

Peer Review Is Threatened, but (P)So What: Patient Safety Organization Utilization in Florida After Amendment 7 as a Troubling Sign for PSQIA

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This Note considers the interaction between medical peer review, patient safety organizations (PSOs) and Florida's Amendment 7, also known as the Patients' Right to Know. All three are directed towards curing the epidemic of medical error in the United States: peer review allows doctors and hospitals to evaluate adverse medical incidents, PSOs were conceived of as a clearinghouse for data about medical error that can be analyzed in exchange for confidentiality and privilege for the data, and Amendment 7 makes information about adverse incidents more accessible to patients and the malpractice litigation system. The confluence of these forces also gave rise to a natural experiment. Because Amendment 7 threatened the confidentiality of the peer review system, Florida healthcare providers had a unique incentive to create PSOs to take advantage of the associated confidentiality and privilege. This Note examines the evidence, primarily from PSO registrations, and concludes that Florida providers in fact did not make use of PSOs in addressing Amendment 7 challenges, suggesting that PSOs might be flawed. The Note examines some of these flaws, and offers some suggestions for improving PSOs to make them more attractive for healthcare providers.

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I. INTRODUCTION

In 2002, while undergoing surgery for sinus problems, Annie Acosta's surgeon punctured her brain and damaged her eye, resulting in double vision unless she walks with her head down.¹ After suing her physician, Acosta was awarded \$350,000.² Five years later, in 2007, the story of another woman, Claudia Mejia drew attention-grabbing headlines across the nation; representative is the Associated Press Wire's headline "Florida Woman Sues Hospital After She Contracted Flesh-Eating Bacteria, Lost All Her Limbs."³ Drawing interest nationwide⁴ but particularly in her native Florida, Mejia's experience with Florida hospitals was truly disturbing: she contracted her condition in the hospital after delivering a healthy boy, and only twelve days later doctors amputated her legs and most of her arms.⁵

Acosta and Mejia were not healed by their interactions with the United States medical system, but were rather left permanently scarred. They are not alone, as medical error has been described as an epidemic.⁶ They also share another feature: both women saw their stories made very public as part of the bitter debate in Florida surrounding Amendment 7, termed the Patients' Right to Know About Adverse Medical Incidents.⁷ Acosta's story was featured in the Florida press as an example of a case that would turn out differently after the passage of Amendment

1. Cherie Black, *Doctors Will Face Tougher Rules With New Laws*, THE FLORIDA TIMES-UNION (Nov. 8, 2004), http://jacksonville.com/tu-online/stories/110804/met_17129292.shtml.

2. *See id.*

3. *Florida Woman Sues Hospital After She Contracted Flesh-Eating Bacteria, Lost All Her Limbs*, ASSOCIATED PRESS FINANCIAL WIRE, Apr. 3, 2007.

4. *See, e.g., Live from 1 PM EST* (CNN television broadcast Jan. 20, 2006) (transcript on file with the *Columbia Journal of Law and Social Problems*).

5. Rene Stutzman, *Mom Sues for Answers About Loss of Limbs*, ORLANDO SENTINEL (Jan. 21, 2006), http://articles.orlandosentinel.com/2006-01-21/news/FLESH21_1_mejia-bacteria-orlando-regional; *see also* Rene Stutzman, *Sanford Mom Settles Flesh-Eating Bacteria Case*, ORLANDO SENTINEL (May 19, 2009), http://articles.orlandosentinel.com/2009-05-19/news/flesh_1_orlando-health-orlando-regional-bacteria; Rene Stutzman, *Hospital Must Provide Records*, ORLANDO SENTINEL, Apr. 28, 2007, at B3.

6. *To Err is Human: Building a Safer Health System (Report Brief)*, INST. OF MED. 1 (Nov. 1999), <http://www.iom.edu/~media/Files/Report%20Files/1999/To-Err-is-Human/To%20Err%20is%20Human%201999%20%20report%20brief.pdf>.

7. FLA. CONST. art. X, § 25.

7,⁸ while papers dubbed Mejia “the woman who has become the symbol for Amendment 7” in the wake of her disturbing incident playing out against a prolonged court battle about the meaning and reach of Amendment 7 in Florida.⁹

There are many systems in place to try to address the medical-error epidemic. This Note considers the interaction of a few of these different institutions: medical peer review, patient safety organizations, and the legal system.

Medical peer review is a process in which a committee assesses the quality of care provided by a particular physician, often in the wake of an adverse medical incident.¹⁰ These committees evaluate a physician’s work with an eye towards determining whether that physician should continue to be allowed to practice in the hospital’s facilities.¹¹ Maintaining a medical peer review process is a requirement for a hospital’s accreditation by the Joint Commission on Accreditation of Hospitals (JCAHO).¹² To encourage doctors to participate in the peer review process, the federal Health Care Quality and Improvement Act (HCQIA) provides federal immunity from civil money damages for the doctors that sit on the committees.¹³ States often provide similar grants of immunity.¹⁴ Moreover, the notes, analyses and work product of the peer review process can be granted protection from certain

8. Black, *supra* note 1. The article also describes the effect on the case of other Florida constitutional amendments passed simultaneously. See Black, *supra* note 1.

9. Carol Gentry, *The Right to Know*, THE TAMPA TRIBUNE (May 17, 2007) <http://m2.tbo.com/content/2007/may/17/the-right-to-know/>.

10. Susan O. Scheutzow, *State Medical Peer Review: High Cost But No Benefit — Is It Time for a Change?*, 25 AM. J.L. & MED. 7, 7–8 (1999).

11. Charles R. Koepke, *Physician Peer Review Immunity: Time to Euthanize a Fatally Flawed Policy*, 22 J.L. & HEALTH 1, 4 (2009).

12. *Standards FAQ Details*, THE JOINT COMMISSION, http://www.jointcommission.org/mobile/standards_information/jcfaqdetails.aspx?StandardsFAQId=76&StandardsFAQChapterId=74 (last visited Jan. 30, 2013); see also Skip Freedman, *How 2007 Joint Commission Standards Expand Hospital Peer Review*, PATIENT SAFETY & QUALITY HEALTHCARE (Sept./Oct. 2007), <http://www.psqh.com/sepoct07/peer.html>; *How To Apply the 2007 Joint Commission Standards to Hospital Peer Review: A Practical Guide*, ALLMED HEALTHCARE MGMT. 2 (2007), http://www.allmedmd.com/landing-pages/ppc-downloads/copy_of_Allmed-JCAHO-Standards.pdf. The JCAHO is an independent non-profit that accredits hospitals. *About the Joint Commission*, THE JOINT COMMISSION, http://www.jointcommission.org/about_us/about_the_joint_commission_main.aspx (last visited Jan. 30, 2013).

13. 42 U.S.C. § 11111 (2006).

14. See, e.g., COLO. REV. STAT. ANN. § 12-36.5-105 (West Supp. 2012).

discovery actions by state confidentiality laws.¹⁵ Though not without skeptics,¹⁶ the consensus is that these protections are an important part of maintaining participation in review committees and thus a functioning peer review system that will reduce the incidence of medical error.¹⁷

Another way to reduce medical error is through patient safety organizations (PSOs). As part of the push to reduce medical error following the influential Institute of Medicine report “To Err is Human,” Congress enacted the Patient Safety Quality Improvement Act (PSQIA) in 2005.¹⁸ PSQIA provides for the creation of PSOs as clearinghouses for patient-safety information and analysis, which will accept data from healthcare providers and provide recommendations about ways to reduce medical error.¹⁹ PSOs can be entities maintained by healthcare providers or can be independent entities that contract with providers for their data.²⁰ While the PSOs report their conclusions and certain non-identifying data to other sources, the patient safety work product (PSWP) the provider sends to a PSO is given confidentiality protections.²¹ After a lengthy process of soliciting comments from stakeholders, the PSO rules were finalized in early 2009 by the Department of Health and Human Services,²² and as of January 2012 the Agency for Healthcare Research and Quality — the agency tasked with supervising PSOs — lists seventy-eight PSOs in thirty-one states.²³

Another important force in combating medical error is the litigation system, which is premised on assessing fault and requiring damages be paid from a blameworthy party to the victim.²⁴ Under the theory of this system, information that is protected by

15. See, e.g., LA. REV. STAT. ANN. § 13:3715.3 (Supp. 2013).

16. E.g., Scheutzow, *supra* note 10.

17. George E. Newton II, *Maintaining the Balance: Reconciling the Social and Judicial Costs of Medical Peer Review Protection*, 52 ALA. L. REV. 723, 728–29 (2001).

18. Patient Safety Quality Improvement Act of 2005, Pub. L. No. 109-41, 119 Stat. 424.

19. 42 U.S.C. § 299b-21 (2006).

20. *Patient Safety Organization Information*, AGENCY FOR HEALTHCARE RESEARCH & QUALITY, <http://www.pso.ahrq.gov/psos/overview.htm> (last visited Jan. 30, 2013).

21. *Id.*

22. Patient Safety and Quality Improvement Final Rule, 42 C.F.R. § 3 (2012).

23. *Listed Patient Safety Organizations*, AGENCY FOR HEALTHCARE RESEARCH & QUALITY, <http://www.pso.ahrq.gov/listing/psolist.htm> (last visited Jan. 30, 2013).

24. Charles Key, *Toward a Safer Health System: Medical Injury Compensation and Medical Quality*, 37 U. MEM. L. REV. 459, 466–67 (2007).

peer review is part of the litigation process and should be discoverable and admissible under the general principles of civil procedure and evidence law.²⁵ This means that the litigation system and the peer review system often find themselves at cross-purposes despite both serving to help patients and reduce the total incidence of medical error.²⁶

This Note will center on Amendment 7, passed by Florida voters in 2004, which added Section 25 to the Florida Constitution.²⁷ As part of a fight between Florida's medical community and the state plaintiff bar, the amendment provides that "patients have 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."²⁸ After a struggle in the legislature and court system over the scope of this amendment, the Florida Supreme Court issued a seemingly final word in 2008, reading the amendment broadly and using it to strike down some of the statutory protections that Florida had offered peer review.²⁹ Following this determination, Florida's healthcare providers were in a tough position, particularly with regard to peer review. They were required to and interested in maintaining the process, but with all the information open to discovery, the integrity of the peer review process seemed in danger.³⁰

One potential response to this threat was the increased use of PSOs. By identifying peer review materials as PSWP, Florida's hospitals could have used the federal protections offered by PSQIA to restore some of the protections for peer review stripped by Amendment 7.³¹ This use of PSOs as a strategic option for combating Amendment 7's effects has been described in recent

25. Newton, *supra* note 17, at 727.

26. Newton, *supra* note 17, at 728.

27. FLA. CONST. art. X, § 25.

28. *Id.*

29. Fla. Hosp. Waterman, Inc. v. Buster, 984 So. 2d 478 (Fla. 2008). This case's broad interpretation of Amendment 7 is discussed in Part II.D.

30. Laura V. Yaeger, *Amendment 7: Medical Tradition v. the Will of the People: Has Florida's Peer Review Privilege Vanished?*, 13 MICH. ST. U. J. MED. & L. 123, 148 (2009).

31. Kelly Dunberg, 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)*, 64 FLA. L. REV. 513, 518 (2012). Peer review materials are generally considered to be candidates for PSWP. 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, 186 (2007); *infra* Part III.A.

secondary literature;³² the Florida healthcare community knew the possible Amendment 7 implications of PSQIA soon after the bill's passage.³³

This Note will not diagnose the state of peer review in the wake of Amendment 7.³⁴ While this Note will explain the promise of the PSO solution relative to other potential responses to Amendment 7, a more comprehensive description of how PSOs could be used in Florida can be found elsewhere.³⁵ Rather, this Note will attempt to determine whether Florida's healthcare providers have actually adopted the PSO solution. Amendment 7's pressures created ideal conditions for the early and widespread adoption of PSOs, so the unique circumstances of Florida make it a particularly useful case study to get early empirical evidence on whether PSQIA has created an attractive set of institutions for addressing the incidence of medical error.

This Note proceeds in three Parts. Part II proves further factual background on medical error, medical peer review, and the history of the passage and interpretation of Amendment 7. Part III explains potential responses of healthcare providers to the intersection of these forces and explains why the situation in Florida can be interpreted as an early experiment about the viability and attractiveness of PSOs to healthcare providers. Part IV will examine registration records and other sources to evaluate the results of this experiment: evidence suggests PSO utilization in Florida is not substantially greater than other states. This Part finds that, even with the added incentive to create and use PSOs, the Florida healthcare community has not enthusiastically adopted them; this suggests there might be some serious flaws in the PSO model. Part IV concludes by offering some particular solutions to make PSOs more attractive based on the lessons of Florida's experiences with Amendment 7.

32. See Dunberg, *supra* note 31.

33. See, e.g., *The Amendment 7 Challenge: Is a PSO Hype or Hope?*, FOLEY & LARDNER LLP (Apr. 29, 2008), <http://www.foley.com/the-amendment-7-challenge-is-a-pso-hype-or-hope/> [hereinafter *Hype or Hope?*] (advertising a conference on the implications of Amendment 7); see also Memorandum from Bruce Rueben, President, Fla. Hosp. Ass'n & Linda Quick, President, S. Fla. Hosp. & Healthcare Ass'n, to Hospital Executive (Sept. 21, 2009) [hereinafter *Rueben & Quick Memorandum*], available at <http://www.psoflorida.org/about.html> (follow "PSO Welcome Letter" hyperlink).

34. For a full discussion, see, for example, Yaeger, *supra* note 30.

35. For a full exegesis, see Dunberg, *supra* note 31.

II. HISTORICAL BACKGROUND OF INSTITUTIONS AND RELEVANT LAWS

Part II gives further background to the four central aspects of this Note. Part II.A describes some of the history of concern with medical error, Part II.B outlines the institution of medical peer review, Part II.C examines the text and structure of PSQIA, and Part II.D provides history of the passage and interpretation of Amendment 7.

A. MEDICAL ERROR

It is impossible to understand the situation in Florida without appreciating the emphasis placed on reducing medical error by the health profession in recent years — which, in turn, requires appreciating the enormous scale of the problem. The Institute of Medicine (IOM), an outgrowth of the National Academy of Sciences founded in 1970, has become one of the most important drivers of the national conversation about healthcare.³⁶ The single most important document produced in the effort to combat medical error was IOM's enormously influential³⁷ “To Err is Human” report published in 1999.³⁸ The culmination of extensive research, the report painted a grim picture of the state of the US healthcare system and the sometimes dramatic consequences of the deficiencies.³⁹ The report and its successors included a mountain of factual findings about the scope and costs of medical error, a new vocabulary to describe medical error as part of a larger culture, and recommendations for a comprehensive national strategy for addressing medical error.⁴⁰

Compiling numerous studies and statistics representing years of research, “To Err is Human” presented some remarkable fig-

36. *About the IOM*, INST. OF MED., <http://www.iom.edu/About-IOM.aspx> (last visited Sept. 14, 2012).

37. *See, e.g.*, S. REP. NO. 108–196, pt. 1, at 1 (2003) (explaining that the IOM report prompted five hearings concerning medical error and patient safety in the four years following the release of the report).

38. Linda T. Kohn et al., *To Err is Human: Building a Safer Health System*, INST. OF MED. 26 (2000), <http://www.nap.edu/openbook.php?isbn=0309068371> (follow “PDF Book” hyperlink).

39. *See id.* at 26–49 (describing how errors in healthcare are a leading cause of death and injury).

40. *See id.* at 1–7.

ures about different kinds of errors. The report concluded that between 44,000 and 98,000 people die in hospitals every year as a result of medical error.⁴¹ Including factors like lost productivity and additional care, the report estimated that medical error cost \$17 billion to \$29 billion nationwide.⁴² Overall, the report showed the heavy toll medical error was taking on the United States' health system.

Besides its factual findings, "To Err Is Human" had other important results. For example, the report laid out a vocabulary for discussing medical error where one had been lacking before.⁴³ The report also was one of the first to introduce the concept of root cause analysis, a method borrowed from aviation, as a way of addressing systemic problems in the healthcare delivery system.⁴⁴

Finally, the IOM report and some of its follow-ups laid out a national strategy for addressing medical error.⁴⁵ The solution required the coordination of many different actors: governments to create mandatory reporting systems, professional organizations to create and enforce performance standards, and healthcare organizations to implement numerous safety programs.⁴⁶ One of the most important suggestions was Recommendation 8.1, calling for healthcare organizations and governments to improve patient safety by "implement[ing] non-punitive systems for reporting and analyzing errors within their organizations."⁴⁷ Some of the specific attributes of the recommended systems were manifested later in PSQIA, described below in Part II.C.

Unfortunately, the IOM's identification of the problem has not actually resolved the danger of medical error. A recent *Lancet* editorial argues that since the IOM's report "the problem of medical errors remains and might even have escalated."⁴⁸ Discoura-

41. *Id.* at 26.

42. *Id.* at 27.

43. *See, e.g., id.* at 54 (introducing a typology borrowed from James Reason and Charles Perrow distinguishing between "slips" and "mistakes"); *id.* at 55 (differentiating "latent" error, such as poor design or incorrect installation, and "active" errors, which arise from the "frontline operator" and are felt immediately).

44. *Id.* at 94.

45. William E. Fassett, *Patient Safety and Quality Improvement Act of 2005*, 40 THE ANNALS OF PHARMACOTHERAPY 917, 917 (2006).

46. Kohn et al., *supra* note 38, at 3–4.

47. Kohn et al., *supra* note 38, at 14.

48. Editorial, *Medical Errors in the USA: Human or Systemic?*, 377 THE LANCET 1289, 1289 (2011).

gingly, the *Lancet* notes that even in practice areas where patient safety has been emphasized by local governments, the number of adverse incidents has not actually decreased.⁴⁹

Decreasing medical error, then, is still as necessary and desirable a goal as it was in 1999, and an analysis of the different institutional structures used to reduce medical error and their efficacy is of the utmost importance.

B. MEDICAL PEER REVIEW

Of course, the concern for medical error predates 1999. One of the more longstanding ways of minimizing medical error is the medical peer review process, in which physicians are assessed by other physicians as to their competence, qualifications, and often their role in an adverse medical event.⁵⁰ This practice is one of the most important ways the medical profession regulates medical error.⁵¹

Peer review began in the early twentieth century as a way of improving care in the then-relatively recently formalized medical profession.⁵² Originally, peer review focused specifically on the quality of care rendered by a particular doctor, but the process gradually shifted towards a hospital-level focus.⁵³ This shift is traceable to federal and state government incentives to carry out peer review, including “state mandates, prerequisites for funding, and prerequisites for accreditation,” including by the JCAHO.⁵⁴ Now, peer review is frequently used as a way of screening and credentialing by hospitals to grant doctors initial access to facili-

49. *Id.*

50. *See, e.g.,* Patricia 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, 43–56 (2010). For a valuable empirical survey of peer review (including the kinds of analysis that takes place during it, how cases are identified, the sorts of outcomes tracked, and other measures), see Marc T. Edwards & Evan M. Benjamin, *The Process of Peer Review in U.S. Hospitals*, 16 J. OF CLINICAL OUTCOMES MGMT. 461 (2009), available at http://www.turner-white.com/memberfile.php?PubCode=jcom_oct09_peer.pdf.

51. Sullivan & Anderson, *supra* note 50, at 43–56.

52. Richard L. Griffith & Jordan M. Parker, *With Malice Towards None: The Metamorphosis of Statutory and Common Law Protections for Physicians and Hospitals in Negligent Credentialing Litigation*, 22 TEX. TECH L. REV. 157, 158–59 (1991).

53. Scheutzow, *supra* note 10, at 13.

54. Newton, *supra* note 17, at 723.

ties.⁵⁵ Alternatively, if the peer review process has been initiated in the wake of an adverse incident, peer review committees can use the recommendation of the suspension of credentials and/or hospital privileges as a form of discipline.⁵⁶ While peer review committees are not the controlling authority of such credentialing and access matters, governing bodies of hospitals strongly weigh their recommendation.⁵⁷

The underlying premise of medical peer review is the relatively simple and intuitive notion that the qualifications and actions of doctors can be best evaluated by other doctors with similar experiences and training.⁵⁸ Of course, this is hardly a guarantee of competence: the medical profession is incredibly complex and knowledge is always imperfect.⁵⁹ Further, there are obvious drawbacks to having doctors evaluated by their professional brethren, but while “peer review has the appearance of professional self-protection, . . . its primary purpose is to benefit the public through improved standards of medical care.”⁶⁰

Besides the expectation of evaluators’ expertise, another important premise of the peer review process is candor.⁶¹ Certainly, the physician being evaluated must be candid with the evaluating committee about his or her actions, and since medical peer review plays an important function in regulating medical care, it is important that the evaluating physicians are also forthright in their analyses and recommendations.⁶²

55. Since this use of peer review is not triggered by misconduct, it has led to the concern with sham peer review. Sham peer review occurs when a physician has a peer review proceeding instigated where the result is not in question. Roland Chalifoux, Jr., *So What Is Sham Peer Review?*, 7 MEDSCAPE GEN. MED. 47 (2005), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1681729/>. This can happen if the physician is found by a neutral panel to have fallen short of the required standard of care even if he or she has not, or if the review is undertaken by an outside firm that routinely finds physicians deficient. *Id.* Some have criticized PSQIA as greatly expanding the potential for sham peer review. See, e.g., Leigh Ann Lauth, Note, *The Patient Safety and Quality Improvement Act of 2006: An Invitation for Sham Peer Review in the Health Care Setting*, 4 IND. HEALTH L. REV. 151, 151 (2007).

56. Scheutzow, *supra* note 10, at 38.

57. Koepke, *supra* note 11, at 2.

58. Griffith & Parker, *supra* note 52, at 175.

59. Sullivan & Anderson, *supra* note 50, at 46.

60. Griffith & Parker, *supra* note 52, at 159.

61. Griffith & Parker, *supra* note 52, at 159.

62. Newton, *supra* note 17, at 734.

These two principles — evaluation by those in the same profession and the desire for candor — have prompted the development of numerous protections for various stakeholders. Since doctors are being evaluated by their competitors in the marketplace, there is a general concern for abuses of peer review that would function as anticompetitive conduct;⁶³ therefore, peer review is not allowed to proceed on pretextual grounds.⁶⁴ Additionally, there is protection for whistleblower doctors to make sure they are not punished by retaliatory peer review.⁶⁵ To ensure candor, there must be protections for the doctors that choose to serve on the peer review committees. “Physicians are obviously reluctant to participate in good faith peer review if they are exposed to liability for their actions” so participants sitting on the peer review board are given personal immunity from suit.⁶⁶

This immunity is provided at the federal level by the Health Care Quality Improvement Act (HCQIA).⁶⁷ HCQIA was passed in 1986 in response to the kind of litigation that ultimately reached the Supreme Court in *Patrick v. Burget*.⁶⁸ In that case, the Court struck down a peer review immunity against antitrust claims, which many healthcare providers viewed as a shocking result that would permanently move peer review outside the intraprofessional realm it once occupied.⁶⁹

While HCQIA immunity covers the individuals involved in the peer review process, the Supreme Court has expressly declined to create such a privilege as a matter of federal common law.⁷⁰ However, many states have provided confidentiality protection for the work product that results from peer review processes.⁷¹

63. See, e.g., Josephine M. Hammack, *The Antitrust Laws and the Medical Peer Review Process*, 9 J. CONTEMP. HEALTH L. & POL'Y 419, 423 (1993).

64. Lauth, *supra* note 55, at 171.

65. See, e.g., Amy Lynn Sorrel, *California Law Extends Whistle-Blower Protections*, AM. MED. NEWS (Jan. 14, 2008), <http://www.ama-assn.org/amednews/2008/01/14/prsb0114.htm>.

66. Griffith & Parker, *supra* note 52, at 159.

67. 42 U.S.C. § 1111 (2006).

68. Marilee Frazer, *Patrick v. Burget and the Health Care Quality Improvement Act: The Future Scope of Peer Review*, 35 WAYNE L. REV. 1181, 1192 (1989).

69. *Id.* at 1201 (citing *Patrick v. Burget*, 486 U.S. 94 (1988)).

70. *Univ. of Pa. v. EEOC*, 493 U.S. 182, 182 (1990).

71. See, e.g., ARIZ. REV. STAT. ANN. §§ 36-445, 36-445.01 (2009). Arizona's statutory scheme requires governing bodies of hospitals to convene review panels to evaluate professional practices with an eye to reducing medical error, with the “proceedings, records and

It should be noted that the benefits of peer review are frequently questioned. As one commentator has noted, “published studies specifically examining the mechanics and outcomes of physician peer review efforts consistently find ineffectiveness and inconsistency.”⁷² Critics allege that peer review is not being done with sufficient frequency to actually produce benefits in medical care.⁷³ Others argue that “quality of care” determinations are far too nebulous to be meaningful, either because “no universally accepted norms for care or physician have been developed”⁷⁴ or because the expertise of doctors is not actually reflected in the peer review process.⁷⁵ One study concluded that “physician agreement regarding quality of care is only slightly better than the level expected by chance.”⁷⁶ Nonetheless, peer review continues to be a key tool in the campaign to increase the quality of care and decrease the rate of medical error.

Thus, to summarize, despite some skepticism, peer review remains a valued tool in trying to reduce the incidence of medical error and ensure the delivery of high quality care. To encourage participation, participants on the committee are granted immunity from damages often under state law and under federal law by HCQIA. However, the work product produced during peer review is protected only by state laws which, as Florida’s Amendment 7 experience demonstrates, can change radically.

C. PATIENT SAFETY ORGANIZATIONS

The passage of the Patient Safety and Quality Improvement Act (PSQIA) in 2005 is one of the most important legacies of the “To Err is Human” report.⁷⁷ After the seismic event of the release

materials prepared in connection with the reviews” guaranteed confidentiality and protection from most kinds of discovery. *Id.*

72. Koepke, *supra* note 11, at 7.

73. Scheutzow, *supra* note 10, at 15 (reporting findings that there were only 901 adverse peer review actions per year in the entire United States, far below what would be expected given the startling rate of medical error).

74. Koepke, *supra* note 11, at 7 (internal quotation marks omitted).

75. Scheutzow, *supra* note 10, at 16–17.

76. Scheutzow, *supra* note 10, at 16–17.

77. *See generally* Fassett, *supra* note 45. The legislative history of the PSQIA also reveals this debt to the IOM report, with the 2003 PSQIA Senate report beginning with the IOM’s arresting figure of 98,000 preventable medical-error deaths per year in the United States. S. REP. NO. 108-196, at 1 (2003).

of the IOM's report, policymakers and healthcare experts took many of the recommendations from the report and began working to pass legislation.⁷⁸ The follow-up report, "Patient Safety: Achieving a New Standard for Care," also contained many substantive recommendations for the creation of a centralized reporting and data aggregation system for the advancement of patient safety.⁷⁹ After a few attempts to introduce legislation consistent with the IOM reports that went nowhere, the Senate and House ultimately passed PSQIA, which modified the Public Health Service Act.⁸⁰ PSQIA provided for the formation of patient safety organizations (PSOs) with the mission to "provide for the improvement of patient safety and to reduce incidence of events that adversely effect [sic] patient safety."⁸¹ It was signed into law in 2005.⁸² After soliciting comments in early 2008,⁸³ the final rule was published by the Department of Health and Human Services (HHS) in November 2008, going into effect in January 2009.⁸⁴

While a full exegesis of the mechanics of PSOs is outside the scope of this Note,⁸⁵ understanding the fundamentals of their operation is crucial to understanding the situation in Florida. Broadly, "PSOs are organizations designed to collect, aggregate and analyze confidential information reported by health care providers" with "federal privilege and confidentiality protections to

78. Fassett, *supra* note 45, at 919 (noting that multiple pieces of legislation were introduced in Congress as a result of the report).

79. Philip Aspden et al., *Patient Safety: Achieving a New Standard of Care*, INST. OF MED. (2004), <http://www.nap.edu/openbook.php?isbn=0309090776> (follow "PDF Book" hyperlink).

80. Fassett, *supra* note 45, at 919.

81. Patient Safety and Quality Improvement Act of 2005, Pub. L. No. 109-41, 119 Stat. 424.

82. Mark A. Kadzielski & Lynsey A. Mitchel, *An Analysis of the New Federal Patient Safety Law and Final Rule*, 11 J. OF HEALTH CARE COMPLIANCE 5, 5 (2009).

83. HHS Releases Final Rule for Patient Safety Organizations Under PSQIA, 19 MED. STAFF BRIEFING 1, 2 (2009), available at <http://www.hcpro.com/MSL-227333-236/HHS-releases-final-rule-for-patient-safety-organizations-under-PSQIA.html>.

84. Kadzielski & Mitchel, *supra* note 82, at 1.

85. A wealth of information about the operation of Patient Safety Organizations is available on the website for the Agency for Healthcare Quality and Research. See, e.g., *PSO FAQs*, AGENCY FOR HEALTHCARE RESEARCH & QUALITY, <http://www.pso.ahrq.gov/psos/fastfacts.htm> (last visited Mar. 31, 2013). There are also many guides prepared for healthcare professionals that give a good sense of what the operation of a Patient Safety Organization looks like day to day. See, e.g., *The Physician's Guide to Patient Safety Organizations*, AM. MED. ASS'N (2009), <http://www.ama-assn.org/resources/doc/cqi/patient-safety-organizations.pdf>.

information that is reported to or developed by a PSO.”⁸⁶ There are three important issues relevant to this discussion: what kinds of organizations can form PSOs, what kind of information is collected by PSOs, and how that information is given confidentiality.

First, PSQIA limits what kinds of organizations can form a PSO. PSOs can be formed by “public or private entities; profit or nonprofit entities’ and provider entities, such as hospital chains.”⁸⁷ PSOs may not be formed by a health insurer.⁸⁸ Groups that seek to operate a PSO as a component of a larger organization are subject to certain requirements relating to confidentiality and conflicts of interest.⁸⁹ In the wake of the passage of PSQIA and the finalization of the rules, healthcare providers explored whether to form their own independent PSO or pay to use an existing one.⁹⁰ The fees paid by providers to use PSOs set up by an outside organization are generally not burdensome.⁹¹ The process for registration of PSOs is overseen by the Agency for Healthcare Research and Quality (AHRQ), within HHS.⁹²

The second important issue is what sort of information a PSO can accept from a healthcare provider. PSO protection extends only to material deemed “patient safety work product” (PSWP).⁹³ PSWP can be many different kinds of material, as long as it satisfies the statutory requirement that it be created for patient safe-

86. Michael A. Murphy, *Patient Safety Organizations: Challenges and Rewards for Health Care Industry*, 60 R.I. B.J. 27, 27 (2011), available at [https://www.ribar.com/UserFiles/File/Sept-Oct_2011%20Journal%20\(2\).pdf](https://www.ribar.com/UserFiles/File/Sept-Oct_2011%20Journal%20(2).pdf).

87. *Patient Safety Organizations: Challenges and Rewards for Health Care Industry*, The PSO Advisory (Sept. 9, 2011), <http://thepsoadvisory.com/2011/09/patient-safety/patient-safety-organizations-challenges-and-rewards-for-health-care-industry/>; See 42 U.S.C. § 299b-24(b)(1) (2006) (statutory criteria for PSOs).

88. 42 U.S.C. § 299b-24(b)(1)(D) (2006).

89. Fassett, *supra* note 45, at 920.

90. James A. Barclay & Lisa A. Barclay, *The Case for Using Patient Safety Organizations in Florida*, AKERMAN SENTERFIT 2 (Feb. 2009), http://www.akerman.com/documents/PatientSafetyOrganizations_Feb2009.pdf. In the final rule, HHS stated that “for a provider, establishing its own PSO is an option, not a necessity.” Patient Safety and Quality Improvement Act, 73 Fed. Reg. 70,732, 70,746 (Nov. 21, 2008) (codified at 42 C.F.R. pt. 3).

91. See, e.g., Rueben & Quick Memorandum, *supra* note 33, at 2 (noting that PSOFlo-rida charges \$35 per licensed bed for FHA members, representing a very small operating expense for most hospitals; even unaffiliated members can contract with PSOFlo-rida for \$38.50 per bed, suggesting low rates are broadly available).

92. See generally 42 C.F.R. pt. 3 (2012).

93. 42 U.S.C. § 299b-21(7) (2006).

ty-related purposes.⁹⁴ The first subpart of the definition allows for “any data, reports, records, memoranda,” and so forth that are assembled for “patient safety activities” or will be reported to a PSO.⁹⁵ “Patient safety activities” is also defined broadly by the statute, including any effort to “improve patient safety and quality of healthcare delivery.”⁹⁶ The second subpart of the definition excludes billing information and the patient’s medical record from this definition of PSWP.⁹⁷ Since the definition is broad and the exclusions are narrow, PSWP encompasses a wide range of materials produced by healthcare providers. Those reports that meet the definition of PSWP are processed through a “patient safety evaluation system” (PSES) that will be managed by the provider as a way of sending the information to a PSO.⁹⁸

The key element of PSQIA, however, is the privilege and confidentiality protections afforded to PSWP.⁹⁹ According to the statute, PSWP is not “subject to Federal, State or local civil, criminal or administrative subpoena or order” and is not subject to discovery, including in a proceeding against the provider.¹⁰⁰ Structurally similar to the broad definition of PSWP above, the exceptions to this wide-ranging privilege and confidentiality protection are specific and narrow.¹⁰¹ The early response to PSQIA privilege and confidentiality was positive, with one commentator saying it seemed to “compar[e] favorably” to state privileges.¹⁰²

Besides the confidentiality protections, PSQIA also includes other incentives to participate in the formation of PSOs. For example, the statute states that HHS “may provide technical assistance” to PSOs, including leading a conversation on “methodology, communication, data collection, [and] privacy concerns” re-

94. *Id.*

95. § 299b-21(7)(A) (emphasis added).

96. 42 U.S.C. § 299b-21(5)(A) (2006).

97. § 299b-21(7)(B) (2006).

98. Barclay & Barclay, *supra* note 90, at 1–2.

99. Fassett, *supra* note 45, at 920.

100. 42 U.S.C. § 299b-22(a)(1) (2006). The section describing the privilege afforded to PSWP includes five different areas: protection from subpoena or order, protection from discovery, protection from information requests, protection from admission as evidence in any kind of government proceedings, and protection from admission in professional disciplinary proceedings. § 299b-22(a).

101. 42 U.S.C. § 299b-22(c) (2006).

102. Charles M. Key, *The Role of PSQIA Privilege in Medical Error Reduction*, 21 HEALTH LAWYER 24, 27 (2008).

lated to PSOs.¹⁰³ At least one lawyer with experience representing healthcare providers concluded that the “incentives for participation have real value for providers.”¹⁰⁴

Through the operation of privilege and confidentiality protection, the drafters of PSQIA hoped that the widespread adoption of PSOs would lead to an influx of large amounts of data. Depersonalized data collected by PSOs are to be put into a “network of patient safety databases,” a provision that was met with general enthusiasm.¹⁰⁵ The expectation was that analysis of this data generated by the network of PSOs could serve as “an interactive evidence-based management resource for providers, patient safety organizations, and other entities.”¹⁰⁶ Perhaps more importantly, however, PSQIA was meant to spark a cultural change in the healthcare industry, with PSOs serving to “promote a learning environment that is needed to move beyond the existing culture of blame and punishment . . . to a ‘culture of safety’ that focuses on information sharing, improved patient safety and quality and the prevention of future medical errors.”¹⁰⁷

D. FLORIDA’S AMENDMENT 7

Amendment 7, codified in the Florida Constitution in Article X, Section 25 as “Patients’ right to know about adverse medical incidents,” reads in substantive part, “patients have 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.”¹⁰⁸ This provision requires the elimination of identifying details of the patients in the information disclosed.¹⁰⁹

103. 42 U.S.C. § 299b-25 (2006).

104. Key, *supra* note 102, at 27.

105. 42 U.S.C. § 299b-23(a) (2006); see Patient Safety and Quality Improvement, 73 Fed. Reg. 70,732, 70,780 (Nov. 21, 2008) (codified at 42 C.F.R. pt. 3) (showing no public comment opposing § 3.205(b)(5), which allows for the disclosure of Nonidentifiable Patient Safety Work Product).

106. 42 U.S.C. § 299b-23 (2006).

107. S. REP. NO. 108-196, at 2 (2003).

108. FLA. CONST. art. X, § 25(a).

109. FLA. CONST. art. X, § 25(b).

It includes seemingly very broad definitions of “patient,”¹¹⁰ “adverse medical incident,”¹¹¹ and “have access to any records.”¹¹²

Amendment 7 arose out of a larger attempt by the Florida medical community to advance malpractice reform.¹¹³ After an unsuccessful attempt to push ambitious malpractice reform by influencing a 2002 task force set up by Governor Jeb Bush, the medical community, led by the Florida Medical Association, pursued a constitutional amendment that would impose a cap on non-damage malpractice awards.¹¹⁴ This was unsurprisingly met with strong resistance by the Florida plaintiffs’ bar, which proposed two constitutional amendments of its own.¹¹⁵ One was the provision that would become Amendment 8, which provided that, after a third incident of malpractice, a doctor’s license would be revoked.¹¹⁶ The second provision would become Amendment 7, and was promoted as the “Patients’ Right to Know.”¹¹⁷ The introduction of these amendments was widely seen in the medical community as retaliation for its attempts at malpractice reform¹¹⁸ and described as a strategy of mutually assured destruction.¹¹⁹ Following the introduction of these responsive measures, the attempt to diffuse the conflict between doctors and lawyers was unsuccessful. Florida has an unusual system for ballot issues

110. FLA. CONST. art. X. § 25(c)(2) (“An individual who has sought, is seeking, is undergoing, or has undergone care or treatment in a health care facility or by a health care provider.”).

111. FLA. CONST. art. X. § 25(c)(3) (“[M]edical negligence, 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 or death of a patient, including, but not limited to, those incidents that are required by state or federal law to be reported to any governmental agency or body, and incidents that are reported to or reviewed by any health care facility peer review, risk management, quality assurance, credentials, or similar committee, or any representative of any such committees.”).

112. FLA. CONST. art. X. § 25(c)(4) (“[M]aking the records available for inspection and copying upon formal or informal request by the patient or a representative of the patient, provided that current records which have been made publicly available by publication or on the Internet may be “provided” by reference to the location at which the records are publicly available.”).

113. Mary Coombs, *How Not To Do Medical Malpractice Reform: A Florida Case Study*, 18 HEALTH MATRIX 373, 382-83 (2008).

114. *Id.* at 380–81 (explaining that amendment would impose a 30% cap on non-damage awards going to lawyers in amounts below \$250,000 and 10% in excess of that).

115. Yaeger, *supra* note 30, at 127.

116. Coombs, *supra* note 113, at 392.

117. Coombs, *supra* note 113, at 392.

118. Yaeger, *supra* note 30, at 127.

119. Coombs, *supra* note 113, at 383.

that requires a pre-election review by the state supreme court,¹²⁰ but all three amendments made their way onto the 2004 ballot.¹²¹

It became clear early in the process that the passage of Amendments 7 and 8 could have profound consequences for the Florida medical community: the Associated Industries of Florida, the Florida Chamber of Commerce, the Florida Association of Health Plans, and the Florida Insurance Council all urged the Florida Medical Association to abandon Amendment 3 (their damage-cap proposal) because of the potential effects of Amendment 7 and 8.¹²² Editorials were generally negative on all of the amendments.¹²³ Amendment 3 was called “the worst of the proposals”¹²⁴ and condemned as an attempt to “close off access to the court for most victims.”¹²⁵ Amendment 8’s “Three Strikes and You’re Out” campaign was condemned as “arbitrary”¹²⁶ and lacking “flexibility and discretion” necessary in dealing with medical error.¹²⁷ While doctors and provider-side advocates attempted to explain the benefits of confidentiality to the peer review process,¹²⁸ Amendment 7 was met with somewhat more support in the state’s editorial pages, which argued that “full disclosure will benefit the many good physicians and hurt the bad ones.”¹²⁹

Ultimately, all three measures passed. Amendment 3 was the closest, passing with 63.6% of the vote.¹³⁰ The lawyer-supported provisions passed more convincingly, with Amendment 8 receiv-

120. FLA. CONST. art. XI, § 3; FLA. STAT. § 101.161 (2007). This process ensures that ballot initiatives satisfy a constitutional requirement that they relate to only a single-subject and that the ballot summaries are unambiguous. Coombs, *supra* note 113, at 378.

121. Coombs, *supra* note 113, at 385–86.

122. Coombs, *supra* note 113, at 384.

123. Coombs, *supra* note 113, at 386.

124. Editorial, *Keep Malpractice Fight Out of State Constitution*, PALM BEACH POST, Oct. 7, 2004, at 18A [hereinafter PALM BEACH POST Editorial].

125. *Id.*

126. Editorial, *Amendment 7 and 8: ‘Yes’ on Open Records, ‘No’ on Malpractice Regulation*, SARASOTA HERALD-TRIBUNE (Oct. 18, 2004), http://www.accessmylibrary.com/coms2/summary_0286-14055890_ITM.

127. *Id.*

128. See, e.g., Joseph Portoghese, Op-Ed., *The Hidden Agenda of Amendment 7*, ORLANDO SENTINEL (Oct. 19, 2004), http://articles.orlandosentinel.com/2004-10-19/news/0410190160_1_patient-care-medical-staff-amendment-7.

129. PALM BEACH POST Editorial, *supra* note 124.

130. Black, *supra* note 1.

ing 71% of the vote and Amendment 7 passing overwhelmingly with 81%.¹³¹

Healthcare providers and their lawyers acted quickly in response to Amendment 7. They first filed injunctions trying to block the implementation of Amendment 7, and were simultaneously forced to counter arguments in active malpractice suits that the new law allowed for broad discovery of documents.¹³² Hospitals blocked production of some documents and were successful in early cases.¹³³ The hospitals began to lobby to try to influence the state legislature in how Amendment 7 would be implemented,¹³⁴ and were rewarded with House Bill 1797, which narrowed the scope of Amendment 7.¹³⁵ Among the limiting effects of the bill were provisions that narrowed the amendment's retroactive effect; another limited Amendment 7's effect to requests of final reports and records, which would protect the deliberative notes and materials produced by institutions like peer review boards; another limited document requests to reports concerning the same diagnosis, treatment, or condition as the patients' own; and another maintained prohibitions on admissibility in trial and the availability of medical incident reports during pre-trial discovery.¹³⁶

The early lower court decisions interpreting Amendment 7 took varied approaches,¹³⁷ but the Florida Supreme Court gave authoritative pronouncement in 2008.¹³⁸ Combining appeals from two lower court decisions, *Florida Hospital Waterman, Inc. v. Buster* addressed three issues: "whether Amendment 7 is self-executing and whether it can be applied retroactively, and whether [the limiting provisions] are constitutional."¹³⁹ The court first held that Amendment 7 was self-executing.¹⁴⁰ Second, the

131. Black, *supra* note 1. While Amendment 3 and Amendment 8 have been implemented, they no longer intersect with the debate surrounding Amendment 7 and have little to no effect on the use of PSOs in Florida.

132. Coombs, *supra* note 113 at 395.

133. Coombs, *supra* note 113 at 395.

134. Coombs, *supra* note 113 at 396.

135. Yaeger, *supra* note 30, at 129.

136. Coombs, *supra* note 113, at 396.

137. For a good discussion of the lower courts' interpretation, see Yaeger, *supra* note 30, at 133.

138. Coombs, *supra* note 113, at 400.

139. 984 So. 2d 478, 484–85 (Fla. 2008).

140. *Id.* at 484–86.

court analyzed the plain language of Amendment 7 (“any record relating to *any adverse medical incident*, and defines “patient” to include individuals who *had previously undergone treatment*”),¹⁴¹ the apparent purpose of the amendment,¹⁴² and the fact that providers never had a vested right to the secrecy in the records in question¹⁴³ to hold that Amendment 7 applied retroactively to already existing records. Third, and most significantly, the court struck down some of the most important provisions of the legislative attempt to narrow Amendment 7, including the limitation on final records, the limitation that patients must have a substantially similar treatment to request records, the limitation of retroactivity, the provision maintaining existing privilege statutes, the limitation on patients only requesting records from facilities where they receive treatment, and the restriction on admissibility.¹⁴⁴

The decision was “an almost complete triumph for the plaintiffs”: the *Buster* opinion confirmed the broadest reading of Amendment 7 on nearly every issue.¹⁴⁵ Following the court’s final word, the healthcare community was low on options to fight Amendment 7: the court’s broad reading had limited the feasibility of legal challenges under Florida law and a major effort to enact change legislatively had been struck down. There was, however, a lawsuit challenging Amendment 7 under a HCQIA preemption theory and a theory based on the Health Insurance Portability and Accountability Act (HIPAA) filed in federal court in July 2008.¹⁴⁶ While the suit survived a motion to dismiss,¹⁴⁷ the plaintiffs voluntarily decided to withdraw the case.¹⁴⁸ Not pursuing this strategy aggressively was likely wise on the part of

141. *Id.* at 487.

142. *Id.* at 488.

143. *Id.* at 489–92.

144. *Id.* at 493.

145. Coombs, *supra* note 113, at 399.

146. Complaint, Fla. Hosp. Ass’n v. Viamonte, No. 4:08cv312-RH/WCS (N.D. Fla. 2008).

147. See Fla. Hosp. Ass’n v. Viamonte, No. 4:08cv312-RH/WCS, 2008 WL 5101755 (N.D. Fla. Nov. 26, 2008).

148. J.B. Harris, *Riding the Red Rocket: Amendment 7 and the End to Discovery Immunity of Adverse Medical Incidents in the State of Florida*, 83 FLA. B.J. 20 (2009), available at <http://www.floridabar.org/divcom/jn/jnjournal01.nsf/Author/258FDD31C33E3CDA85257567006B3148>. The reason for this is unclear, though likely motivated by not wanting to set bad precedent.

providers, since most HCQIA preemption theories to establish a peer review privilege have been rejected.¹⁴⁹ Recently, another Florida Supreme Court decision rejected a HCQIA preemption theory and confirmed a broad reading of Amendment 7.¹⁵⁰

Given that the various efforts to limit Amendment 7 had failed or were unlikely to succeed if tried, Florida healthcare providers had to come up with a way to exist in a post-*Buster*, Amendment 7 world.

This Part has described the medical error epidemic, the institution of peer review, PSQIA and PSOs, and Florida's Amendment 7. The confluence of these forces makes for a valuable case study about PSQIA and the utility of PSOs. Part III below explains the case study by describing the different approaches to peer review healthcare providers could have taken following *Buster* and the reason Florida is a valuable natural experiment, while Part IV explains the result of that experiment and some recommendations suggested by the result.

III. THE FLORIDA CASE STUDY

With legislative modifications to Amendment 7 reversed by *Buster* and both state and federal litigation seemingly at dead ends, healthcare providers in Florida were at a decision point regarding their peer review processes.¹⁵¹ Part III.A discusses the different possible solutions healthcare providers could have adopted, and Part III.B explains how Florida can be seen as a unique experiment about the viability of PSOs.

149. See, e.g., *Agster v. Maricopa Cnty.*, 422 F.3d 836 (9th Cir. 2005). In this interesting and representative case, plaintiffs sued following the death of their son in police custody, and forced production of a mortality review produced during a "Critical Incident Report." *Id.* at 838. While the court emphasized that the peer review participants are immune, it refused to create a federal peer review privilege for the documents given the particular facts of the case and, more generally, since Congress had the opportunity to do so and pointedly declined. *Id.* at 839.

150. See *W. Fla. Reg'l Med. Ctr. v. See*, 79 So. 3d 1 (Fla. 2012).

151. See, e.g., Gary D. Koch et al., *Florida Peer Review After Amendment 7: Challenges and Solutions to a National Trend*, FOLEY & LARDNER LLP (May 5, 2008), <http://www.foley.com/florida-peer-review-after-amendment-7-challenges-and-solutions-to-a-national-trend-05-05-2008/> ("Hospitals and health care providers are scrambling to understand exactly what protections, if any, remain for the peer review process.").

A. HEALTHCARE PROVIDERS' OPTIONS

In response to Amendment 7, Florida's healthcare providers had four viable options.

First, providers could have made no changes from their Amendment 7 procedures. Because of the sweeping ruling in *Buster*, Florida providers would have been forced to turn over the records in many cases where they would have previously been protected. Of course, this would not have been a particularly attractive option. Doctors would have been significantly more hesitant to serve on peer review committees because their opinions and peer review materials would be more likely to be turned over in discovery, particularly since the definition of "patient" the *Buster* court adopted was so broad.¹⁵² Had hospitals had too much difficulty in staffing their peer review committees, they would have found themselves running afoul of JCAHO, federal, and state requirements that have made peer review ubiquitous.¹⁵³ Besides the concern about doctor resistance, hospitals would also have been resistant to running peer review the same way because of the administrative burden in maintaining so many documents and records that would later be subpoenaed. Thus, because of pressures from doctors and hospitals, it was very unlikely that peer review would continue unchanged following the passage of Amendment 7.

The second option providers could have taken was to continue to use the same procedures for peer review but minimize the creation of records by doing as little peer review as possible. This, too, however, was likely not an attractive solution. First, as mentioned previously, there are numerous incentives that encourage hospitals to engage in peer review and some of them are even mandates.¹⁵⁴ Moreover, while doctors would likely have not objected to the minimization of peer review, it seems doubtful that hospitals would be willing to reduce the process significantly. Since peer review plays such an important role in regulating access to hospital facilities (and thereby reducing potential hospital liabilities) the hospitals have a strong disincentive to sub-

152. See 984 So. 2d 478, 486–87 (Fla. 2008).

153. See, e.g., *Standards FAQ Details*, *supra* note 12.

154. See, e.g., *Standards FAQ Details*, *supra* note 12.

vert Amendment 7 by merely reducing the number of peer review panels that are convened.

Third, hospitals could have continued doing peer review at approximately the same pace as before, while adopting some new procedures to frustrate the Amendment 7 provisions. For example, peer review could have been done with the same frequency but minimizing the amount of paperwork involved: this would still allow the credentialing and corrective benefits of peer review, but without a paper trail of records that could be requested later by patients or plaintiff attorneys. Hospitals could also have instituted new procedures to try to make securing the records as difficult as possible while still maintaining nominal compliance with Amendment 7 by turning over what limited records are produced.¹⁵⁵

Fourth, and most importantly for the purposes of this Note, the Florida healthcare providers could have used PSOs as a way of solving their Amendment 7 dilemma.¹⁵⁶ Instead of attempting to frustrate Amendment 7, healthcare providers could have contracted with PSOs to categorize the analyses, notes, and documents produced during the course of peer review as PSWP that would be subject to the federal privilege and confidentiality protections granted by PSQIA.

The potential applicability of PSQIA privilege to peer review materials was clearly in the minds of the Florida healthcare industry during the relevant period. Foley & Lardner LLP, a prominent Florida law firm that frequently represents healthcare providers held a meeting just after the HHS comment window had closed in April 2008 discussing whether PSQIA was “hype or hope” as a solution to the Amendment 7 difficulties.¹⁵⁷ A few months later, an article appeared asking, “Is a Patient Safety Organization a Solution?” with some notes of cautious optimism.¹⁵⁸ In February 2009, after the PSO certification process had opened, Akerman Senterfitt, another Florida law firm, published a practice update arguing that healthcare providers “reeling from the effects of Amendment 7 . . . may find refuge in [PSQIA]” be-

155. See *supra* Part IV for a further discussion of this strategy.

156. See Dunberg, *supra* note 31, at 543.

157. *Hype or Hope?*, *supra* note 33.

158. Koch et al., *supra* note 151.

fore summarizing PSOs and their benefits.¹⁵⁹ In 2009, while promoting their PSO, the Florida Hospital Association touted a major benefit of PSOs, that providers could “pursue robust peer review activities through PSOFlorida with less risk of Amendment 7 disclosure.”¹⁶⁰ Clearly, the healthcare community recognized that PSOs were a potential avenue for protecting some of the material exposed by Amendment 7.¹⁶¹

While the statute makes no explicit mention of peer review or peer review materials, the PSQIA privilege likely extends to them.¹⁶² The materials created during peer review frequently take the form of root cause analyses that are expressly included by the statute as a kind of material that is considered “patient safety work product” (PSWP).¹⁶³ The hospital’s role in aggregating the peer review materials satisfies the statutory requirement that PSWP be assembled by a provider.¹⁶⁴ Hospitals that process the peer review materials would only need to shift that processing into the channels of a “patient safety evaluation system” (PSES) to qualify; alternatively, for hospitals without a PSES, the pre-existing peer review processing apparatus could be a natural and logical starting point for developing one.¹⁶⁵ As described above, peer review is used to improve patient safety and the quality of healthcare delivery (or, relatedly, as a credentialing process to ensure the utilization of qualified staff),¹⁶⁶ and in either case this means the peer review materials would be relevant to “patient safety activities.”¹⁶⁷ The desire to include peer review is

159. See Barclay & Barclay, *supra* note 90, at 1.

160. Rueben & Quick Memorandum, *supra* note 33, at 1.

161. The merits of the PSO solution have also been noted in secondary literature. See, e.g., Dunberg, *supra* note 31; Leaman, *supra* note 31, at 186.

162. Indeed, at least one commentator has argued that the failure to mention peer review explicitly is not meant to exclude peer review materials from the definition of PSWP but to ensure that the definition is more expansive than just peer review materials. See Leaman, *supra* note 31, at 187.

163. 42 U.S.C. § 299b-21(7)(A) (2006).

164. § 299b-21(7)(A)(i)(I).

165. See Leaman, *supra* note 31, at 189. As part of the normal peer review process, there are already many documents produced that qualify as PSWP that are being tracked and evaluated by hospitals. For example, a majority of peer review systems use root-cause analyses and comparative evaluation of performance measures, and a majority of hospitals use peer review to track trends in adverse event rates. Edwards & Benjamin, *supra* note 50, at 463.

166. See *supra* Part II.B.

167. 42 U.S.C. § 299b-21(5) (2006).

also apparent in the legislative history of the PSQIA.¹⁶⁸ Even under a narrow reading, peer review materials are entitled to the privilege and confidentiality protections of PSQIA.¹⁶⁹

Even further, however, PSQIA could give rise to another attempt to find a common-law peer review privilege where attempts referencing HCQIA have been unsuccessful.¹⁷⁰ Such a broad interpretation of peer review protection post-PSQIA is bolstered by several very recent cases that have determined the PSQIA privilege's applicability to peer review materials. Several courts have emphasized that HCQIA "no longer represents Congress' final word on the issue of medical peer review."¹⁷¹ In *KD ex rel. Dieffenbach v. United States*, the district court suggested that the general policy motivations behind PSQIA might lead to a broader peer review privilege whether or not the "review bodies at issue here meet the technical requirements for listing as PSOs."¹⁷² Similarly, in *Francis v. United States*, another district court recognized that, while the quality-assurance documents in question were not provided to a PSO (meaning they are not PSWP and not afforded PSQIA protection), a peer review privilege nonetheless existed based on PSQIA's stated policy justifications.¹⁷³ A narrower reading was set out in *Schlegel v. Kaiser Foundation Health Plan*, where the court emphasized that the peer review

168. Leaman, *supra* note 31, at 188.

169. Leaman, *supra* note 31, at 196.

170. This seems to be part of the long-term strategy of Florida healthcare providers. As part of a conference about the potential utility for PSOs as a solution to Amendment 7 concerns, Florida healthcare attorneys presented an interesting list of HCQIA cases where the privilege was not recognized and then wondered whether PSQIA provided an "opportunity to examine judicial conclusions". See Gary D. Koch, *The Health Care Quality Improvement Act: Is There a Federal Peer Review Privilege?* 6–25 (Apr. 29, 2008) presented at *The Amendment 7 Challenge: Is a PSO Hype or Hope?* (presentation available at <http://www.foley.com/files/Event/06eb8893-c1dd-4ca4-a62b-d6851aa5e8d7/Presentation/EventAttachment/cc17673b-a8b8-43c0-9907-dd8ecb642883/TheAmendment7.pdf>).

171. *KD ex rel. Dieffenbach v. United States*, 715 F. Supp. 2d 587, 595 (D. Del. 2010); *Francis v. United States*, No. 09 Civ. 4004, 2011 WL 2224509, at *6 (S.D.N.Y. 2011) (quoting *Dieffenbach*, 715 F. Supp. 2d at 595).

172. *Dieffenbach*, 715 F. Supp. 2d at 596. Notably, though, the court only stated that applying a Maryland state privilege would *not frustrate* the underlying policies of PSQIA, but did not take the full step of applying a federal peer review privilege arising from PSQIA. *Id.* at 591–92, 597.

173. *Francis*, 2011 WL 2224509, at *5. Note that this, too, was a rather unique case, dealing with a claim under Federal Tort Claims Act, which allows for a unique meshing of state and federal law that might make the conclusions of limited relevance to other situations.

privilege enacted by Congress was a narrow one crucially limited to the patient-safety functions allowed under the definition of PSWP, since Congress could have used PSQIA to enact a broader peer review privilege but did not do so.¹⁷⁴ Even in this case, however, the court indicated that the case turned on the fact that the investigative material was not presented to a PSO and had not been created for patient-safety purposes.¹⁷⁵ This suggests that, even if the broad common-law peer review privilege fails to gain widespread acceptance, even stingier courts are clearly willing to apply PSQIA protections to peer review materials so long as they fall within the definition of PSWP.

The only other potential obstacle is ensuring that Florida providers can get PSQIA protection, notwithstanding conflict with Amendment 7. At least one paper has noted a potential problem, in that PSQIA fails to preempt some state laws,¹⁷⁶ but this should not be a problem with Amendment 7. The authors of that paper explore the ability of providers to use the PSQIA privilege while still being subject to a Rhode Island statute mandating the disclosure of peer review materials to a state government body; that government body lies outside a PSES, meaning that that material is not afforded PSQIA privilege.¹⁷⁷ However, the situation of Florida providers is distinguishable. First, the authors argue that PSQIA does not explicitly preempt state laws governing the reporting of results of peer review procedure.¹⁷⁸ Unlike reporting laws, PSQIA *does* explicitly preempt state laws when it grants its privilege.¹⁷⁹ Second, the authors are correct that PSQIA does not

174. No. CIV 07-0520 MCE KJM, 2008 WL 4570619, at *4 (E.D. Cal. Oct. 14, 2008).

175. *Id.* at *3. This suggests that Florida healthcare providers could avail themselves of PSQIA privilege so long as their materials meet the definition of PSWP, which as noted above, they likely do.

176. Sullivan & Anderson, *supra* note 50, at 42–43.

177. Sullivan & Anderson, *supra* note 50, at 42–43.

178. Sullivan & Anderson, *supra* note 50, at 42–43. The information turned over to state reporting systems is excluded on the grounds that it is outside of a PSES, by virtue of its disclosure to the reporting authorities. Thus, they are excluded from the definition of PSWP by the statutory “clarification,” which reads: “Information described in subparagraph (A) does not include information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system. Such separate information or a copy thereof reported to a patient safety organization shall not by reason of its reporting be considered patient safety work product.” 42 U.S.C. § 299b-21(7)(B)(ii) (2006).

179. 42 U.S.C. § 299b-22(a) (2006). The statute explicitly preempts state law with regard to each of the five protections afforded to PSWP (protection from subpoena or or-

manifest any intent to preempt the field of peer review in general, but it much more clearly manifests an intent to preempt the field of peer review confidentiality standards.¹⁸⁰ Third, while the Rhode Island statute they discuss does not clearly conflict with PSQIA,¹⁸¹ the disclosure mandated by Amendment 7 and forbidden by PSQIA are clearly in conflict. Thus, Florida providers should not be greatly concerned about preemption problems preventing their use of PSOs to secure PSQIA privilege for peer review materials.

Thus, Florida healthcare providers can use PSOs to secure PSQIA privilege and confidentiality protections as a way of avoiding the disclosure mandated by Amendment 7. In Part IV, this Note will attempt to determine which of the four options discussed above the Florida healthcare providers have actually used. First, though, it is worth exploring why this might be a particularly useful situation in which to analyze the efficacy of PSOs and PSQIA.

B. EVALUATING PSO'S WITH FLORIDA AS AN EXPERIMENT

Policymakers and healthcare experts have had questions about the effectiveness of the PSOs but have expressed some caution on commenting prematurely.¹⁸² Indeed, given that HHS's rule only went into effect in 2009,¹⁸³ it might still be too soon to make an authoritative argument about the efficacy of PSOs. Yet, after a decade-long push for institutions like PSOs in the wake of "To Err is Human," and after the lengthy process of soliciting comments from stakeholders, one might expect that the pump had been sufficiently primed and there would be a number of organizations registering when the process officially opened in 2009. However, registrations have not come in at a blistering

der, discovery, information requests, admission as evidence in any kind of government proceedings, and admission in professional disciplinary proceedings). *Id.*

180. See Leaman, *supra* note 31, at 186–87 (discussing legislative intent).

181. Sullivan & Anderson, *supra* note 50. Note that Florida courts have agreed that HCQIA presents no issue of preemption for Amendment 7 since the two laws do not conflict with each other. *W. Fla. Reg'l Med. Ctr., Inc. v. See*, 79 So. 3d 1, 20 (Fla. 2012).

182. See, e.g., U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-10-281, PATIENT SAFETY ACT: HHS IS IN THE PROCESS OF IMPLEMENTING THE ACT, SO ITS EFFECTIVENESS CANNOT YET BE EVALUATED (2010).

183. Kadzielski & Mitchel, *supra* note 82, at 5.

pace: as of January 2012, there are a total of seventy-eight PSOs registered with AHRQ.¹⁸⁴ Note that there is no guarantee that a PSO that is registered is actually contracting with any hospitals to receive PSWP.¹⁸⁵ Defenders might argue that the actual total registered is not important; even if that's true, there are four other troubling signs suggesting PSOs are not being embraced.

First, the seventy-eight registrations cover only thirty-one states. Given the important mission of PSOs, it seems troubling that nineteen states still lack the sort of centralized clearing-house for medical error reporting that PSOs provide.

Second, even in the states with at least one PSO, there are legitimate questions about the extent of coverage. For example, California has only two registered PSOs for the entire state.¹⁸⁶

Third, there are many lapsed registrations. As of January 2012, thirty-one PSOs have been delisted from the AHRQ database.¹⁸⁷ Of those thirty-one, thirty have been deemed "voluntary relinquishment" and only one record is found for "delisted for cause" based on a "failure to correct deficiencies."¹⁸⁸ Thus, just under 30% of the PSOs that have been listed have voluntarily relinquished their registration, suggesting that a rather large number of PSOs have not proved to be useful enough to maintain. Indeed, the high number of lapsed registrations is even more dis-

184. *Geographic Directory of Listed Patient Safety Organizations*, AGENCY FOR HEALTHCARE RESEARCH & QUALITY, <http://www.pso.ahrq.gov/listing/geolist.htm> (last visited Mar. 4, 2013).

185. See U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 182, at 10. The GAO noted that, "at the time of GAO's review, few of the 17 PSOs randomly selected for interviews had entered into contracts to work with providers or had begun to receive patient safety data." See U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 182, at 10. Of course, the entire premise of that report was that the PSO model was so new that a full evaluation was not possible, but it certainly demonstrates that there is no guarantee that a listed PSO is actually receiving PSWP.

186. *Geographic Directory of Listed Patient Safety Organizations*, *supra* note 184. Concededly, one of those PSOs is the California Hospital Patient Safety Organization, which is affiliated with the California Association of Hospitals and Health Systems and the California Hospital Association. *Geographic Directory of Listed Patient Safety Organizations*, *supra* note 184. With such an affiliation it seems likely that this PSO would cover many of the hospitals within California, but even this is not necessarily reassuring: while centralization creates some economies of scale for PSOs, there is the potential that it will not be as quick to pick up on local or regional trends, or trends specific to a particular hospital system.

187. *Delisted Patient Safety Organizations*, AGENCY FOR HEALTHCARE RESEARCH & QUALITY, <http://www.pso.ahrq.gov/delisted/delistedpsos.htm> (last visited Mar. 4, 2013).

188. *Id.*

turbing, since it indicates that, even when the administrative difficulties that come with the initiation of a PSO are not at issue, there might be difficulties in maintaining a functioning PSO. This suggests a more fundamental problem holding back PSOs rather issues concerning initial administrative red tape.

Fourth, the pace of registrations has actually slowed, rather than increased. According to the AHRQ listing, only fifteen PSOs were initially listed in 2011 or 2012 as of February 2012.¹⁸⁹ By contrast, seventeen of the delistings have occurred in 2011 or 2012.¹⁹⁰

While the issue of medical error and the potential for PSOs to address it was at the forefront of the healthcare conversation throughout the 2000s, the somewhat slow response can still be excused. The final rules concerning PSOs were only promulgated in 2008¹⁹¹ and recent years have seen a few different events that could have justifiably made PSO formation a lower priority for healthcare providers. Most obviously, President Obama's reform efforts in the form of the Patient Protection and Affordable Care Act (PPACA) have consumed much of the oxygen in the healthcare field¹⁹² (though as discussed below, the PPACA does have some provisions relevant to PSOs).¹⁹³ Further, potential and actual cuts to Medicaid and Medicare reimbursement rates have been of primary concern to healthcare providers.¹⁹⁴ While the

189. *Id.* These PSOs are: the Society for Vascular Surgery PSO in Chicago; the Child Health PSO in Shawnee Mission, Kansas; Schumacher Group PSO in Lafayette, Louisiana Specialty Benchmarks PSO in New Gloucester, Maine; Fresenius Medical Care PSO in Waltham, Massachusetts; University Safety Solution PSO in Minneapolis; Ascension Health PSO in St. Louis; Somnia PSO in New Rochelle, New York; Society of Hospital Medicine PSO in Philadelphia; Leadership Triad in Providence; Verge PSO in Mount Pleasant, South Carolina; CHS PSO in Franklin, Tennessee; Premerus PSO in Franklin, TN; Independent Data Safety Monitoring in North Salt Lake, Utah; and GE PSO in Waukesha, Wisconsin. *Id.*

190. *Id.*

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

192. For example, a Google Scholar search for PPACA yielded 4090 results since 2008. GOOGLE SCHOLAR, <http://www.scholar.google.com> (last visited Mar. 13, 2013) (search for "PPACA" since 2008). A search for papers with the term PSQIA since 2008 nets 81 results. GOOGLE SCHOLAR, <http://www.scholar.google.com> (last visited Mar. 13, 2013) (search for "PSQIA" since 2008).

193. See *infra* Part IV.B.

194. Illustrative is the intense lobbying effort put on by providers during some of the budget fights in 2011, particularly during the ultimately unsuccessful session of the Joint Select Committee on Deficit Reduction (the "Super Committee"). See Stephanie Condon,

steady refrain concerning the reduction of medical error has become well-known, it would be unrealistic to expect it to supplant budget concerns on the list of priorities.

However, Florida provides a unique case. PSQIA was signed into law less than a year after Amendment 7's passage, while the final interpretation of its scope in *Buster* was handed down in March 2008,¹⁹⁵ well into the comment-gathering stages of the PSO rulemaking process.¹⁹⁶ In other words, the promise of PSOs was available as soon as the threat posed by Amendment 7 became clear, and PSOs themselves could be formed shortly after the full extent of Amendment 7's effect was set. To the extent that PSOs provide any kind of solution to the Amendment 7 conundrum facing healthcare providers, the response in Florida is a useful bellwether of the likelihood of PSOs being effective more broadly: the hypothesis is that because of the unique factors presented by Amendment 7, Floridians would be particularly likely to be early adopters of PSOs.

Indeed, as indicated above, Florida healthcare providers were aware of the solution, too; there were conferences specifically geared towards whether PSQIA would be the solution to Florida's Amendment 7 problem.¹⁹⁷ Law firms made it the focus of practice updates.¹⁹⁸ The PSOs made their status as a potential solution to Amendment 7 problems a focus of their advertising.¹⁹⁹

Amendment 7 presented a serious problem that needed a quick resolution, with PSOs offering an imminently viable and widely known solution. This adds an entirely new dimension to the analysis of the behavior of Florida healthcare providers post-Amendment 7 and post-PSQIA. While there are factors that arguably make quick adoption of PSOs perhaps unlikely in other states, Florida presents a roughly controlled experiment with

Lobbyists, Special Interests Swarm Super Committee, CBS NEWS (Nov. 16, 2011, 11:02 AM), http://www.cbsnews.com/8301-503544_162-20124749-503544/lobbyists-special-interests-swarm-super-committee/ ("The health care industry has reportedly sent the most lobbyists to pressure the 12 lawmakers"); Tim Reid & Anna Yukhananov, *Healthcare Lobbyists Want Debt Committee to Fail*, REUTERS, Sept. 6, 2011, available at <http://www.reuters.com/article/2011/09/06/us-healthcare-lobbyists-idUSTRE7855WT20110906>.

195. Coombs, *supra* note 113, at 399.

196. The final rule was released in November 2008. See Patient Safety and Quality Improvement Act, 73 Fed. Reg. 70,732 (Nov. 21, 2008) (codified at 42 C.F.R. pt. 3).

197. See, e.g., *Hype or Hope?*, *supra* note 33.

198. See, e.g., Barclay & Barclay, *supra* note 90.

199. See Rueben & Quick Memorandum, *supra* note 33, at 1.

Amendment 7 acting as the independent variable. Confronted with the options of making no change, changing the frequency of peer review, trying to resist Amendment 7 with different peer review procedures, and opting to make extensive use of PSOs and PSQIA protection for peer review materials, evidence of Florida providers embracing PSOs would suggest that PSOs are a viable, desirable institution. Conversely, their failure to embrace PSQIA would suggest that PSOs might have some sort of fundamental flaw.

IV. RESULTS AND RECOMMENDATIONS

With Part III laying out why Florida represents something of a controlled experiment on PSOs, Part IV.A will show that Florida healthcare providers have not enthusiastically adopted PSOs and IV.B will draw some conclusions about what this says about PSQIA and provide recommendations to improve the structure of PSOs.

A. RESULTS OF THE FLORIDA EXPERIMENT

Unfortunately for the long-term outlook of the viability of the PSO model, there appears to be little evidence that Florida healthcare providers have turned to PSQIA to run peer review despite the pressures induced by Amendment 7. Florida has not particularly exploited PSOs to protect the peer review work-product using the PSWP protections granted by PSQIA.

Analyzing the PSO registration data kept by AHRQ shows that Florida has not particularly embraced the PSO model. First, Florida has had three PSOs delisted.²⁰⁰ For all three, the reason given is “voluntary relinquishment.”²⁰¹ Though having a PSO delisted for cause would hardly be cause for excitement, given that Florida should have an enthusiastic rather than apathetic response to the PSO model, the fact PSOs are allowing themselves to lapse is troubling. Indeed, among the three PSOs that have voluntarily relinquished their status is the Florida Patient Safety Corporation, which was the first in the nation to register and re-

200. *Delisted Patient Safety Organizations, supra* note 187.

201. *Delisted Patient Safety Organizations, supra* note 187.

ceived PSO Number P0001.²⁰² Only Michigan, California, Illinois, and Florida have three delisted PSOs.²⁰³ Florida's seven total listed PSOs is still among the top few states in the nation, but the lapsing of registrations should be concerning.

Second, it seems unlikely that the PSOs are delisting because of a saturation of the market. One of the remaining PSOs is PSOForida, a component entity of the Florida Hospital Association (FHA) and South Florida Hospital & Healthcare Association (SFHHA).²⁰⁴ According to a March 2012 newspaper article, PSOForida currently serves thirty-six hospitals.²⁰⁵ This is a surprisingly low number given that the FHA had 205 hospital members as of 2010,²⁰⁶ and the SFHHA has 154 members listed on its website.²⁰⁷ If one of the potential problems of forming a PSO is establishing a familiar working relationship, having the FHA and SFHHA running the PSO should have made that a non-issue. That the PSO operated as a component of an organization that has brought together so many of the hospitals in the state already and yet collects data from only thirty-six providers suggests that the actual usage of PSOs might be very low indeed.

Some of the other Florida PSOs also likely represent relatively few hospitals. For example, the Ryder Trauma Center is a registered PSO that is registered as a component entity of Jackson Memorial Hospital.²⁰⁸ While Jackson is a large hospital,²⁰⁹ that one of the seven PSOs serves exclusively one hospital suggests limited statewide coverage. The UM-JMH Center for Patient

202. *Delisted Patient Safety Organizations*, *supra* note 187.

203. *Delisted Patient Safety Organizations*, *supra* note 187.

204. *Geographic Directory of Listed Patient Safety Organizations*, *supra* note 184.

205. *Florida Hospitals Join Initiative to Improve Patient Safety*, FLORIDA SUN SENTINEL (Mar. 14, 2012), http://articles.sun-sentinel.com/2012-03-14/health/fl-jjps-hospitals-0314-20120314_1_readmissions-bruce-rueben-florida-hospitals.

206. *About Munroe*, MUNROE REG'L MED. CTR., <http://www.munroeregional.com/about-munroe/FLHospitalAssoc.aspx> (last visited Mar. 31, 2013). As of late 2012, the Florida Hospital Association's website listed 213 member hospitals; however, it was recently redesigned and now only lists the total number of hospitals in the state (303). *Facts & Stats*, FLA. HOSP. ASS'N, <http://www.fha.org/reports-and-resources/facts-and-stats.aspx> (last visited Mar. 31, 2013).

207. *About Us*, S. FLA. HOSP. & HEALTHCARE ASS'N, http://www.sfha.com/about_us (last visited Mar. 3, 2013).

208. *Delisted Patient Safety Organizations*, *supra* note 187.

209. As of March 2013, the hospital has 1259 beds. *Hospital Directory*, FLA. HOSP. ASS'N, <http://www.fha.org/reports-and-resources/hospital-directory.aspx> (choose "Jackson Memorial Hospital" in "Institution Name" drop-down list) (last visited Mar. 31, 2013).

Safety is a PSO that is a component entity of the University of Miami, Miller School of Medicine.²¹⁰ The University of Miami Health System operates three hospitals with a total of 700 beds.²¹¹ Another PSO registered in Florida is the Baptist Health Safety Partnership, operated as a component of Baptist Health South Florida, Inc.²¹² Baptist Health South Florida, Inc. is a health system comprised of six hospitals, three with fewer than 200 beds.²¹³ Thus, four of the seven currently registered Florida PSOs (PSO-Florida, Ryder, UM-JMH, and Baptist Health South Florida, Inc.) represent a grand total of only forty-six hospitals out of the hundreds in the state.²¹⁴

The fact that there appears to be a relatively high number of lapsed PSO registrations and a relatively sparse coverage of Florida hospitals suggests that PSOs are not being used as a way of protecting peer review data.

Besides AHRQ registration data, there are other sources of information indicating that Florida healthcare providers have not taken the PSO solution to the Amendment 7 pressure. According to an investigation by CBS4 in Miami, Florida hospitals were systematically not complying with Amendment 7.²¹⁵ However, the grounds on which the hospitals denied the investigative journalists' requests suggests that routing peer review material or other PSWP through PSOs was also not the preferred method of resisting to Amendment 7. Rather, based on replies to the investigators' questions, it appears that providers have fashioned their responses to information requests as narrowly as they possibly can under Amendment 7.²¹⁶

210. *Delisted Patient Safety Organizations*, *supra* note 187.

211. *Hospital Directory*, FLA. HOSP. ASS'N, <http://www.fha.org/reports-and-resources/hospital-directory.aspx> (follow "Advanced Filters" hyperlink; then choose "University of Miami Health System" in "Parent System" drop-down list) (last visited Mar. 31, 2013).

212. *Geographic Directory of Listed Patient Safety Organizations*, *supra* note 184.

213. *Hospital Directory*, FLA. HOSP. ASS'N, <http://www.fha.org/reports-and-resources/hospital-directory.aspx> (follow "Advanced Filters" hyperlink; then choose "Baptist Health South Florida" in "Parent System" drop-down list) (last visited Mar. 31, 2013).

214. According to the Florida Hospital Association, there are 303 total hospitals in the state of Florida. *Facts & Stats*, FLA. HOSP. ASS'N, <http://www.fha.org/reports-and-resources/facts-and-stats.aspx> (last visited Mar. 31, 2013).

215. *See I-Team: Ignoring Patients Right to Know*, CBS MIAMI (May 23, 2011, 10:52 AM), <http://miami.cbslocal.com/2011/05/23/i-team-ignoring-patients-right-to-know/>.

216. *See id.* The investigation found that hospitals have adopted a narrow definition of "patient," and, as such, a narrow understanding of who can request information. *Id.* Significantly, the investigation also quotes a deposition of a Northside Hospital risk man-

Clearly, then, Florida healthcare providers have not opted for the PSO solution, and instead have generally taken the third option discussed in Part III.A.²¹⁷ It seems they have maintained the same level of peer review, but have changed the procedures by minimizing to the greatest extent possible the amount of material that ends up in writing. There are a few pieces of evidence that this is the approach that has been taken. First, this was the main solution offered at a conference about peer review post-*Buster* in 2008,²¹⁸ which recommended “[m]inimizing the amount of records that must be reported . . . [and taking a] different approach to peer review . . . [with] more conversation and little to no written notes.”²¹⁹ Another media report suggests this approach was actually adopted by hospitals.²²⁰ Such tactics would indeed frustrate Amendment 7 since fewer records would be kept and hence fewer records that could be forced to be divulged, but also clearly indicates that PSOs and PSQIA protection are not being used. Indeed, legal counsel for the Florida Hospital Association noted that the major result of Amendment 7 was that authors of peer review materials are “a little more cautious in what they write down and that’s not helpful.”²²¹

Thus, the evidence indicates that the Florida experiment was not a success for PSOs. Using the roughly controlled conditions provided by Amendment 7 and the pressure it represents to find

ager saying that they have “done nothing” to make documents easily accessible and that the hospital is not keeping track of adverse medical incidents. *Id.*

217. There are, of course, a wide variety of responses. For example, at least one law firm has marketed a service attempting to use attorney-client privilege as a way of protecting physician reports used in peer review. *Amendment 7 Program*, PRESLEY LAW & ASSOCS., P.A., <http://www.plaa-pa.com/a7.html> (last visited Jan. 20, 2013).

218. Nathaniel M. Lacktman & Tina E. Dunsford, Florida Peer Review After Amendment 7: Challenges and Solutions 18 (Apr. 29, 2008), presented at The Amendment 7 Challenge: Is a PSO Hype or Hope? (presentation available at <http://www.foley.com/files/Event/06eb8893-c1dd-4ca4-a62b-d6851aa5e8d7/Presentation/EventAttachment/cc17673b-a8b8-43c0-9907-dd8ecb642883/TheAmendment7.pdf>).

219. *Id.*

220. David Rosenfeld, *Florida Supreme Court Lifts Veil on Peer Review Decades of Records About Medical Errors Are Up for Grabs*, MANATEE-SARASOTA MED. NEWS (May 2008), <http://mana-sara.medicalnewsinc.com/florida-supreme-court-lifts-veil-on-peer-review-br-decades-of-records-about-medical-errors-are-up-for-grabs-cms-676>. When asked about the fate of the peer review process, counsel for the Florida Hospital Association, Bill Bell, said, “Certainly peer review will continue. People will just be more careful about what they write down.” *Id.*

221. *Is the Patients Right To Know Constitutional?*, HOSPITAL PEER REVIEW, Oct. 1, 2008, at 139 (quoting remarks by Bill Bell, counsel for the Florida Hospital Association).

some sort of solution to a pressing problem, providers seem to be using peer review with the same frequency but changing procedures to write down less information and to narrowly construe requests for information. There is little evidence of providers turning to PSOs.

B. RECOMMENDATIONS

There have been a few attempts to analyze how the passage of Amendment 7 has affected Florida's use of peer review.²²² However, there has been no analysis of what the Florida case study says about PSQIA and how the PSO model could be improved.

Most broadly, the Florida case study suggests that there are problems. If PSOs were going to be embraced anywhere, Florida in the wake of Amendment 7 would be the ideal situation. If PSOs are less viable a solution to Florida healthcare providers' problems than trying to continually evade requests for information or complete peer review without written notes, it suggests that the progress made between the passage of PSQIA and the promulgation of the final rule might not have been enough: PSOs might be not sufficiently useful to be worth setting up.

Since 2008, there has been some movement towards making PSOs more widely adopted. President Obama's healthcare legislation, PPACA, includes numerous reforms to the healthcare delivery system. Two provisions of the PPACA have the potential to make PSOs more ubiquitous. Under § 1311(h), starting in 2015 a health plan can only contract with a hospital of over fifty beds if such hospital "utilizes a patient safety evaluation system."²²³ While this would doubtless increase the number of hospitals using a PSES to deliver some amount of data to a PSO, the statute does not appear to make any requirement about the scale of utilization. While a broad interpretation of "utilize" could make PSO usage ubiquitous, this is not guaranteed. Even if the mandate makes PSOs common, one might question whether a mandate solution is consistent with the vision of patient safety being improved through voluntary collection of data in a learning- rather

222. See, e.g., Koch et al., *supra* note 151.

223. 42 U.S.C. § 18031(h)(1)(A)(i) (2006).

than punishment-focused atmosphere.²²⁴ Second, under § 3025, HHS is to make available to certain hospitals a program that makes use of PSOs as a way of lowering admission rates.²²⁵ The mandate to implement a PSES has not yet begun and the HHS program has at time of writing not yet been released, but these two provisions should make PSOs more common and generate more data.

Besides these solutions, there are at least four other ways to make PSOs more attractive to healthcare providers. First, Congress could make it clearer that PSQIA preempts state laws like Amendment 7. As described above, preemption depends on the nature of the state law that would be preempted.²²⁶ While it seems unlikely that Florida providers avoided the PSO solution because of concerns about preemption, the fact that it is a possible issue at all might be reason enough for a cautious healthcare provider to avoid using PSQIA protections for their peer review. An unfortunate scenario would involve a provider claiming PSQIA protection for peer review materials, then facing a long litigation process as it defended itself from a state like Florida interested in maintaining its sovereignty. Such an investment of time and litigation resources might raise the estimated cost of contracting with a PSO, meaning more explicit language regarding preemption might encourage greater PSO formation. Though not relevant to Florida, one set of commentators crucially observe that “neither the text nor the structure of the PSQIA suggests that the PSQIA preempts any state reporting requirement.”²²⁷ This is particularly troubling, since without preempting other reporting requirements, providers will have no incentive to ever report to a PSO, as they will have already been required to divulge the information to state authorities. While it might be politically difficult, one of the best ways to make PSOs more attractive would be to amend the language to make PSQIA preemption broader and more explicit and to make it more likely that the PSWP of a provider using a PSO would be protected.

224. Kohn et al., *supra* note 38, at 14 (recommending the “implement[ion of] *non-punitive* systems for reporting and analyzing errors”) (emphasis added).

225. 42 U.S.C. §§ 280j-3, 1395ww(q)(8)(A) (2006).

226. See Sullivan & Anderson, *supra* note 50.

227. See Sullivan & Anderson, *supra* note 50.

Second, the PSQIA definition of PSWP could be changed so there is no doubt that peer review materials are protected. While the argument that PSO materials are properly deemed PSWP is strong,²²⁸ simply making the inclusion of “peer review materials” explicit might reduce some uncertainty and make providers more likely to entrust their peer review materials to a PSO. This change seems more politically palatable, since the only real alteration it would entail would be returning to the language of the House version of PSQIA rather than the Senate version.²²⁹

Third, and perhaps paradoxically, one way for PSOs to gain more widespread acceptance would be for more states to remove state-law peer review confidentiality protections. At least one commentator has argued that narrowing state-law peer review privilege would make it more likely for states to adopt the PSO model.²³⁰ This would have a few advantages. First, it would create a nationally uniform standard of peer review privilege; as it stands, peer review confidentiality laws are inconsistent from state to state, so a widespread constriction of state laws prompting reliance on PSQIA would be one way to achieve a nationally uniform standard. Second, the shift to PSOs would make the AHRQ database of information reported by PSOs more comprehensive; as “To Err is Human” laid out, the more information presented forthrightly and honestly, and made available for analysis, the more likely the healthcare system is to reduce the epidemic of medical error.

Finally, the federal government could provide a subsidy for the formation of PSOs.²³¹ Currently, the cost of forming and maintaining a PSO is placed entirely on the founding entity and the fees paid by the member hospitals, without assistance from the federal government.²³² Indeed, the AHRQ described the PSO

228. See *supra* Part III.A.

229. See Leaman, *supra* note 31, at 186–99 (noting that the House version of PSQIA explicitly described its privilege as “Confidentiality and Peer Review Protections”).

230. See Eric Scott Bell, *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 (2009).

231. Kadzielski & Mitchel, *supra* note 82, at 15 (“There are serious drawbacks to the PSO system, starting with no governmental funding for PSOs. Thus, many PSOs will be forced at some point to charge fees to users. In this tight economy in which health care reimbursement to providers is declining, the prospect of paying user fees to PSOs for ‘benefits’ that are largely theoretical and with no measurable return is daunting.”).

232. *PSO FAQs*, AGENCY FOR HEALTHCARE RESEARCH & QUALITY,

rule as one involving “little federal involvement.”²³³ While the Florida situation does not particularly identify administrative cost as a crucial factor in the tepid adoption of PSOs as a solution to the Amendment 7 challenge, more direct federal involvement or direct funding of PSOs would make the organizations more attractive. Indeed, the IOM reports that prompted the enactment of PSQIA recommended that Congress should take an active role in funding programs that support patient safety data standards.²³⁴ The rulemaking process addressed some of the most important logistical concerns brought up by comment letters, suggesting that federal regulators would be receptive to arguments focusing on administrative costs.²³⁵ The source of such funding would, of course, be controversial and possibly politically infeasible, particularly if PSOs are seen to be ineffective.

V. CONCLUSION

Unfortunately, the damage caused by medical error is frequently irreversible. The stories of Annie Acosta and Claudia Mejia attest to the enormous individual cost attending medical error, while “To Err is Human” demonstrates the shocking cost to society as well. To address this pressing problem, PSQIA presented a bold solution in the form of PSOs. Unfortunately, the natural experiment of Florida in the aftermath of Amendment 7 did not show that healthcare providers used PSOs even when they were potentially most useful, suggesting there might be some important flaws with the PSO model. Whether the particular solutions suggests in this Note hold the key to unlocking the potential of PSOs, or whether it takes more fundamental changes or a new institution altogether, the stakes and urgency of the problem are great.

<http://www.pso.ahrq.gov/psos/fastfacts.htm#ff04> (last visited Mar. 4, 2013).

233. Patient Safety and Quality Improvement Act, 73 Fed. Reg. 70,732, 70,732 (Nov. 21, 2008) (codified at 42 C.F.R. pt. 3) (“The proposed rule emphasized that this program is not federally funded and will be put into operation by the providers and PSOs that wish to participate with little direct federal involvement.”).

234. *See, e.g.*, Aspden, *supra* note 79, at 96–126.

235. Patient Safety and Quality Improvement Act, 73 Fed. Reg. at 70,733 (describing the many changes that HHS made to the final rule after the comment-gathering process, with many designed to clarify the duties of providers and allow them greater flexibility).