spotlight in 2010, when Congress passed new healthcare reform measures.¹⁵ Even after that reform, healthcare continues to be hotly debated nationally.¹⁶ One of the concerns about the reform has been its potential to decrease the quality of healthcare nationwide.¹⁷ However, unbeknownst to many Floridians, the 2004 enactment of Florida's Patients' Right to Know About Adverse Medical Incidents,¹⁸ commonly referred to as Amendment 7,¹⁹ has already

8. See Patient Safety and Quality Improvement, 73 Fed. Reg. 70,732, 70,732 (Nov. 21, 2008) (codified at 42 C.F.R. pt. 3 (2009)).

9. TO ERR IS HUMAN SUMMARY, *supra* note 6, at 3.

10. See *infra* Section IV.B.

11. 42 U.S.C. § 299b-22 (2006); 42 C.F.R. §§ 3.204, 3.206 (2010).

12. See *infra* note 133 and accompanying text (describing physicians' fear of liability as the primary reason for not engaging in the open discussion of patient safety events).

13. Patient Safety and Quality Improvement, 73 Fed. Reg. at 70,732.

14. *Geographic Directory of Listed Patient Safety Organizations*, AGENCY FOR HEALTHCARE RES. & QUALITY, <http://www.pso.ahrq.gov/listing/geolist.htm> (last visited Jan. 29, 2012) [hereinafter *Geographic Directory*].

15. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010); see also Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010).

16. See, e.g., Bill Mears, *Federal Judge Tosses out Sweeping Health Care Reform Act*, CNN POLITICS (Feb. 1, 2011), <http://www.cnn.com/2011/POLITICS/01/31/health.care.unconstitutional/index.html?iref=allsearch>; see also, e.g., Elizabeth Sheyn, *Toward a Specific Intent Requirement in White Collar Crime Statutes: How the Patient Protection and Affordable Care Act of 2010 Sheds Light on the "General Intent Revolution,"* 64 FLA. L. REV. 449 (2012).

17. See, e.g., Ceci Connolly & Jon Cohen, *Most Want Health Reform but Fear Its Side Effects*, WASH. POST, June 24, 2009, at A01 (discussing fears of lower quality, fewer choices, and higher costs).

18. FLA. CONST. art. X, § 25.

19. See Richard Johns, *Amendment 7: The Patients' Right to Know Flexes Its Muscle in Florida*, LAW WATCH (Foley & Lardner LLP, Orlando, Fla.), May 25, 2006, at 1, available at http://www.foley.com/files/tbl_s31Publications/FileUpload137/3390/Law%20Watch%20May%2025,%202006.pdf.

created the potential for a decrease in the quality of healthcare statewide due to its negative impact on Florida's peer review system.²⁰

Amendment 7 provides Florida patients access to any records or reports of past adverse medical incidents involving doctors, hospitals, and healthcare providers.²¹ It was one of three medical malpractice amendments featured on the November 2004 statewide ballot.²² Through the citizen initiative process authorized by the Florida Constitution,²³ all three of the proposed amendments passed and were incorporated into the Florida Constitution.²⁴ Although Amendment 7 appeared to enjoy strong

20. See James C. Sawran & Robert C. Weill, *Amendment 7: Will the Patient's Right to Know Come at Too High a Price?*, TRIAL ADVOC. Q., Spring 2005, at 7, 8–10 (describing Amendment 7's detrimental effect on the quality of healthcare because of the eradication and undermining of existing peer review and self-critical analysis protections); see also Eric S. Matthew, Note, *A New Prescription: How a Thorough Diagnosis of the "Medical Malpractice" Amendments Reveals Potential Cures for Florida's Ailing Citizen Initiative Process*, 14 U. MIAMI BUS. L. REV. 331, 351 (2006) (stating that Amendment 7 may decrease the quality of healthcare due to its repeal of statutory privileges designed to protect the analysis of the quality of treatment and physicians).

21. FLA. CONST. art. X, § 25(a).

22. *November 2, 2004 General Election, Official Results, Constitutional Amendment*, DIV. ELECTIONS, FLA. DEP'T STATE, <http://doe.dos.state.fl.us/elections/resultsarchive/SummaryRpt.asp?ElectionDate=11/2/2004&Race=AMD> (last visited Jan. 29, 2012) [hereinafter *2004 Election Results*].

23. FLA. CONST. art. XI, § 3. The Florida citizen initiative process enables voters to adopt constitutional amendments through a general election. See Jon Mills & Timothy McLendon, *Setting a New Standard for Public Education: Revision 6 Increases the Duty of the State to Make "Adequate Provision" for Florida Schools*, 52 FLA. L. REV. 329, 359 n.146 (2000); see also Sawran & Weill, *supra* note 20, at 7. A sponsor submits an initiative's ballot title and proposed amendment text to the Division of Elections of the Department of State. After receiving approval from the Department of State, the sponsor must then gather the required number of signatures. Before the initiative is placed on the ballot, the Florida Supreme Court reviews the proposed initiative via a petition for an advisory opinion from the Attorney General. *Id.* at 7–8; see also Mary Coombs, *How Not to Do Medical Malpractice Reform: A Florida Case Study*, 18 HEALTH MATRIX 373, 378 (2008). The Florida Supreme Court's advisory opinion determines if the initiative meets the single subject requirement and if the ballot title and text are unambiguous. Coombs, *supra*, at 378. The initiative will then appear on the ballot if the Florida Supreme Court does not reject the proposed initiative and if the sponsor receives the required number of signatures at least ninety-one days before the general election. See Sawran & Weill, *supra* note 20, at 7.

24. Amendment 3 and Amendment 8 were the other two medical malpractice amendments. See Coombs, *supra* note 23, at 376. Known as the Medical Liability Claimant's Compensation Amendment, Amendment 3 limits attorney contingency fees in malpractice suits. Amendment 3 is now article I, section 26 of the Florida Constitution. *The Medical Liability Claimant's Compensation Amendment*, DIV. ELECTIONS, FLA. DEP'T. STATE, <http://election.dos.state.fl.us/initiatives/initdetail.asp?account=37767&seqnum=1> (last visited Jan. 29, 2012). Amendment 8, commonly referred to as "Three Strikes and You're Out," requires the revocation of a physician's license after the physician has committed medical malpractice three or more times. Coombs, *supra* note 23, at 376, 392 (quoting Editorial, *Keep Malpractice Fight out of State Constitution*, PALM BEACH POST, Oct. 7, 2004, at 18A (internal quotation marks omitted)). Amendment 8 is now article X, section 20 of the Florida Constitution. *Public Protection from Repeated Medical Malpractice*, DIV. ELECTIONS, FLA. DEP'T STATE, <http://election.dos.state.fl.us/initiatives/initdetail.asp?account=>

electoral support,²⁵ a “firestorm of litigation” concerning Amendment 7’s application and constitutionality quickly commenced following its passage.²⁶ Since that time, Amendment 7 has been anything but “a simple amendment directed to overruling an exemption.”²⁷

This Note addresses the impact of Amendment 7 on the peer review process and the quality of healthcare in Florida. By promoting the quality of healthcare through the sharing of patient safety information, the PSQIA can counteract Amendment 7’s detrimental effect on the peer review process. Part I summarizes the peer review process. Part II discusses peer review protections in Florida before Amendment 7. The enactment of Amendment 7 and the responses by the Florida legislature and Florida courts then follow. Part II concludes with a description of the current landscape under Amendment 7. Part III outlines the enactment and purpose behind the PSQIA, explains the creation of PSOs and the Network of Patient Safety Databases (NPSD), and describes the confidentiality and privilege protections under patient safety work product (PSWP) and patient safety evaluation systems (PSES). Part III concludes with a discussion of the judicial response to the PSQIA and the future of the PSQIA. Part IV discusses the PSQIA as a potential solution to ensure the quality of healthcare by counteracting Amendment 7’s detrimental effect on the sharing and analysis of patient safety events through the peer review process. Part IV also explains the process of becoming a PSO and the advantages and disadvantages of joining a PSO. Finally, this Note concludes that while it is still too early to determine Amendment 7’s impact on the peer review system and consequently on the quality of healthcare systems statewide, any possible solution to counteract Amendment 7 is beneficial to the consumer patient.

Under Amendment 7, 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. It follows, then, that peer review will no longer yield the kind of discourse that is necessary for its

35169&seqnum=8 (last visited Jan. 29, 2012).

25. A total of 81.2% of Floridians (5,849,125) voted for Amendment 7 in comparison to the 18.8% of Floridians (1,358,183) who voted against it. *2004 Election Results*, *supra* note 22.

26. Sawran & Weill, *supra* note 20, at 7; *see also* J.B. Harris, *Riding the Red Rocket: Amendment 7 and the End to Discovery Immunity of Adverse Medical Incidents in the State of Florida*, FLA. B.J., Mar. 2009, at 20, 20–21 (“[F]rom the point of ignition until now, Amendment 7 has taken off like a rocket, leaving in its trail a plume of litigation and court rulings that have had a dramatic impact on the way medical malpractice attorneys engage in discovery, and the way doctors, hospitals, and other health care providers conduct peer review, credentialing, investigations, quality assurance, and risk assessments.”).

27. Mark D. Killian, *Academy, FMA Square Off over Amendments*, FLA. B. NEWS, July 1, 2004 (quoting former Florida Supreme Court Justice Harry Lee Anstead) (internal quotation marks omitted), <http://www.floridabar.org/DIVCOM/JN/jnnews01.nsf/cb53c80c8fabd49d85256b5900678f6c/d2df312684ca6d7985256ebb0054607f>.

full effectiveness. As a result, Florida patients will likely suffer a decrease in the quality of healthcare. Additionally, Amendment 7's broad scope will probably increase the number of medical malpractice claims, thus increasing medical malpractice insurance premiums. As these premiums increase, Florida consumer patients will be forced to pay higher medical costs. Therefore, Florida patients' quality and cost of healthcare are potentially at stake.

I. THE PEER REVIEW PROCESS

The first peer review committees were created in 1918 by the American College of Surgeons to assess the quality of care at local hospitals; these committees began the national recognition of medical errors.²⁸ Over the past century, the peer review process has become key in assuring the quality of medical care and "has become an institutionalized practice."²⁹ The process begins at the credentialing stage, when peer review committees (composed of physicians with specialized medical knowledge) review a medical staff applicant's education, experience, qualifications, and training.³⁰ Peer review continues for existing medical staff by analyzing "quality assurance data, diagnostic and laboratory utilization reports, and other information regarding each staff member's actual practice at the hospital."³¹ Generally, each member of a hospital's medical staff is required to undergo peer review every two years regardless of whether a quality concern has occurred; however, a physician's clinical privileges are reviewable whenever quality concerns warrant more immediate action.³²

Peer review creates a system of "self-policing and self-regulating,"³³ among doctors, hospitals, and healthcare providers. The information gathered from peer review reports enables medical professionals to take corrective actions and measures, such as increasing training programs, creating standardized procedures, and revoking physician privileges when

28. See Kathryn Leaman, Note, *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).

29. Talia Storch, Note, *Medical Peer Review in Florida: Is the Privilege Under Attack?*, 32 NOVA L. REV. 269, 269–70 (2007) (citing Susan O. Scheutzow & Sylvia Lynn Gillis, *Confidentiality and Privilege of Peer Review Information: More Imagined than Real*, 7 J.L. & HEALTH 169, 169 (1992–93)).

30. See Lisa M. Nijm, Note, *Pitfalls of Peer Review: The Limited Protections of State and Federal Peer Review Law for Physicians*, 24 J. LEGAL MED. 541, 543 (2003).

31. Susan O. Scheutzow, *State Medical Peer Review: High Cost but No Benefit—Is It Time for a Change?*, 25 AM. J.L. & MED. 7, 14 (1999).

32. See *id.*

33. Laura V. Yaeger, Note, *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, 124 (2009).

necessary.³⁴ The process creates a higher standard of quality of care by weeding out “incompetence in the medical profession.”³⁵

Peer review supporters assert that three main premises underlie the strength of the peer review process.³⁶ First, physicians are best situated, due to their specialized training, to evaluate and observe other physicians’ practice methods and potential risks.³⁷ Second, the candid evaluation and criticism of fellow medical providers is the best way to determine subpar and superlative care.³⁸ Third, peer review motivates participants to maintain a high standard of care within their medical practice.³⁹ Hence, the peer review process promotes learning from providers’ past medical errors and “near misses,” rather than assigning blame to individuals.⁴⁰ This strong belief in the peer review process is evidenced by the fact that hospitals must have a peer evaluation system in place in order to receive accreditation by the Joint Commission (formerly known as the Joint Commission on Accreditation of Healthcare Organizations).⁴¹ The peer review process is thus “one of medicine’s most effective risk management and quality improvement tools.”⁴²

34. Johns, *supra* note 19, at 1.

35. Alissa Marie Bassler, Comment, *Federal Law Should Keep Pace with States and Recognize a Medical Peer Review Privilege*, 39 IDAHO L. REV. 689, 692 (2003) (citing *Nilavar v. Mercy Health Sys.-W. Ohio*, 210 F.R.D. 597, 600 (S.D. Ohio 2002)).

36. See Ilene N. Moore et al., *Rethinking Peer Review: Detecting and Addressing Medical Malpractice Claims Risk*, 59 VAND. L. REV. 1175, 1177–78 (2006).

37. See *id.* (“Peer review offers an incentive for similarly trained physicians working in the same environment to identify colleagues with knowledge gaps or deficiencies in technical skills, facilitate their remediation, and monitor their progress and performance, in preference to external parties assuming this responsibility.”).

38. See *id.* at 1177; see also Eric Scott Bell, Comment, *Make Way: Why Arkansas and the States Should Narrow Health Care Peer Review Privileges for the Patient Safety and Quality Improvement Act of 2005*, 62 ARK. L. REV. 745, 749–54 (2009).

39. See Moore et al., *supra* note 36, at 1177; see also Bell, *supra* note 38, at 752–53.

40. See Patricia A. Sullivan & Jon M. Anderson, *The Health Care Debate: If Lack of Tort Reform Is Part of the Problem, Federalized Protection for Peer Review Needs to Be Part of the Solution*, 15 ROGER WILLIAMS U. L. REV. 41, 47 (2010). It is argued that this blame game persistent in medical malpractice litigation and the tort system has become a reason for providers to conceal medical mistakes and “near misses.” *Id.* at 44 (quoting Bryan A. Liang & Steven D. Small, *Communicating About Care: Addressing Federal-State Issues in Peer Review and Mediation to Promote Patient Safety*, 3 HOUS. J. HEALTH L. & POL’Y 219, 220–21, 223 (2003)) (internal quotation marks omitted).

41. See Scheutzow & Gillis, *supra* note 29, at 172–73; see also Christopher S. Morter, Note, *The Health Care Quality Improvement Act of 1986: Will Physicians Find Peer Review More Inviting?*, 74 VA. L. REV. 1115, 1116–18 (1988). Although the Joint Commission is a nongovernmental, voluntary private accreditation association, it is very influential because both state and federal governments rely on Joint Commission accreditation for hospital licensure as well as Medicare and Medicaid hospital programs. FURROW ET AL., *supra* note 1, at 149.

42. Nijm, *supra* note 30, at 541.

II. AMENDMENT 7: PATIENTS' RIGHT TO KNOW ABOUT ADVERSE MEDICAL INCIDENTS

A. Florida's Peer Review Protections Before Amendment 7

Before the passage of Amendment 7, the Florida Legislature and the state's courts long recognized the importance of affording confidentiality and privilege protections⁴³ to peer review reports in order to maintain the quality of healthcare for patients throughout the state.⁴⁴ Florida statutes additionally privileged other medical review systems such as credentialing, medical review committees, and risk management.⁴⁵ Florida enacted a peer review statute before the Health Care Quality Improvement Act of 1986 (HCQIA)⁴⁶ introduced national standards for peer review.⁴⁷ Under Florida's statutory protections,⁴⁸ medical peer review records were confidential, privileged, and excluded from discovery.⁴⁹ The protection of

43. Confidentiality and privilege are two separate legal concepts. Under confidentiality protections, parties must refrain from disclosing information discussed in the peer review process outside a judicial proceeding. *See id.* at 548; *see also* Storch, *supra* note 29, at 276–77. Privilege protections safeguard particular information from disclosure during discovery or at trial. Nijm, *supra* note 30, at 546. Privileged information will often also be considered confidential information. *See id.* at 548.

44. Sawran & Weill, *supra* note 20, at 8–9.

45. Matthew, *supra* note 20, at 351 n.108. For examples of these statutory protections, see *infra* note 48.

46. Health Care Quality Improvement Act of 1986, Pub. L. No. 99-660, 100 Stat. 3784 (codified at 42 U.S.C. §§ 11101–52 (2006)). The HCQIA “granted immunity to peer review committee members” and required healthcare providers “to report physician misconduct to the National Practitioner’s Data Bank.” Bell, *supra* note 38, at 751–52. In addition to the HCQIA’s purpose to improve the quality of healthcare, the HCQIA was also created “to restrict the ability of incompetent physicians to move from State to State without disclosure or discovery of the physician’s previous damaging or incompetent performance.” 42 U.S.C. § 11101(2). Generally, courts do not find that the HCQIA enacts a broad privilege protecting the non-discoverability of peer review reports. *See KD ex rel. Dieffenbach v. United States*, 715 F. Supp. 2d 587, 594–96 (D. Del. 2010).

47. Christina M. Graham, Comment, *Hide and Seek: Discovery in the Context of the State and Federal Peer Review Privileges*, 30 CUMB. L. REV. 111, 125 (2000) (citing FLA. STAT. ANN. § 766.101(5) (West 1997)).

48. *See, e.g.*, FLA. STAT. § 395.0191 (2010) (requiring hospitals to create credentialing rules and granting discovery protection for credentialing records); *id.* § 395.0193 (requiring mandatory peer review for hospitals and protecting any peer review records from disclosure); *id.* § 395.0197 (requiring hospitals to create “an internal risk management program” that includes the production of confidential, non-discoverable reports of adverse incidents); *id.* § 400.118 (requiring nursing homes to conduct quality-of-care monitoring reports); *id.* § 459.016 (providing confidentiality and non-discoverability protections to disciplinary reports by medical organizations); *id.* § 766.101(5) (protecting a medical review committee’s investigations, proceedings, and records from discovery and evidence); *id.* § 766.1016(2) (protecting patient safety data).

49. *See Florida Peer Review After Amendment 7: Challenges and Solutions to a National Trend*, FOLEY & LARDNER LLP, 1–3 (May 5, 2008), <http://www.foley.com/abc.aspx?Publication=5012> [hereinafter *Florida Peer Review After Amendment 7*].

peer review reports was “based on a conventional belief that the medical profession could not deliver first-class healthcare without a high level of self-oversight, coupled with near bulletproof immunity from discovery of behind-the-scenes activities related to these pursuits.”⁵⁰ These protections encouraged physicians “to be candid and vigorous in the performance evaluations of their peers, without fear that those evaluations would be used for improper purposes,” such as medical malpractice suits.⁵¹ Thus, the “rationale for cloaking peer review . . . in confidentiality” follows from the need to promote full candor among peer review participants in order to improve, or at least maintain, the quality of healthcare.⁵²

As states began to enact peer review privilege statutes in the 1970s and 1980s,⁵³ Florida courts led the way with an expansive approach to peer review protections.⁵⁴ Florida courts saw confidentiality protections as integral to improving the quality of healthcare for patients statewide.⁵⁵ Thus, courts “firmly guarded”⁵⁶ the state’s various peer review protection statutes. In *Holly v. Auld*,⁵⁷ the Florida Supreme Court provided an economic justification for the peer review privilege, stating, “In an effort to control the escalating cost of healthcare in the state, the legislature deemed it wise to encourage a degree of self-regulation by the medical profession through peer review and evaluation.”⁵⁸ The *Holly* court additionally emphasized the need for confidentiality in peer review in order to provide for “full, frank medical peer evaluation.”⁵⁹

Eight years later, in *Cruger v. Love*,⁶⁰ the Florida Supreme Court reaffirmed its expansive view of peer review protection in order to

50. Harris, *supra* note 26, at 20.

51. *Florida Peer Review After Amendment 7*, *supra* note 49, at 1.

52. Sawran & Weill, *supra* note 20, at 9.

53. See Bell, *supra* note 38, at 751.

54. See Graham, *supra* note 47, at 125.

55. See *Dade Cnty. Med. Ass’n v. Hlis*, 372 So. 2d 117, 120 (Fla. 3d Dist. Ct. App. 1979) (“Confidentiality is essential to effective functioning of these staff 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 quo 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.” (quoting *Bredice v. Doctors Hosp., Inc.*, 50 F.R.D. 249, 250 (D.D.C. 1970), *aff’d mem.*, 479 F.2d 920 (D.C. Cir. 1973)) (internal quotation marks omitted)).

56. Yaeger, *supra* note 33, at 126.

57. 450 So. 2d 217 (Fla. 1984). In *Holly*, a plaintiff physician filed a defamation claim against another physician for the physician’s statements to the credentialing committee regarding the plaintiff’s staff privileges. The plaintiff sought discovery of these credentialing records. *Id.* at 218.

58. *Id.* at 219–20.

59. *Id.* at 220.

60. 599 So. 2d 111 (Fla. 1992). In *Cruger*, the plaintiff brought a claim against the defendant physician for alleged negligent treatment of the plaintiff’s son’s fractured thumb. The plaintiff sought discovery of three local hospitals’ records regarding the defendant’s application for staff privileges. *Id.* at 112.

“prohibit the chilling effect of the potential public disclosure of statements made to or information prepared for and used by the committee in carrying out its peer review function.”⁶¹ The court explained that this “chilling effect”⁶² causes doctors, absent peer review protection, “to be reluctant to engage in strict peer review due to a number of apprehensions: loss of referrals, respect, and friends; possible retaliations; vulnerability to torts; and fear of malpractice actions in which the records of the peer review proceedings might be used.”⁶³ The court held that a privilege protection statute applied to any documents that were reviewed by a hospital board or committee during its peer-review process, including a physician’s application for staff privileges.⁶⁴ The court reasoned that full disclosure of a physician’s information in an application is pertinent to the determination of staff privileges; without this statutory protection, a physician would be reluctant to engage in full, detailed reporting because of his fear that the reported information may be used against him in the future.⁶⁵ Thus, under the *Cruger* court’s broad interpretation, “essentially all [peer review] documents are privileged.”⁶⁶

B. *The Enactment of Amendment 7*

As the Florida Legislature and the state’s courts continued to protect the peer review process, the war between doctors and plaintiffs’ attorneys, which had waged since the 1990s, culminated at the November 2, 2004 general election.⁶⁷ Amendment 7 made it onto the ballot due to the efforts of a movement by plaintiffs’ attorneys to “open up to public scrutiny a medical community cloistered behind a veil of secrecy.”⁶⁸ The state statutory protections, advocates of Amendment 7 argued, “crowned the medical profession with an almost unlimited degree of authority, not only to regulate itself, but to conduct clandestine deliberations involving peer review.”⁶⁹ Sponsored by Floridians for Patient Protection⁷⁰ and supported

61. *Id.* at 115.

62. *Id.*

63. *Id.* (quoting Gregory S. Gosfield, Comment, *Medical Peer Review Protection in the Health Care Industry*, 52 TEMP. L.Q. 552, 558 (1979)).

64. *Id.* at 114.

65. *Id.*

66. Yaeger, *supra* note 33, at 126.

67. See Harris, *supra* note 26, at 20; see also Greg Groeller, *Doctor-Lawyer Tussle Plays out Before Voters*, ORLANDO SENT., Oct. 27, 2004, at B1; Bob LaMendola, *Doctors, Lawyers Lock Horns over 3 Ballot Questions*, SUN-SENT. (Fort Lauderdale, Fla.), Oct. 20, 2004, at 1A.

68. Sawran & Weill, *supra* note 20, at 12 n.5 (internal quotation marks omitted).

69. Harris, *supra* note 26, at 20. Amendment 7 proponents argued that the self-policing nature of peer review created “an aura of controversy . . . surround[ing] the idea of allowing health care personnel to police themselves in order to ensure high quality patient care.” Morter, *supra* note 41, at 1115.

70. *Patients’ Right to Know About Adverse Medical Incidents*, DIV. ELECTIONS, FLA. DEP’T STATE, <http://election.dos.state.fl.us/initiatives/initdetail.asp?account=35169&seqnum=3> (last

by the Academy of Florida Trial Lawyers,⁷¹ Amendment 7 was titled the “Patients’ Right to Know About Adverse Medical Incidents.”⁷² The ballot summary read:

Current Florida law restricts information available to patients related to investigations of adverse medical incidents, such as medical malpractice. This amendment would give patients the right to review, upon request, records of health care facilities’ or providers’ adverse medical incidents, including those which could cause injury or death. Provides that patients’ identities should not be disclosed.⁷³

Proponents advocated Amendment 7 as a consumer information and protection measure,⁷⁴ claiming that it would provide Florida patients with information about doctors, hospitals, and healthcare providers statewide; patients would no longer have to base their decision primarily on the word of mouth of the type of care rendered by these providers.⁷⁵

However, in light of the underlying war between doctors and attorneys, Amendment 7 was often referred to by its opponents as a “tit for tat”⁷⁶ amendment, created in response to Amendment 3’s proposal⁷⁷ “to limit plaintiffs’ attorney’s fees.”⁷⁸ This accusation is based on the fact that Amendment 7 enables plaintiffs’ attorneys to access peer review’s candid criticism of the delivery of care in order to achieve higher settlements and verdicts.⁷⁹

visited Jan. 29, 2012).

71. See Killian, *supra* note 27.

72. *Patients’ Right to Know About Adverse Medical Incidents*, *supra* note 70.

73. *Id.*

74. See Harris, *supra* note 26, at 21; see also Killian, *supra* note 27; Robert C. Weill, *Buster and the Continuing Saga over the Patients’ Right-to-Know-About-Medical-Incidents-Amendment*, TRIAL ADVOC. Q., Winter 2009, at 14, 14.

75. Sawran & Weill, *supra* note 20, at 7 n.5 (citation omitted) (internal quotation marks omitted).

76. Killian, *supra* note 27 (quoting Florida Supreme Court Justice Barbara Pariente) (internal quotation marks omitted).

77. Pursuant to Amendment 3, the claimant in a medical liability case with a contingency fee will receive no less than 70% of the first \$250,000 and 90% of all damages in excess of that amount, exclusive of customary and reasonable costs and regardless of the number of defendants. FLA. CONST. art. I, § 26.

78. Sawran & Weill, *supra* note 20, at 7; see also Matthew, *supra* note 20, at 350–51 (“Many defense lawyers and health care professionals actually believe the amendment was proposed in direct response to Amendment 3. Metaphorically speaking, the electorate inadvertently supported Amendment 7 which treats the disease (tort reform hindering plaintiff attorneys) instead of the patient (health care as a whole).” (footnote omitted)); Michael A. Wasyluk, *Keep Our Best Doctors*, TAMPA TRIB., Oct. 27, 2004, at 11 (“Amendments 7 and 8 are intimidation tactics by the trial lawyers in response to Amendment 3.”).

79. See Sullivan & Anderson, *supra* note 40, at 42.

During oral arguments and review of the proposed amendment in June 2004,⁸⁰ the Florida Supreme Court questioned the proponents of Amendment 7 regarding voters' understanding of the amendment—namely, that they would not understand that the amendment would, in effect, allow for all medical records to be public.⁸¹ In response, counsel for Floridians for Patient Protection stated, “[T]he average voters of reasonable intelligence’ will understand the chief purpose of the amendment is to make medical records available.”⁸² Amendment 7 seemed to provide a helpful method of gaining access to information critical for potential lawsuits.⁸³ Amendment 7’s proponents downplayed the proposed amendment’s effect on the peer review privilege.⁸⁴ The Florida Dental Association, which opposed the amendment, expressed concern that the ballot summary failed to inform voters of the effect and impact on Florida’s peer review system.⁸⁵ However, in its Advisory Opinion regarding Amendment 7, the Florida Supreme Court stated that even if Amendment 7 could impact the peer review process, “[i]t cannot be said that the lack of a prediction as to the amendment’s effect on the peer review statutes misleads the public as to the chief purpose of the amendment.”⁸⁶ After receiving the requisite number of signatures⁸⁷ and gaining the approval of the Florida Supreme Court,⁸⁸ Amendment 7 was added to the November 2, 2004 ballot.

Doctors throughout the state lobbied against Amendment 7; they argued that peer review protection is necessary to maintain a high quality of healthcare for Florida patients.⁸⁹ Major newspapers throughout Florida

80. See Killian, *supra* note 27.

81. Justice Charles T. Wells raised this concern during the argument. *Id.*

82. *Id.* (quoting attorney Timothy McLendon).

83. See Matthew, *supra* note 20, at 351.

84. See *id.*

85. Advisory Op. to Att’y Gen. re Patients’ Right to Know About Adverse Med. Incidents, 880 So. 2d 617, 622 (Fla. 2004).

86. *Id.*

87. In order to be placed on the ballot, Amendment 7 was required to have 488,722 signatures. *Patients’ Right to Know About Adverse Medical Incidents*, *supra* note 70. Amendment 7 proponents received an estimated 519,838 signatures. *Id.*

88. Advisory Op. to Att’y Gen. re Patients’ Right to Know About Adverse Med. Incidents, *supra* note 85, at 618.

89. See Dennis S. Agliano, *Protect Your Health Care*, TAMPA TRIB., Oct. 10, 2004, at 1 (“Amendment 7, the so-called Patient’s Right to Know amendment, will destroy key measures in place to help Florida’s patients. Adverse incident reports have always been under the confidentiality of the peer review committee, which is extremely important for quality assurance and patient safety. Vote no on 7.”); LaMendola, *supra* note 67 (“But doctors and hospitals argue that the complaints often prove groundless, and if aired, could unfairly tarnish reputations. They say going public would kill the well-established process of ‘peer review,’ in which physician panels study deaths and injuries in secret to learn how to prevent errors.”); Joseph D. Portoghese, *The Hidden Agenda of Amendment 7*, ORLANDO SENT., Oct. 19, 2004, at A13 (“[T]he real intent of this amendment is to open a hospital’s internal reviews of patient safety and quality-assurance efforts to

also opposed Amendment 7.⁹⁰ Despite this resistance, Amendment 7 passed with an overwhelming 81.2% of the vote on November 2, 2004.⁹¹ The Florida Constitution was subsequently amended to include Amendment 7 in article X, section 25, which provides Florida patients with “a right to have access to any records made or received in the course of business by a health care facility or provider relating to any adverse medical incident.”⁹² However, Amendment 7 conforms to the privacy requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA)⁹³ by protecting patients’ identities from disclosure and mandating adherence to all federal privacy restrictions.⁹⁴

C. *The Legislative and Judicial Responses to Amendment 7*

The enactment of Amendment 7 “sparked a flurry of litigation in the courts across Florida.”⁹⁵ Within days of the November 2, 2004 election, Floridians filed lawsuits and courts ordered injunctions in response to Amendment 7.⁹⁶ Opponents of Amendment 7 also “sought protection from the Florida [L]egislature.”⁹⁷ In June 2005, the Florida Legislature implemented section 381.028.⁹⁸ This statute attempted to limit Amendment 7’s broad scope in a number of ways.⁹⁹ First, section 381.028 stated that Amendment 7 was not retroactive; thus it applied only to adverse incident reports created on or after November 2, 2004.¹⁰⁰ Second, Amendment 7

trial attorneys for the purpose of lawsuits.”); Wasylik, *supra* note 78 (“The truth is, only the worst doctors in our state will be in favor of Amendment 7, as it will reduce the internal hospital reviews of medical errors that enable us to discipline unskilled physicians. . . [sic] Peer review is the only way for hospitals to immediately protect citizens from the unprofessional actions of bad doctors.”).

90. See Editorial, *Limit Changes—Our Position: Only 2 of 8 Constitutional Amendments Deserve Voter Support*, ORLANDO SENT., Oct. 17, 2004, at G2; see also Editorial, *The Tribune’s Picks*, TAMPA TRIB., Oct. 18, 2004, at 15; Editorial, *Vote No on 3 Medical Issues*, SUN-SENT. (Fort Lauderdale, Fla.), Oct. 24, 2004, at 4J.

91. See *supra* Introduction and notes 20–26 and accompanying text (discussing the November 2, 2004 General Election results).

92. FLA. CONST. art. X, § 25(a).

93. Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (codified in scattered sections of 26, 29, and 42 U.S.C.).

94. FLA. CONST. art. X, § 25(b).

95. Johns, *supra* note 19, at 1.

96. See Coombs, *supra* note 23, at 394; see also Guy Boulton, *Hospitals Tried to Pre-Empt Malpractice Amendments*, TAMPA TRIB., Nov. 6, 2004, at MONEYSSENSE 1; Greg Groeller, *Medical Initiatives Already Face Suits: The Malpractice Amendments Likely Will Take a While to Implement, Experts Say*, ORLANDO SENT., Nov. 4, 2004, at A16.

97. Coombs, *supra* note 23, at 396.

98. The Florida Legislature first enacted this law as chapter 2005-265, Laws of Florida, effective June 20, 2005. The law was codified as section 381.028 of the Florida Statutes in 2007. See Fla. Hosp. Waterman, Inc. v. Buster, 984 So. 2d 478, 482 (Fla. 2008).

99. See Coombs, *supra* note 23, at 396; see also Weill, *supra* note 74, at 14; *Florida Peer Review After Amendment 7*, *supra* note 49, at 1.

100. FLA. STAT. § 381.028(5).

applied only to final reports and provided confidentiality and non-discoverability protection to preliminary reports and other materials used by review committees.¹⁰¹ Third, requesting patients were entitled only to records that involved an incident concerning the same condition, diagnosis, or treatment as their own.¹⁰² Fourth, any information received by a patient was still subject to existing Florida statutes that protected against admissibility and discovery.¹⁰³

The enactment of Amendment 7 and section 381.028 resulted in a conflict between two Florida District Courts of Appeal.¹⁰⁴ In *Florida Hospital Waterman, Inc. v. Buster*,¹⁰⁵ the Florida Supreme Court addressed this conflict and other issues surrounding Amendment 7.¹⁰⁶ The court's ruling firmly solidified Amendment 7's constitutional scope.¹⁰⁷ First, the court held that Amendment 7 is self-executing.¹⁰⁸ Second, Amendment 7 applies retroactively to adverse medical incident reports in existence prior to November 2, 2004.¹⁰⁹ Third, several subsections of section 381.028 unconstitutionally impinged upon Amendment 7 and the court effectively severed them from the statute.¹¹⁰ Regarding these conflicting subsections, the Florida Supreme Court stated that section 381.028 could not limit Amendment 7's application to final reports because the amendment applied to any records that relate to an adverse medical incident. Additionally, the court stated that the statute could not limit patients' records requests to records that involved an incident with the same condition, diagnosis, or treatment as their own.¹¹¹

101. *Id.* § 381.028(3)(j); *see also* Coombs, *supra* note 23, at 396.

102. FLA. STAT. § 381.028(7)(a).

103. *Id.* § 381.028(6); *see also* Coombs, *supra* note 23, at 396–97.

104. In *Florida Hospital Waterman, Inc. v. Buster*, the appellees sought production of documents regarding the investigation of an adverse medical incident. 932 So. 2d 344, 348 (Fla. 5th Dist. Ct. App. 2006). In *Notami Hospital of Florida, Inc. v. Bowen*, the appellees sought production of documents regarding the selection, retention, or termination of a doctor. 927 So. 2d 139, 142 (Fla. 1st Dist. Ct. App. 2006). In both cases, the appellant hospitals argued that the information was confidential and protected under various statutes in existence before Amendment 7. *See Buster*, 984 So. 2d 478, 482 (Fla. 2008). Florida's Fifth District Court of Appeal held that Amendment 7 is self-executing and allows for discovery, but does not apply retroactively. *Buster*, 932 So. 2d at 356. The First District also found that Amendment 7 is self-executing; in addition, that court held that section 381.028 is unconstitutional. However, the First District held that Amendment 7 does apply retroactively to existing records, creating the circuit conflict. *Bowen*, 927 So. 2d at 145.

105. 984 So. 2d 478 (Fla. 2008).

106. *Id.* at 480–81.

107. *See Florida Peer Review After Amendment 7*, *supra* note 49, at 1.

108. *Buster*, 984 So. 2d at 494.

109. *Id.* Section 381.028's time limitation for records generated only after November 2, 2004 was severed as unconstitutional. *Id.* at 492–94.

110. *Id.* The Florida Supreme Court explained that any substantial limitation imposed by the legislature on a right in an amendment is unconstitutional. *Id.* at 492.

111. *Id.*

Demonstrating judicial deference to the citizen initiative process, the Florida Supreme Court cited the lower court's opinion to explain its decision to uphold Amendment 7:

We believe that Amendment 7 heralds a change in the public policy of this state to lift the shroud of privilege and confidentiality in order to foster disclosure of information that will allow patients to better determine from whom they should seek health care, evaluate the quality and fitness of health care providers currently rendering service to them, and allow them access to information gathered through the self-policing processes during the discovery period of litigation filed by injured patients or the estates of deceased patients against their health care providers.¹¹²

In addition to supporting the voters, the court further explained that healthcare providers had never been granted a vested substantive right for peer review protection; they had simply expected that the Florida Legislature would continue to protect the access and use of peer review documents.¹¹³ The Florida Supreme Court's 4–3 decision¹¹⁴ represented a clear victory for Amendment 7. This ruling affected multiple Florida statutes¹¹⁵ that had previously provided protection to peer review reports; the Florida Supreme Court decisively concluded that Amendment 7 preempts all statutory peer review privileges in Florida.¹¹⁶

112. *Id.* at 494 (quoting *Buster*, 932 So. 2d 344, 348, 355–56 (Fla. 5th Dist. Ct. App. 2006)) (internal quotation marks omitted). The court continued to quote the Fifth District's opinion to explain:

We have come to this conclusion because we are obliged to interpret and apply Amendment 7 in accord with the intention of the people of this state who enacted it, and we have done so. It is not for us to judge the wisdom of the constitutional amendments enacted or the change in public policy pronounced through those amendments, even in instances where the change involves abrogation of long-standing legislation that establishes and promotes an equally or arguably more compelling public policy.

Id. (quoting *Buster*, 932 So. 2d at 356) (internal quotation marks omitted).

113. *Id.* at 491.

114. *Florida Peer Review After Amendment 7*, *supra* note 49, at 1.

115. The affected statutes included Florida Statutes sections 395.0191(8), 395.0193(7), 395.0193(8), 395.0197(6)(c), 395.0197(7), 395.0197(9), 395.0197(11), 766.101(5), and 766.1016(2). *Florida Peer Review After Amendment 7*, *supra* note 49, at 1.

116. *Buster*, 984 So. 2d at 488–94; see also *The Amendment 7 Challenge: Is a PSO Hype or Hope?*, FOLEY & LARDNER LLP, 6 (Apr. 29, 2008), http://www.foley.com/files/tbl_s88EventMaterials/FileUpload587/1670/TheAmendment7.pdf [hereinafter *The Amendment 7 Challenge*] (compiling materials from the firm's program on the topic).

Since the *Buster* decision, Amendment 7 continues to be a controversial issue in Florida.¹¹⁷ Throughout the state, Florida courts have varied in the application of Amendment 7.¹¹⁸ For instance, in October 2008, the Third District Court of Appeal restricted the reach of Amendment 7 in *Baptist Hospital of Miami, Inc. v. Garcia*,¹¹⁹ while the Fourth District Court of Appeal expanded Amendment 7's scope in *Amisub North Ridge Hospital, Inc. v. Sonaglia*.¹²⁰ In *Garcia*, the Third District restricted the full disclosure of a physician's complete credentialing files because the disclosure and production of the files would reveal names and confidential information unrelated to adverse medical incidents under Amendment 7.¹²¹ In contrast, in *Sonaglia*, the Fourth District stated that Amendment 7 "does not require the information a patient seeks to be relevant to a pending medical malpractice action or to a medical care decision."¹²²

In *Baldwin v. Shands Teaching Hospital & Clinics, Inc.*,¹²³ the First District Court of Appeal further expanded the scope of Amendment 7.¹²⁴ The court explained that an "adverse medical incident" under Amendment 7 means not only "medical negligence," but also includes "intentional misconduct, and any other act, neglect, or default of a health care facility or health care provider that caused or could have caused injury to . . . a patient."¹²⁵ If Amendment 7 only applies to incidents of medical negligence, then to avoid falling under this rule, medical providers likely would not label incidents as medical negligence.¹²⁶

The controversy surrounding the scope and validity of Amendment 7 has continued well after the Florida Supreme Court affirmed the broad scope of the amendment in *Buster*. Opponents of Amendment 7 have challenged the amendment based on federal preemption by statutes that

117. See Weill, *supra* note 74, at 18 (describing unresolved issues surrounding Amendment 7 after the Florida Supreme Court's decision in *Buster*).

118. See Paula J. Parisi & Areti G. Tsitsakis, *The Wake of Amendment 7: Moving Forward to Protect Privileged Information*, LITIG. Q. (Cole, Scott & Kissane, P.A., Fla.), June 1, 2009, at 11, <http://www.csklegal.com/wp-content/uploads/JuneQuarterly.pdf>.

119. 994 So. 2d 390, 393 (Fla. 3d Dist. Ct. App. 2008).

120. 995 So. 2d 999, 1001 (Fla. 4th Dist. Ct. App. 2008).

121. 994 So. 2d at 393. The court reasoned that these files were statutorily privileged and exempt from discovery under sections 395.0191(8) and 766.101(5), Florida Statutes. *Id.*

122. 995 So. 2d at 1001. The Fourth District thus permitted the production of peer review records in a physician's action against a fellow physician for defamation and tortious interference with a business relationship. *Id.* at 1000–02.

123. 45 So. 3d 118 (Fla. 1st Dist. Ct. App. 2010).

124. *Id.* at 120, 123–25.

125. *Id.* at 125 (quoting FLA. CONST. art. X, § 25(c)(3)) (internal quotation marks omitted).

126. Pursuant to Florida Statutes section 381.028(7)(b), healthcare providers are responsible for the identification of records that are records of adverse medical incidents. See *The Amendment 7 Challenge*, *supra* note 116, at 12–13.

require the confidentiality of certain records.¹²⁷ However, Florida's First and Fourth District Courts of Appeal both decided in 2009 that neither the HCQIA nor the federal Contracts Clause preempt Amendment 7.¹²⁸ Therefore, despite these challenges, Amendment 7 remains in effect.

D. *The Current Landscape Under Amendment 7*

The recent rulings affirming Amendment 7's broad scope will likely have a significant impact on the peer review process in Florida.¹²⁹ The protective veil of confidentiality and privilege in Florida "has been ripped away."¹³⁰ Experts predict that the loss of confidentiality and privilege under Amendment 7 will negatively affect the quality of healthcare statewide¹³¹ because healthcare providers will be reluctant to participate in peer review.¹³² In 2002, 59% of physicians surveyed stated that fear of liability was the primary reason they did not engage in open discussion of patient injury cases.¹³³ If physician participation in peer review does diminish as predicted, Amendment 7 "threatens to eradicate all existing protections for self-critical analysis."¹³⁴ Thus, Amendment 7 completely undermines the legislative intent and public policy reasons behind previous peer review statutes¹³⁵ because without statutory protections, the peer review process will be ineffective.¹³⁶

In contrast, proponents of Amendment 7 can find support in similar arguments made by critics of peer review protections. The peer review process has been the subject of recent debate concerning whether it actually promotes healthcare quality and safety.¹³⁷ Critics of peer review protection state that safety and quality issues often are not referred for peer

127. See Parisi & Tsitsakis, *supra* note 118, at 11–12.

128. See *Columbia Hosp. Corp. of S. Broward v. Fain*, 16 So. 3d 236, 241–44 (Fla. 4th Dist. Ct. App. 2009); *W. Fla. Reg'l Med. Ctr. v. See*, 18 So. 3d 676, 684–88 (Fla. 1st Dist. Ct. App. 2009).

129. See Coombs, *supra* note 23, at 401.

130. Yaeger, *supra* note 33, at 123.

131. Sawran & Weill, *supra* note 20, at 10.

132. *Id.*

133. HARRIS INTERACTIVE INC., FEAR OF LITIGATION STUDY: THE IMPACT ON MEDICINE 32 (2002), <http://www.harrisinteractive.com/vault/Harris-Interactive-Poll-Research-Most-Doctors-Report-Fear-of-Malpractice-Liability-2002-05.pdf> [hereinafter FEAR OF LITIGATION STUDY] (reporting the results of a survey conducted for Common Good).

134. Sawran & Weill, *supra* note 20, at 8.

135. See *Cruger v. Love*, 599 So. 2d 111, 114 (Fla. 1992) ("While we recognized in *Holly* that the discovery privilege would impinge upon the rights of litigants to obtain information helpful or even essential to their cases, we assumed that the legislature balanced that against the benefits offered by effective self-policing by the medical community." (citing *Holly v. Auld*, 450 So. 2d 217, 220 (Fla. 1984))).

136. See Johns, *supra* note 19, at 1.

137. Moore et al., *supra* note 36, at 1182.

review.¹³⁸ In addition, they argue that peer review protections conceal information that is often related to “contested issues in malpractice cases.”¹³⁹ Critics also argue that the peer review privilege has a negative effect on disciplined physicians because a contesting physician is unable to use the privileged peer review materials upon which his disciplinary action is based in his defense.¹⁴⁰ Some critics even allege that peer review protections foster pettiness between competing physicians and encourage them to make adverse peer review statements against each other.¹⁴¹ Others argue that the peer review process results in physicians spending less time with patients.¹⁴²

Although “promoted as a consumer protection measure,”¹⁴³ Amendment 7 predominantly has been used in medical malpractice lawsuits; it has rarely been used in the service of investigative journalism or as a check on doctors, hospitals, and health providers by the consumer patient.¹⁴⁴ Thus, the use of Amendment 7 as a “litigation tool”¹⁴⁵ will result in more medical malpractice lawsuits and greater healthcare costs.¹⁴⁶ Florida is already plagued by a “medical malpractice crisis,” as evidenced by the record number of recent verdicts against Florida hospitals.¹⁴⁷ In 2004, Florida’s Second District Court of Appeal noted that “[m]edical malpractice claims remain among the most intensively litigated in trial practice.”¹⁴⁸ Due to this crisis, malpractice insurance premiums have drastically increased.¹⁴⁹ As a result of these increasing insurance

138. *See id.* at 1186.

139. *See id.* at 1183; *see also* Bassler, *supra* note 35, at 695.

140. *See* Moore et al., *supra* note 36, at 1184–85.

141. *See* Sullivan & Anderson, *supra* note 40, at 49–50; *see also* Bassler, *supra* note 35, at 695.

142. *See* Sullivan & Anderson, *supra* note 40, at 50.

143. *See* Coombs, *supra* note 23, at 418; *see also* Killian, *supra* note 27.

144. Coombs, *supra* note 23, at 394–95. Healthcare providers’ performances and evaluations are available through other means. For instance, the National Practitioner Data Bank (NPDB) has information on adverse actions taken by licensing boards, medical malpractice payments and settlements, and hospitals’ actions concerning clinical privileges. However, the general public cannot access the NPDB. In Florida, the Practitioner Profile has information on licensed practitioners (such as their education, staff privileges, and legal and disciplinary actions against them). Yet, because providers themselves report a majority of the information, negative information may be omitted. *Id.* at 418–19.

145. Sawran & Weill, *supra* note 20, at 7; *see also* Sullivan & Anderson, *supra* note 40, at 42 (“The problem is that peer review and medical malpractice litigation are in tension with each other in that medical malpractice litigation feeds off candid criticism of care by converting peer review into a tool to achieve higher verdicts and settlements in individual cases.”).

146. *See* Sawran & Weill, *supra* note 20, at 10.

147. Mike Segal, *The Medical Malpractice Crisis: What’s Going on Here?*, BROAD & CASSEL, <http://www.broadandcassel.com/articles/Mike%20Segal%20Medical%20Malpractice.pdf> (last visited Jan. 29, 2012).

148. *Fassy v. Crowley*, 884 So. 2d 359, 370 (Fla. 2d Dist. Ct. App. 2004).

149. *See* Segal, *supra* note 147, at 1; *see also* FURROW ET AL., *supra* note 1, at 496; Mark V.

premiums, healthcare providers will likely charge higher rates for their services.¹⁵⁰ Additionally, the increase in medical malpractice lawsuits has affected physicians' ability to provide quality healthcare; a 2002 report found that 76% of physicians stated that their concern about medical malpractice litigation has become detrimental to their ability to provide for their patients.¹⁵¹ Therefore, it has been noted that Florida patients, ironically, will suffer the *most* from Amendment 7 because of a decrease in the quality of healthcare and an increase in healthcare costs.¹⁵²

III. THE PATIENT SAFETY AND QUALITY IMPROVEMENT ACT (PSQIA)

A. History and Enactment

Congress passed the PSQIA¹⁵³ in response to the startling findings of the IOM Report.¹⁵⁴ The IOM Report asserted that “the majority of medical errors do not result from individual recklessness or the actions of a particular group—this is not a ‘bad apple’ problem. More commonly, errors are caused by faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent them.”¹⁵⁵ In order to address these systemic flaws, the report recommended that healthcare organizations “develop and participate in voluntary reporting systems” nationwide.¹⁵⁶ Thus, the release of the IOM Report in 1999 fueled the debate about the need for a patient safety law.¹⁵⁷

Pauly, *Who Pays when Malpractice Premiums Rise?*, in *MEDICAL MALPRACTICE AND THE U.S. HEALTH CARE SYSTEM* 71, 71 (William M. Sage & Rogan Kersh eds., 2006); Sullivan & Anderson, *supra* note 40, at 41–42 (describing a debate regarding the degree to which medical malpractice litigation has added substantial clinical and transactional costs). As a result of the recent spike in medical malpractice insurance premiums, many physicians throughout the state have chosen to go “bare” by practicing without insurance. Segal, *supra* note 147, at 1.

150. See Diana Furchtgott-Roth, *The High Cost of Medical Malpractice*, REAL CLEAR MARKETS (Aug. 6, 2009), http://www.realclearmarkets.com/articles/2009/08/06/the_high_cost_of_medical_malpractice_97346.html; Anne Underwood, *Would Tort Reform Lower Costs?*, N.Y. TIMES: PRESCRIPTIONS BLOG (Aug. 31, 2009, 3:45 PM), <http://prescriptions.blogs.nytimes.com/2009/08/31/would-tort-reform-lower-health-care-costs/> (describing an agreement between Senators Orrin G. Hatch (R-UT) and John Kerry (D-MA) that medical malpractice lawsuits are increasing healthcare costs). *But see* TOM BAKER, *THE MEDICAL MALPRACTICE MYTH 3* (2005) (stating that “the real costs of medical malpractice” are not due to litigation, but are a result of malpractice victims’ lost lives, medical expenses, and time out of work).

151. FEAR OF LITIGATION STUDY, *supra* note 133, at 8.

152. See Sawran & Weill, *supra* note 20, at 10.

153. Patient Safety and Quality Improvement Act of 2005, Pub. L. No. 109-41, 119 Stat. 424 (2005) (codified at 42 U.S.C. §§ 299b-21 to -26 (2006)).

154. See Douglas B. Dotan, *Patient Safety Organizations: A New Paradigm in Quality Management and Communication Systems in Healthcare*, 34 J. CLINICAL ENGINEERING 142, 142–43 (2009). For the IOM Report’s findings, see *supra* notes 1–5 and accompanying text.

155. TO ERR IS HUMAN SUMMARY, *supra* note 6, at 2.

156. *Id.* at 3.

157. See Bell, *supra* note 38, at 761.

In 2000, Senator James Jeffords, an independent from Vermont, introduced a patient safety law called the Patient Safety and Errors Reduction Act.¹⁵⁸ However, that Act failed to pass both houses.¹⁵⁹ In 2005, Senator Jeffords sponsored the PSQIA,¹⁶⁰ it was signed into law on July 29, 2005.¹⁶¹ Despite a general acknowledgement of the value of the PSQIA, skeptics questioned the Act's ability to achieve its proposed goals.¹⁶² These concerns regarded the PSQIA's lack of firm requirements ensuring the protection of confidential information, the high financial and administrative costs of implementation, and the unclear relationship between federal and state patient safety legislation.¹⁶³ Despite this skepticism, the Agency for Healthcare Research and Quality (AHRQ) of the Department of Health and Human Services (HHS) published the final rule implementing the PSQIA on November 21, 2008.¹⁶⁴ The Act then became effective on January 19, 2009.¹⁶⁵

Congress enacted the PSQIA to promote "a learning environment that is needed to move beyond the existing culture of blame and punishment that suppresses information about healthcare errors to a 'culture of safety' that focuses on information sharing, improved patient safety and quality and the prevention of future medical errors."¹⁶⁶ Through the PSQIA, Congress sought to improve patient safety and reduce the prevalence of adverse medical incidents by encouraging voluntary peer review participation¹⁶⁷ without the fear of legal disclosure.¹⁶⁸ The IOM Report

158. See Robert A. Kerr, Note, *The Patient Safety and Quality Improvement Act of 2005: Who Should Pay for Improved Conditions?*, 17 HEALTH MATRIX 319, 328 (2007); see also S. 2738, 106th Cong. (2000).

159. See Kerr, *supra* note 158, at 328.

160. S. 544: *Patient Safety and Quality Improvement Act of 2005*, GOVTRACK.US., <http://www.govtrack.us/congress/bill.xpd?bill=s109-544> (last visited Feb. 3, 2012).

161. See Key, *supra* note 7, at 24 (citing Patient Safety and Quality Improvement Act of 2005, Pub. L. No. 109-41, 119 Stat. 424 (2005) (codified at 42 U.S.C. §§ 299b-21 to -26 (2006))). The PSQIA "received bipartisan support each year it was presented to Congress." Kerr, *supra* note 158, at 327.

162. Mark A. Kadzielski & Lynsey A. Mitchel, *An Analysis of the New Federal Patient Safety Law and Final Rule*, J. HEALTH CARE COMPLIANCE, Mar.-Apr. 2009, at 5, 6. Much of this skepticism occurred after the proposed rule implementing the Act was published on February 12, 2008. *Id.* at 6. Beginning February 12, 2008, and ending April 14, 2008 (the public notice-and-comment period), the Department of Health and Human Services (HHS) provided sixty days for public feedback and suggestions for revisions to the proposed rule. *Id.*

163. *Id.*

164. Patient Safety & Quality Improvement, 73 Fed. Reg. 70,732 (Nov. 21, 2008) (codified at 42 C.F.R. pt. 3 (2009)).

165. *Id.*

166. *KD ex rel. Dieffenbach v. United States*, 715 F. Supp. 2d 587, 595 (D. Del. 2010) (quoting S. REP. NO. 108-196, at 3 (2003)) (internal quotation marks omitted).

167. See *id.*

168. See Carolyn M. Clancy, *New Patient Safety Organizations Lower Roadblocks to Medical Error Reporting*, 23 AM. J. MED. QUALITY 318, 319 (2008).

stated that the prevalence of medical errors could be explained by healthcare providers' reluctance to identify errors due to a fear that such information would be used against them in medical malpractice lawsuits.¹⁶⁹ Additional fears include adverse action by hospital disciplinary staff and licensing boards, as well as potential injury to providers' reputations.¹⁷⁰ The PSQIA thus provides that data reported to a PSO are confidential and privileged.¹⁷¹ Healthcare providers may create internal patient safety evaluation systems (PSES) to facilitate the collection and analysis of patient safety event data and can voluntarily report this information to a PSO.¹⁷² By providing privilege and confidentiality protections through the PSQIA, Congress envisioned a patient safety network that provides interactive and evidence-based information to enable healthcare providers to analyze and provide insight into patient safety events and systemic failures.¹⁷³

B. *The Creation of Patient Safety Organizations and the Network of Patient Safety Databases*

A major objective of the PSQIA is the creation of PSOs. As a private or public entity or a component of another organization (a component organization), a PSO's primary purpose is to conduct activities that improve healthcare quality and patient safety.¹⁷⁴ A PSO must be certified and listed by the AHRQ.¹⁷⁵ A listing lasts for three years; in order to remain a PSO, the organization must apply for recertification.¹⁷⁶ However, certain entities cannot qualify as a PSO;¹⁷⁷ excluded entities include any health insurance issuer or component of an insurance issuer and any healthcare oversight entity, such as an accreditation or licensing entity.¹⁷⁸ A "provider" is defined as an individual or entity licensed by a state to provide healthcare services.¹⁷⁹ A PSO must work with more than one provider.¹⁸⁰ There are approximately eighty listed PSOs in roughly thirty

169. See TO ERR IS HUMAN, *supra* note 1, at 109–12.

170. See Key, *supra* note 7, at 24.

171. 42 U.S.C. § 299b-22(a)–(b) (2006); 42 C.F.R. §§ 3.204(a), 3.206(a) (2010); see also Kadzielski & Mitchel, *supra* note 162, at 5.

172. See Kadzielski & Mitchel, *supra* note 162, at 5.

173. See *id.*

174. See *Patient Safety Organizations Fast Facts*, AGENCY FOR HEALTHCARE RES. & QUALITY, <http://www.pso.ahrq.gov/psos/fastfacts.htm> (last visited Jan. 29, 2012) [hereinafter *PSO Fast Facts*]; see also Key, *supra* note 7, at 25.

175. *PSO Fast Facts*, *supra* note 174.

176. 42 U.S.C. § 299b-24(a)(2) (2006); 42 C.F.R. § 3.102(a)(3) (2010).

177. *Id.* § 3.102(a)(2).

178. See *id.*; see also Key, *supra* note 7, at 25.

179. 42 C.F.R. § 3.20 (2010). Examples of providers include hospitals, nursing facilities, physicians, physician assistants, registered nurses, physical or occupational therapists, pharmacists, and certified social workers. *Id.*

180. 42 U.S.C. § 299b-24(b)(1)(C); 42 C.F.R. § 3.102(b)(2)(i)(C); see also Dotan, *supra* note

states and the District of Columbia.¹⁸¹

In order to qualify as a PSO, an entity must meet fifteen general certification requirements.¹⁸² These are divided into eight patient safety activities and seven PSO criteria.¹⁸³ The eight patient safety activities are:

- (1) Efforts to improve patient safety and the quality of health care delivery;
- (2) The collection and analysis of patient safety work product;
- (3) The development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices;
- (4) The utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk;
- (5) The maintenance of procedures to preserve confidentiality with respect to patient safety work product;
- (6) The provision of appropriate security measures with respect to patient safety work product;
- (7) The utilization of qualified staff; and
- (8) Activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system.¹⁸⁴

An entity must also certify the following seven PSO criteria:

- (1) The mission and primary activity of the organization are to conduct activities to promote patient safety and improve the quality of health care delivery;
- (2) The organization must demonstrate that it has appropriately qualified staff;
- (3) It must show that it has contracts with more than one provider to receive and review PSWP;
- (4) It must not be a health insurance issuer;

154, at 144. The multiple healthcare provider requirement guarantees that patient safety event information is, in fact, being exchanged and analyzed in order for one provider to learn from another provider's experiences. *See* Clancy, *supra* note 168, at 319.

181. *Geographic Directory*, *supra* note 14.

182. 42 C.F.R. § 3.102(b).

183. *Id.*

184. 42 C.F.R. § 3.20 (2010).

(5) It must disclose any financial, reporting, or contractual relationship with providers, and whether it is managed, controlled, and operated independently from any provider that contracts with the entity;

(6) It must show that it collects PSWP in a standardized manner; and

(7) It must show that it uses PSWP to provide direct feedback and assistance to providers.¹⁸⁵

In addition to the fifteen general PSO requirements, an organization must also certify that it will (1) keep patient safety work product (PSWP)¹⁸⁶ separate from the parent organization; (2) not make any unauthorized disclosures to the parent organization; and (3) not be in a conflict of interest with the parent organization.¹⁸⁷ The AHRQ is responsible for administering the certification process for a PSO listing and verifying that a PSO has met its requirements.¹⁸⁸ The AHRQ works with a PSO to help resolve compliance issues in order to avoid revoking a PSO's listing.¹⁸⁹ However, if a PSO does not comply with the PSQIA requirements, the AHRQ may revoke that PSO's listing.¹⁹⁰

The PSQIA additionally calls for the creation of a Network of Patient Safety Databases (NPSD) in order to aggregate, analyze, and archive patient safety information received from PSOs.¹⁹¹ The NPSD's goal "is to facilitate aggregation and analyses of patient safety event information to help reduce adverse events and improve healthcare quality."¹⁹² PSOs and other entities, such as HHS and the Center for Medicare & Medicaid Services, will voluntarily contribute non-identifiable PSWP to the NPSD.¹⁹³ The NPSD's findings will be reported to Congress in the AHRQ's annual National Healthcare Quality Report.¹⁹⁴ In order to facilitate the sharing of information, data in the NPSD will conform to

185. 42 U.S.C. 299b-24(b)(1); 42 C.F.R. § 3.102(b)(2)(i); *see also* Key, *supra* note 7, at 27.

186. *See infra* notes 199–201 and accompanying text (defining PSWP).

187. 42 U.S.C. § 299b-24(b)(2); 42 C.F.R. § 3.102(c)(2); *see also* Key, *supra* note 7, at 27.

188. *PSO Fast Facts*, *supra* note 174.

189. *See* Clancy, *supra* note 168, at 320.

190. *Id.* As of early 2012, there were thirty-three delisted PSOs. One PSO was delisted for cause, and one PSO was delisted for expired listing. However, the rest of the delisted PSOs voluntarily relinquished their listing. *Delisted Patient Safety Organizations*, AGENCY FOR HEALTHCARE RES. & QUALITY, <http://www.pso.ahrq.gov/delisted/delistedpsos.htm> (last visited Jan. 21, 2012).

191. *See Network of Patient Safety Databases*, AGENCY FOR HEALTHCARE RES. & QUALITY, <http://www.pso.ahrq.gov/npsd/npsd.htm> (last visited Jan. 29, 2012); *see also* Dotan, *supra* note 154, at 143–44.

192. *Network of Patient Safety Databases*, *supra* note 191.

193. *See id.*; *see also* Dotan, *supra* note 154, at 144.

194. Clancy, *supra* note 168, at 320.

“common formats”—standardized definitions and reporting formats.¹⁹⁵ The AHRQ initially anticipated that the NPSD would begin to receive PSO information in 2010,¹⁹⁶ yet in January 2010 it reported that the database would not launch before February 2011.¹⁹⁷ AHRQ is expected to release a report featuring NPSD information in 2012.¹⁹⁸ As the number of PSOs continues to grow and they begin to submit their patient safety information to the NPSD, the PSQIA will help increase the quality of healthcare by analyzing trends in the delivery of care locally, regionally, and nationally.

C. Patient Safety Work Product and Patient Safety Evaluation Systems: Privilege and Confidentiality Protections

PSWP is “any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements” which: (1) are assembled or created by a provider for PSO reporting and are reported to a PSO; (2) are developed by a PSO in order to conduct patient safety activities; or (3) identify the analysis of a PSES.¹⁹⁹ PSWP does not include a patient’s original patient, provider, medical record, billing, or discharge information.²⁰⁰ Nor does a PSWP include information that is collected or maintained separately from a PSES.²⁰¹

PSWP is submitted to a provider’s patient safety evaluation system (PSES).²⁰² A PSES is “the collection, management, or analysis of information for reporting to or by a [PSO].”²⁰³ A provider’s PSES is a separate and secure physical and electronic space from the provider’s internal risk management, which clearly specifies how and when a provider will report information to its PSO and how such communication will occur.²⁰⁴ PSWP may be removed from a PSES before it has been reported to a PSO; after PSWP has been removed, it is no longer protected under the PSQIA.²⁰⁵

195. See *Network of Patient Safety Databases*, *supra* note 191.

196. *PSO Fast Facts*, *supra* note 174.

197. U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-10-281, REPORT TO CONGRESSIONAL COMMITTEES: PATIENT SAFETY ACT: HHS IS IN THE PROCESS OF IMPLEMENTING THE ACT, SO ITS EFFECTIVENESS CANNOT YET BE EVALUATED 13 (2010).

198. *UHC Patient Safety Organization Featured in National Quality Forum State-Based Reporting Group*, UHC NEWS (Feb. 2011), <https://www.uhc.edu/38712.htm>.

199. 42 U.S.C. § 299b-21(7) (2006); 42 C.F.R. § 3.20 (2010).

200. 42 U.S.C. § 299b-21(7); 42 C.F.R. § 3.20.

201. 42 U.S.C. § 299b-21(7); 42 C.F.R. § 3.20; *see also* AM. MED. ASS’N, THE PHYSICIAN’S GUIDE TO PATIENT SAFETY ORGANIZATIONS 21 (2009), *available at* <http://www.ama-assn.org/ama1/pub/upload/mm/370/patient-safety-organizations.pdf> (illustrating the separation between a provider’s internal risk-management system and PSES).

202. See AM. MED. ASS’N, *supra* note 201, at 10–11, 21.

203. 42 U.S.C. § 299b-21(6); 42 C.F.R. § 3.20.

204. AM. MED. ASS’N, *supra* note 201, at 10, 21 (illustrating the separation between a provider’s internal risk-management system and PSES).

205. *Id.* at 14; *see also* 42 C.F.R. § 3.20.

The PSQIA provides privilege protections to PSWP.²⁰⁶ PSWP is not discoverable pursuant to a federal or state “civil, criminal or administrative subpoena or order.”²⁰⁷ Additionally, PSWP is neither discoverable nor admissible in a federal or state “civil, criminal or administrative proceeding,” including an “administrative proceeding against a provider.”²⁰⁸ PSWP is also inadmissible in a proceeding by a professional disciplinary board authorized by state law.²⁰⁹ Exceptions to PSWP privilege are permitted for the disclosure: (1) of PSWP relevant to a criminal proceeding;²¹⁰ (2) “to provide equitable relief in a private cause of action”;²¹¹ (3) after receiving authorization from each provider;²¹² and (4) “of non-identifiable PSWP.”²¹³ PSWP privilege under the PSQIA is determined and enforced by the court in which the PSWP evidence is presented.²¹⁴ The PSQIA is not a broad federal peer review privilege; instead, Congress created a limited and narrow exception for peer review privilege for PSWP created under PSOs.²¹⁵

In addition to privilege protections, the PSQIA also provides confidentiality protections. PSWP is confidential and not subject to disclosure.²¹⁶ Exceptions to PSWP confidentiality are permitted for the disclosure: (1) of relevant PSWP in a criminal proceeding after an in camera inspection by the court; (2) to provide equitable relief under the Public Health Act; (3) after receiving authorization from identified providers; (4) to perform patient safety activities; (5) of non-identifiable PSWP; (6) for research; (7) to the Food and Drug Administration; (8) to an accrediting entity; (9) for business operations; and (10) to law enforcement.²¹⁷ If the disclosing entity is not a PSO, the disclosure of PSWP is not a confidentiality violation if the PSWP does not include information that either “assesses the quality of care of a provider” or “describe[s] or pertain[s] to one or more actions or failures . . . by a provider.”²¹⁸ The Office of Civil Rights is responsible for the administration and enforcement of PSWP’s confidentiality protections; it investigates all allegations of violations based on “a complaint-driven

206. 42 C.F.R. § 3.204(a).

207. *Id.* § 3.204(a)(1).

208. *Id.* § 3.204(a)(2), (a)(4).

209. *Id.* § 3.204(a)(5).

210. *Id.* § 3.204(b)(1).

211. Key, *supra* note 7, at 26; 42 C.F.R. § 3.204(b)(2).

212. 42 C.F.R. § 3.204(b)(3); *see also* Key, *supra* note 7, at 26.

213. Key, *supra* note 7, at 26; 42 C.F.R. § 3.204(b)(4).

214. *See* Key, *supra* note 7, at 27.

215. Schlegel v. Kaiser Found. Health Plan, 2008 WL 4570619, at *3–4 (E.D. Cal. Oct. 14, 2008).

216. 42 U.S.C. § 299b-22(b) (2006); 42 C.F.R. § 3.206(a).

217. *Id.* § 3.206(b).

218. *Id.* § 3.206(c).

system.”²¹⁹ For each disclosure of confidential PSWP, the HHS Secretary may impose a civil penalty of up to \$10,000 against any PSO, provider, or individual.²²⁰ While a PSO must also comply with HIPAA requirements,²²¹ the same violation for a disclosure of confidential information cannot cause a PSO to be subject to penalties under both the PSQIA and HIPAA.²²²

If PSWP has been disclosed, it remains privileged and confidential unless the disclosure is in a criminal proceeding (in which case PSWP is still privileged, but is no longer confidential) or the disclosure is of non-identifiable PSWP (in which case PSWP is no longer privileged or confidential).²²³ PSQIA privilege protections preempt all federal, state, and local laws that would otherwise limit the protection of PSWP; however, any federal, state, or local law that provides more confidentiality and privilege protection than PSQIA is permissible.²²⁴ In contrast to the HCQIA’s narrow protection for peer review activities affecting individual physicians, the PSQIA provides a broad protection for all PSWP.²²⁵

D. *The Judicial Response to and the Future of the PSQIA*

Since 2005, few cases have involved the PSQIA. In 2008, in a California case, *Schlegel v. Kaiser Foundation Health Plan et al.*,²²⁶ the defendant healthcare company argued that the PSQIA created a broad federal peer review privilege and objected to the plaintiff’s request for production of peer review documents relating to an investigation of the defendant’s transplant program.²²⁷ The court stated that the PSQIA created a limited, narrow exception for peer review privilege for PSWP; it is not “a broad federal peer review privilege.”²²⁸ The court refused to apply the PSQIA’s privilege protections because there was no evidence that the contested documents were prepared for or reported to a PSO by the defendant. The court additionally pointed out that none of the defendant entities was a listed PSO itself.²²⁹

219. *PSO Fast Facts*, *supra* note 174. A complaint must be filed with the HHS Secretary within 180 days of when the complainant knew or should have known of a violation. 42 C.F.R. § 3.306. There is a six-year statute of limitations for a violation under the PSQIA. *Id.* § 3.414.

220. *PSO Fast Facts*, *supra* note 174.

221. *Id.*

222. 42 C.F.R. § 3.418.

223. *Id.* § 3.208.

224. *Key*, *supra* note 7, at 26.

225. *See KD ex rel. Dieffenbach v. United States*, 715 F. Supp. 2d 587, 594–96 (D. Del. 2010).

226. 2008 WL 4570619, at *1 (E.D. Cal. Oct. 14, 2008).

227. *Id.* at *1–2.

228. *Id.* at *3.

229. *Id.*

In contrast, a Delaware court, in *KD ex rel. Dieffenbach v. United States*,²³⁰ prevented the disclosure of peer review documents by the National Heart, Lung, and Blood Institute of the National Institutes of Health even though the review bodies may not have met “the technical requirements for listing as PSOs.”²³¹ That court reasoned even if the defendant review bodies did not meet the technical requirements for a listed PSO, “they clearly perform the same functions Congress intended the PSQIA to encourage.”²³² The court further explained that the defendant’s review process “collects the same kind of safety data as enumerated in the PSQIA, within the same organizational structure, to accomplish the same goal (i.e., ensuring participant safety and effectiveness of care).”²³³ Additionally, the *Dieffenbach* court stated that, as compared to the HCQIA, the PSQIA “announces a more general approval of the medical peer review process and more sweeping evidentiary protections for materials used therein.”²³⁴ The court explained that while the HCQIA was created to restrict physicians from moving across states without disclosing their previous performances, the PSQIA was implemented to address healthcare’s systemic weaknesses that result in preventable adverse medical incidents.²³⁵

While PSQIA case law currently remains limited, litigation involving the PSQIA will likely increase in the coming years due to the growing number of PSOs.²³⁶ PSOs have recently been listed as one of the top ten issues in health law.²³⁷ As the scope of the PSQIA remains undecided within the judicial system, the functioning and application of the PSQIA is in the hands of healthcare providers.²³⁸ Joining a PSO and submitting information to the NPSD are voluntary acts.²³⁹ Therefore, for the PSQIA to have a beneficial effect on the healthcare system, healthcare providers must actively participate by willingly submitting patient safety information and learning from the data to improve the quality of healthcare.²⁴⁰

230. 715 F. Supp. 2d 587 (D. Del. 2010).

231. *Id.* at 588–90, 596–98.

232. *Id.* at 596.

233. *Id.* at 597.

234. *Id.* at 595.

235. *Id.*

236. *See supra* text accompanying note 181 (describing the approximate number of listed PSOs).

237. Molly Merrill, *Top 10 Health Law Issues for 2010*, HEALTHCARE IT NEWS (Feb. 19, 2010), <http://www.healthcareitnews.com/news/top-ten-health-law-issues-2010>.

238. *See* Clancy, *supra* note 168, at 319 (“Health care providers will make the key decisions about how this system will work in practice.”).

239. *Id.* at 319. Providers also choose what information they will submit to a PSO or the NPSD. *Id.*

240. *Id.* at 319–20.

IV. WILL THE PSQIA BE THE CURE TO AMENDMENT 7?

A. *Amendment 7 and the PSQIA*

Although Amendment 7 remains in full effect, Florida healthcare practitioners are well aware that the scope of its application is limited to records.²⁴¹ Amendment 7 has not removed many of the legal protections against disclosure of peer reviewers' identity, compelling of testimony, and use of litigation information.²⁴² Yet, the peer review process in Florida remains in potential peril.

Effective confidentiality and privilege protections are essential to peer review reporting in order to address medical errors.²⁴³ Thus, critics of Amendment 7 suggest that the PSQIA may provide protection from Amendment 7's broad scope.²⁴⁴ Still, the interplay between Amendment 7 and the PSQIA remains unknown.²⁴⁵ While Amendment 7 has been (unsuccessfully) challenged based on federal preemption, these federal claims included alleged conflict with the HCQIA, the Contracts Clause, and HIPAA; however, Amendment 7 has not yet been challenged as being federally preempted by the PSQIA.²⁴⁶

241. See Parisi & Tsitsakis, *supra* note 118, at 11–12.

242. Memorandum, Benedict & Assoc., Inc., Peer Review in Florida Since Constitutional Amendment 7 Passed, available at http://www.benedictriskmanagement.com/docs/Peer_review_06062006.pdf (last visited Jan. 29, 2012).

243. See Key, *supra* note 7, at 27.

244. See Coombs, *supra* note 23, at 418 (“[T]he Patient Safety & Quality Improvement Act of 2005 may provide federal protection against discoverability for at least some of these records.”); see also Parisi & Tsitsakis, *supra* note 118, at 12 (“[The PSQIA] could form the basis for a preemptive challenge to Amendment 7.”); Yaeger, *supra* note 33, at 149 (“Since the passage of Amendment 7, more hospitals may choose to voluntarily report patient safety work product to patient safety organizations to benefit from the federal privilege and confidentiality.”); *The Amendment 7 Challenge*, *supra* note 116 (asking whether a PSO is hype or hope in reference to Amendment 7); *Florida Peer Review After Amendment 7*, *supra* note 49, at 3 (“[H]ospitals and hospital systems should consider establishing their own PSO to receive their PSWP.”); *Welcome, MED. PEER REV. RES., LLC*, <http://www.medicalpeerreviewresource.com/index.php> (last visited Oct. 30, 2011) [hereinafter MPRR] (“The PSO can provide Florida physicians and healthcare providers with [Amendment 7] protection.”).

245. While the interplay between Amendment 7 and PSQIA has not yet been determined in the courts, the Medical Peer Review Resource, LLC PSO states on its website that “all patient safety work product is privileged and confidential under federal law, which trumps state law, including Amendment 7.” MPRR, *supra* note 244.

246. See *Columbia Hosp. Corp. of S. Broward v. Fain*, 16 So. 3d 236, 241–44 (Fla. 4th Dist. Ct. App. 2009); see also *W. Fla. Reg. Med. Ctr. v. See*, 18 So. 3d 676, 684–88 (Fla. 1st Dist. Ct. App. 2009); *Complaint for Injunctive and Declaratory Relief* at 20–26, 37–40, *Fla. Hosp. Ass’n v. Viamonte*, 2008 WL 5101755 (N.D. Fla. July 10, 2008) (No. 4:08-cv-312-RH/WCS), ECF No. 1; *Harris*, *supra* note 26, at 27 n.77.

B. How to Become a Patient Safety Organization in Florida

The AHRQ accepts applications for PSO listings at any time; there is no application deadline.²⁴⁷ Applicants are able to access all of the requisite forms and information from the AHRQ website.²⁴⁸ An applicant can either join an existing PSO or create a new PSO by joining with other entities. Of the approximate eighty listed PSOs, there are about eight in Florida.²⁴⁹ However, this does not mean that Florida healthcare providers are restricted to joining a Florida PSO as PSOs are composed of members from various states.²⁵⁰

The PSQIA creates confidentiality and privilege protections for PSWP submitted to a PSO.²⁵¹ However, if the PSWP contains any information that must be reported to the state, then that information cannot be protected under the PSQIA.²⁵² Pursuant to Florida Statutes section 395.0197, a licensed facility's internal risk-management program is required to submit adverse incident reports to the Agency for Health Care Administration: annually, for certain categories of incidents (annual reports); and within fifteen days of the occurrence, for other statutorily defined incidents (Code 15 reports).²⁵³ Therefore, neither annual reports nor Code 15 reports are protected as PSWP under the PSQIA, even if they are submitted to a PSO.²⁵⁴ In contrast, while both Florida²⁵⁵ and the Joint Commission²⁵⁶ require that healthcare providers have a peer review system, the state does not require the reporting of peer review documents,²⁵⁷ which thus remain protected as PSWP. Therefore, when creating a PSO in Florida, it is important to recognize that Code 15 and annual adverse incident reports are not protected PSWP and that the PSES is a separate system from the

247. *PSO Fast Facts*, *supra* note 174.

248. *See Patient Safety Organization Forms*, AGENCY FOR HEALTHCARE RES. & QUALITY, <http://www.pso.ahrq.gov/listing/psoforms.htm> (last visited Jan. 29, 2012); *see also Patient Safety Organization Listing Information*, AGENCY FOR HEALTHCARE RES. & QUALITY, <http://www.pso.ahrq.gov/listing/listprocess.htm> (last visited Jan. 29, 2012).

249. *Geographic Directory*, *supra* note 14.

250. For instance, the UHC Patient Safety Net (PSN) PSO has approximately 100 participating organizations and more than 800 nationwide "Patient Safety Leaders" on its "PSN Quality/Risk/Safety Listserve." *Highlights of the Patient Safety Net Program*, UNITED HEALTH SYS. CONSORTIUM, https://www.uhc.edu/docs/49013841_PSNhighlights.pdf (last visted Sept. 25, 2011). Officially listed on November 5, 2008, and registered in Illinois, UHC PSN is a component entity of the University HealthSystem Consortium. *Geographic Directory*, *supra* note 14.

251. *See supra* Section III.C.

252. 42 U.S.C. § 299b-21(7)(B) (2006).

253. FLA. STAT. § 395.0197(6)–(7); *see also Reporting*, FLA. AGENCY FOR HEALTH CARE ADMIN., <http://www.fdhc.state.fl.us/SCHS/risk/reporting.shtml> (last updated Jan. 31, 2011).

254. *See* 42 U.S.C. § 299b-21(7).

255. FLA. STAT. § 395.0193(2).

256. *See supra* Part I.

257. *See* FLA. STAT. § 395.0193(2).

state-mandated internal risk-management program.²⁵⁸

C. *Why Florida Healthcare Providers Should Join Patient Safety Organizations*

More than ten years after the publication of the IOM Report, the need to address patient safety events remains vital. Recent studies indicate that the number of adverse events has increased.²⁵⁹ A 2002 study stated that an estimated 8.1 million Americans have “experienced a serious medical or drug error.”²⁶⁰ As of 2010, one in seven hospitalized Medicare patients experienced an adverse medical event; these events cause approximately 180,000 deaths a year.²⁶¹ In November 2010, a study of ten North Carolina hospitals reported, “[H]arms remain common, with little evidence of widespread improvement. Further efforts are needed to translate effective safety interventions into routine practice and to monitor healthcare safety over time.”²⁶² Dr. Carolyn M. Clancy, director of the AHRQ since 2003, explained that the increase of adverse events is partly due to better tracking and broader definitions of what are preventable incidents.²⁶³ Since the publication of the IOM Report, healthcare providers have taken measures to improve patient safety.²⁶⁴

One way that Florida healthcare providers can address the prevalence of adverse events is by joining a PSO. As more Florida providers join the approximately eight listed Florida PSOs and the other PSOs listed outside of Florida,²⁶⁵ the quality of healthcare across the state will likely increase because providers will no longer be afraid to participate in the peer review process. If their adverse medical incident reports are PSWP under a listed PSO, such reports would no longer be subject to Amendment 7. Florida providers under a PSO will be able to engage in the type of candid, specialized medical evaluation favored by the *Holly* and *Cruger* courts.²⁶⁶ The PSQIA provides PSWP protections in order to remove barriers, such as Amendment 7, “that can deter the participation of health care providers

258. See AM. MED. ASS'N, *supra* note 201, at 21 (illustrating a depiction of the flow of information between an internal risk-management program and a PSES).

259. Manoj Jain, *Focus on Patient Safety Hasn't Succeeded*, WASH. POST, Dec. 21, 2010, at E05.

260. *New Study Estimates Eight Million American Families Experienced a Serious Medical or Drug Error*, COMMONWEALTH FUND (Apr. 15, 2002), <http://www.commonwealthfund.org/Content/News/News-Releases/2002/Apr/New-Study-Estimates-Eight-Million-American-Families-Experienced-A-Serious-Medical-Or-Drug-Error.aspx>.

261. Jain, *supra* note 259.

262. Christopher P. Landrigan et al., *Temporal Trends in Rates of Patient Harm Resulting from Medical Care*, 363 NEW ENG. J. MED. 2124, 2124 (2010).

263. Jain, *supra* note 259.

264. See Clancy, *supra* note 168, at 318; see also Jain, *supra* note 259.

265. See *supra* note 14 and accompanying text.

266. See *supra* Section II.A (discussing *Holly* and *Cruger*).

in patient safety and quality improvement initiatives, such as fear of legal liability or professional sanctions.”²⁶⁷ However, a healthcare provider cannot merely join a PSO in order to avoid falling under Amendment 7. The primary mission and activity of a PSO must be to conduct activities to improve healthcare quality and patient safety.²⁶⁸ A PSO should not be viewed simply as a method to avoid Amendment 7; instead, healthcare providers across Florida should join PSOs to counteract Amendment 7’s effect on the peer review process. By sharing patient safety information through the protections of a PSO, the quality of healthcare can be increased throughout the state.

Thus, by joining a PSO, Florida healthcare providers will improve the quality of healthcare not only by protecting the peer review process, but also by analyzing and aggregating information submitted to PSOs. Dr. Clancy described two roadblocks that have hindered the improvement of the quality of healthcare since the IOM Report: the lack of uniform federal confidentiality and privilege standards regarding patient safety event information;²⁶⁹ and the inability of healthcare providers to share patient safety data with other providers—locally, regionally and nationally—to identify and analyze trends in order to reduce adverse medical events.²⁷⁰ The PSQIA addresses these two roadblocks by creating federal confidentiality and privilege protections for PSWP as well as information-sharing entities through individual PSOs and the NPSD.

Similar to peer review’s use of medical expert evaluation, PSOs also supply analysis and evaluation of patient safety events by medical experts.²⁷¹ The exchange of information within a PSO offers providers an outside perspective on other providers’ systemic flaws; the peer review process—conducted internally, within a provider’s system—is generally unable to facilitate the same. Participation in a PSO enables providers to learn from the experiences of other providers.²⁷² Submitted information can be aggregated to develop an understanding of the underlying causes and trends of adverse events and near-misses at a local, regional, and national level.²⁷³ For instance, the Illinois-based Society for Vascular Surgery (SVS) PSO²⁷⁴ shares patient safety information between regional

267. *PSO Fast Facts*, *supra* note 174.

268. *See supra* Section III.B.

269. Clancy, *supra* note 168, at 318. Dr. Clancy further explained that state peer review protections are limited or nonexistent (as in Florida); thus, the fluctuating degree of protection has contributed to the fear of liability and sanctions among healthcare providers. *Id.*

270. *Id.*

271. *PSO Fast Facts*, *supra* note 174.

272. *See* AM. MED. ASS’N, *supra* note 201, at 3; *see also* Clancy, *supra* note 168, at 319 (“This continuous confidential flow of information will serve an important educational role for individual and multiple organizations.”).

273. Clancy, *supra* note 168, at 320; *see also* *PSO Fast Facts*, *supra* note 174.

274. *Geographic Directory*, *supra* note 14. As a specialty-based PSO, the SVS PSO enables

groups, including Carolinas Vascular Study Group, Florida Vascular Study Group, Mid-Atlantic Vascular Study Group, Southern California Vascular Study Group, Southern Vascular Outcomes Network, and Vascular Study Group of New England.²⁷⁵ Therefore, a PSO is essentially a “learning organization” that applies acquired knowledge to help the organization adapt to change²⁷⁶ by promoting the sharing of patient safety data outside of a provider’s own system on a larger geographic scale.

Admittedly, joining a PSO presents some disadvantages. For instance, once information is placed in a PSO, it can no longer be removed.²⁷⁷ This inability to retrieve PSO-submitted PSWP is especially critical to a physician who sues after the loss of privileges following a peer review committee review; the physician will be unable to access the document in order to defend against the committee’s allegations.²⁷⁸ Additionally, the terminating committee is unable to use its findings in the peer review document to support its decision to terminate the physician’s privileges. The protection of PSWP submitted to a PSO will also limit a physician’s ability to defend with PSWP in a medical malpractice lawsuit.²⁷⁹ Furthermore, this inability to retrieve documents submitted to a PSO has dramatic implications in combination with Florida’s “Three Strikes” Amendment, which mandates revocation of a physician’s license following three or more instances of medical malpractice.²⁸⁰ The PSQIA is silent on how long PSWP can remain in a PSES; thus, healthcare providers can wait months or even years before submitting patient safety event information to a PSO.²⁸¹ The information is still protected PSWP because it is located within a PSES.²⁸² However, withholding information from a PSO can delay the analysis of current information.

the sharing of data from specific vascular treatments. *See SVS PSO*, VASCULARWEB (Mar. 2011), <http://www.vascularweb.org/practiceresources/svs-psyso/Pages/SVS-PSO.aspx> [hereinafter *SVS PSO*].

275. *SVS PSO*, *supra* note 274.

276. Dotan, *supra* note 154, at 142.

277. 42 C.F.R. § 3.20 (2010); AM. MED. ASS’N, *supra* note 201, at 14.

278. This disadvantage is a similar argument used by peer review critics. *See supra* Section II.D.

279. *See supra* Section II.D.

280. *See supra* note 24.

281. Florida healthcare providers can be guided by the medical malpractice statute of limitations and statute of repose in determining when a provider may need to access the submitted materials in order to defend itself in a medical malpractice lawsuit. *See* FLA. STAT. § 95.11(4)(b). However, because Amendment 7’s application has been upheld in lawsuits other than medical malpractice, such as a lawsuit for defamation and tortious interference with a business relationship in *Amisub North Ridge Hospital, Inc. v. Sonaglia*, 995 So. 2d 999, 1000–01 (Fla. 4th Dist. Ct. App. 2008), healthcare providers should not rely fully on the medical malpractice statute of limitations and statute of repose.

282. *See* AM. MED. ASS’N, *supra* note 201, at 21.

Additionally, PSOs are not federally funded²⁸³ and forming or joining a PSO can be expensive. For instance, the Patient Safety Organization of Florida, Inc., requires an annual subscription fee of \$35.00 per licensed bed.²⁸⁴ Additional costs for joining a PSO include the hiring and training of PSO staff and the creation of facilities for storing PSWP. Because providers within a PSO may not have the same reporting databases or software, PSOs may also incur costs related to the common formatting of PSEs. In order to address this problem, the members of Clarity PSO use Healthcare SafetyZone Portal.²⁸⁵ While the use of the same software addresses common formatting issues, it also increases costs for joining a PSO because a healthcare provider must incur costs for purchasing the software and training staff.

Despite these costs, PSOs foster a “learning organization” in which healthcare providers can learn from their mistakes and from the mistakes of others.²⁸⁶ While Amendment 7 has become an obstacle to peer review’s effectiveness and Florida providers’ ability to analyze and learn from patient safety events, PSOs offer an alternative route to ensure the quality of healthcare. Through the sharing of patient safety event information between providers within PSOs and the NSPD, Florida providers will be able to counteract Amendment 7 and guarantee that the exchange of this data continues. As a result, there will likely be fewer adverse medical incidents and thus fewer medical malpractice lawsuits,²⁸⁷ resulting in reduced court costs, reduced attorney’s fees, fewer settlements, and lower medical malpractice premiums. As consumer patients, Floridians will benefit from reduced medical costs and increased quality of healthcare.

CONCLUSION

The full effect of the PSQIA on the quality of healthcare has yet to be determined. As the number of PSOs continues to increase and the level of interaction between PSOs and the NPSD continues to grow, the assessment of patient safety information will foster a learning environment among healthcare providers. Recognizing the need for development, Dr. Clancy stated, “The AHRQ expects that health providers and PSOs will climb a

283. See Kerr, *supra* note 158, at 323.

284. Memorandum from Bruce Rueben, President, Fla. Hosp. Ass’n, and Linda Quick, President, S. Fla. Hosp. & Healthcare Ass’n, to Hospital Executive (Sept. 21, 2009), available at www.psoflorida.com/files/PSO-ExecutiveLtr0809.doc.

285. See *Healthcare SafetyZone Portal*, CLARITY GRP., INC., http://www.claritygrp.com/media/3783/portal_brochure_2011_-_4_sep._pages.pdf; *Clarity PSO*, CLARITY GRP., INC., <http://www.claritygrp.com/media/9623/claritypsobrochure2011.pdf>.

286. Dotan, *supra* note 154, at 142–44, 146.

287. See Sullivan & Anderson, *supra* note 40, at 46 (“When hospital conditions and patient care improve and the rates of death and disease decline, the number of medical malpractice lawsuits should decline.”).

steep learning curve as they become familiar with this new mechanism.”²⁸⁸

In the meantime, Amendment 7 remains in effect and continues to broaden its scope into the once-privileged and confidential peer review process. Because the Florida Supreme Court firmly ratified Amendment 7,²⁸⁹ Florida healthcare providers’ best hope is for a successful amendment to repeal Amendment 7 in the near future.²⁹⁰ Otherwise, providers can counteract Amendment 7 and ensure the quality of healthcare for Florida patients by joining a PSO and participating in the NPSD. Thus, the “chilling” caused by a lack of confidentiality and privilege protections for peer review documents may be warmed up for providers who participate in PSOs and submit peer review as PSWP. However, preventable adverse medical errors and near-misses may not be effectively analyzed and addressed through the peer review process in Florida unless providers incur the costs of joining a PSO. There may be other methods to avoid the broad reach of Amendment 7. For instance, some suggest that the closer involvement of attorneys in the peer review process could bring peer review records under the protection of the attorney-client privilege or work-product doctrine.²⁹¹ Additional suggestions to help the peer review process adapt to Amendment 7 include: substituting written documents with oral discussions; including only facts in incident reports and eliminating all commentary; and deleting negative language in peer review documents.²⁹²

288. Clancy, *supra* note 168, at 320. Due to this learning curve, AHRQ is available for assistance to help PSOs. *Id.*

289. See *supra* Section II.C.

290. For example, Florida voters approved a constitutional amendment for a high-speed train system throughout the state in the November 2000 election. *November 7, 2000 General Election, Official Results, Constitutional Amendment*, DIV. ELECTIONS, FLA. DEP’T STATE, <http://doe.dos.state.fl.us/elections/resultsarchive/SummaryRpt.asp?ElectionDate=11/7/2000&Race=AMD> (last visited Jan. 29, 2012). Yet in 2004, then-Governor Jeb Bush endorsed an effort to repeal the amendment due to its immense costs. *Overview*, FLA. HIGH SPEED RAIL, http://www.floridabullettrain.com/fhsra/1_overview.html (last visited Jan. 29, 2012). Featured on the same ballot as Amendment 7 in November 2004, the repeal of the high-speed rail amendment was approved by the voters. *2004 Election Results*, *supra* note 22.

291. Coombs, *supra* note 23, at 418. Yet, courts throughout Florida have held that adverse incident reports are not protected under the attorney work-product protection and are subject to discovery under Amendment 7. See *Fla. Eye Clinic v. Gmach*, 14 So. 3d 1044, 1049–50 (Fla. 5th Dist. Ct. App. 2009); *Lakeland Reg’l Med. Ctr. v. Neely ex rel. Neely*, 8 So. 3d 1268, 1269–71 (Fla. 2d Dist. Ct. App. 2009). In *Gmach*, the Fifth District reasoned that when the disputed adverse incident reports were created, defense counsel had not yet been consulted or even involved in the lawsuit. The court further explained that even if the reports were created in anticipation of litigation, they were fact work product because they did not represent defense counsel’s opinions of the lawsuit. *Gmach*, 14 So. 3d at 1050–51. Therefore, later involvement of attorneys will not immunize the disclosure of adverse incident reports under Amendment 7; involvement would have to occur at the earlier creation stages of the reports.

292. See Parisi & Tsitsakis, *supra* note 118, at 12.

The coming years will demonstrate the effect of Amendment 7 on the peer review process in Florida. While the relationship between Amendment 7 and the PSQIA has yet to be fully determined, the peer review process in Florida still remains in potential danger even under the confidentiality and privilege protections of the PSQIA. The PSQIA only provides protection to PSWP and does not afford protection to any reports required under state statutes. Thus, Code 15 and annual reports pursuant to section 395.0197 are still under Amendment 7's scope. Because of this lack of protection by the state, some commentators have advocated for the creation of a uniform and consistent federal peer review privilege by Congress.²⁹³ However, as evidenced by the controversy surrounding the passage of healthcare reform in 2010, any additional proposals to change the national healthcare system will likely face steadfast opposition; therefore, such attempts probably will not be made in the near future. In the meantime, the quality of healthcare for Florida patients remains at stake.

293. See Clancy, *supra* note 168, at 318; Sullivan & Anderson, *supra* note 40, at 86–87.