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Making the Plaintiff 's Bar Earn Its Keep: Rethinking the Hospital Incident Report

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Making the Plaintiff's Bar Earn Its Keep: Rethinking the Hospital Incident Report

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I. INTRODUCTION

Visits to the hospital, particularly for an emergency, are often fraught with anxiety and apprehension for both patients and accompanying family members. It is not unimaginable to think however, that for a patient who feels terrible enough to go to the emergency room, it may be a relief to turn control over to medical professionals. The chance that a doctor might make a mistake *might* cross a patient's mind; at that moment, however, the patient must trust that the doctor will not. But people, and particularly systems, are fallible; it can be easy to misread a number on a script or pick up the wrong vial. When mistakes happen, patients may be angry, or worse, injured. Some patients will want to sue. Whether or not a patient decides to sue, all healthcare consumers want the provider to identify and correct the error. Society as a whole is invested in making sure that the mistake does not happen again to someone else.

Healthcare providers are equally invested in correcting errors. In part, this investment is a result of the complex federal and state regulatory structure that governs their activities.¹ One example of this regulatory complexity can be found in the differing state laws that require reporting of errors made by healthcare providers. These incident reports help providers analyze failures that have led, or may have led, to patient harm, and are part of an ongoing debate about error disclosure, patient rights, and quality of health care.² In some states, incident reports are statutorily granted nearly complete confidentiality.³ Yet in other states, patients have been granted full access to incident reports, including those that were previously held to be confidential.⁴ Recent federal legislation grants some additional protection to these reports of error. Incident reporting is an extremely important piece of the improvement of the quality of the healthcare system, but can only be effective if the information is consistently privileged.

This note argues that the confidentiality of incident reports must be guaranteed in order to satisfy the concurrent and different needs of providers, regulators, and patients. This argument is not new. As early as 1993, researchers proposed various model legislative schemes creating separate or additional privileges for incident re-

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1. Sarah Helene Duggin, *The Impact of the War over the Corporate Attorney-Client Privilege on the Business of American Health Care*, 22 J. CONTEMP. HEALTH L. & POL'Y 301, 304 (2006) ("Few areas of endeavor are steeped so deeply in labyrinthine regulations and convoluted statutory provisions as American health care"); see also Michelle M. Mello, Carly N. Kelly & Troyen A. Brennan, *Fostering Rational Regulation of Patient Safety*, 30 J. HEALTH POL. POL'Y & L. 375 (2005).
 2. The term incident report can refer to many types of reports, some of which will be discussed in Part II below. For the purposes of this note, an incident report is a report that either describes or analyzes a medically related incident that occurred within the course of a patient's care, such as a medication error or a wrong site surgery, and is used for purposes either internal to a hospital or for external reporting to a regulatory or accrediting agency. This note generally will not consider intentional harm to patients or a facility's accidents, such as a chair that breaks underneath a patient in a waiting room. See, e.g., *Berggren v. Saint Vincent's Catholic Med. Ctr. of N.Y., Inc.*, No. 10129/04, 2004 WL 2903641, at *1 (Sup. Ct. Richmond County Dec. 13, 2004).
 3. See, e.g., N.Y. EDUC. LAW § 6527(3) (McKinney 2001 & Supp. 2008); *Megrelishvili v. Our Lady of Mercy Med. Ctr.*, 739 N.Y.S.2d 2, 7 (1st Dep't 2002).
 4. See, e.g., FLA. CONST. art. X, § 25.

ports beyond those that already existed.⁵ In 2005, Congress enacted the Patient Safety and Quality Improvement Act (“PSQIA”), a federal law designed to encourage reporting of patient safety work product⁶ by providing an incentive of confidentiality to those who report to specific patient safety organizations.⁷ This new protection still does not go far enough. Incident reports will continue to be disclosed and errors will still plague our healthcare system.⁸

Part II of this note provides a broad background of the confidentiality generally given to a hospital’s quality assurance process and the privileges that have traditionally been applied to quality assurance material. It then focuses more narrowly on incident reports and compares current confidentiality statutes in two states that represent different ends of the disclosure spectrum, Florida and New York. Part III will

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5. See generally Cynthia Dollar, Note, *Promoting Better Health Care: Policy Arguments for Concurrent Quality Assurance and Attorney-Client Hospital Incident Report Privileges*, 3 HEALTH MATRIX 259 (1993) (proposing a model rule for use by states to create a hospital incident report privilege); Jason M. Healy, William M. Altman & Thomas C. Fox, *Confidentiality of Health Care Provider Quality of Care Information*, 40 BRANDEIS L.J. 595 (2002) (proposing model legislation to provide incentives and method for the reporting of quality information to the federal government by a specific group of institutions).
 6. Patient safety work product is defined in the new law’s proposed regulations as “any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements (or copies of any of this material)” which is ultimately contributed to a patient safety evaluation, or reporting, system. Patient Safety and Quality Improvement, 73 Fed. Reg. 8112, 8120 (proposed Feb. 12, 2008) (to be codified at 42 C.F.R. pt. 3).
 7. See Patient Safety and Quality Improvement Act of 2005, Public L. No. 109-41, 119 Stat. 424 (codified as amended at 42 U.S.C. §§ 201, 299b-1 to c-6 (2000 & Supp. 2005)); Patient Safety and Quality Improvement, 73 Fed. Reg. at 8112, 8113. The analysis of medical errors will be held confidential if disclosed to a certified patient safety organization, but such protection is separate from and does not cover information gathered for a provider’s own internal investigation purposes or for purposes related to required reporting to regulatory and accrediting agencies. *Id.* at 8123.
 8. Steven E. Pegalis, *A Proposal to Use Common Ground That Exists Between the Medical and Legal Professions to Promote a Culture of Safety*, 51 N.Y.L. SCH. L. REV. 1056, 1063 (2006) (citing Lucian L. Leape & Donald M. Berwick, *Five Years After To ERR IS HUMAN: What Have We Learned?*, 293 JAMA 2384, 2384-90 (2005)) (noting that five years after the initial Institute of Medicine’s report on medical errors, progress in patient safety improvements was very slow); see also Brent C. James, *Prologue: Five Years Later—Are We Any Safer?*, in 1 ADVANCES IN PATIENT SAFETY: FROM RESEARCH TO IMPLEMENTATION 1, 1 (2005) (“[A]s a country, progress has fallen far short of the IOM’s ambitious goal. Some members of the original IOM committee have publicly decried the lack of substantial progress . . .”) (citing D.M. Berwick, Op-Ed., *Invisible Injuries*, WASH. POST, July 29, 2003, at A17; J. MORRISEY, *Patient Safety Proves Elusive*, MOD. HEALTH, Nov. 2004, at 1, 6-7, 25, 30, 32); HEALTH GRADES, THE FOURTH ANNUAL HEALTH GRADES PATIENT SAFETY IN AMERICAN HOSPITALS STUDY 6 (April 2007), <http://www.healthgrades.com/media/DMS/pdf/PatientSafetyinAmericanHospitalsStudy2007.pdf> (“Despite the flurry of research, publications and process improvement activity that has occurred since the IOM report, there is a growing consensus that not much progress has been made leading to a visible national impact. Our findings support this consensus.”). A Health Grades study of patient safety in U.S. hospitals using Medicare hospitalization records between the years 2003 and 2005 found that 1.16 million patient safety incidents had occurred in that timeframe, and that 247,662 patient deaths could have been prevented. *Id.* at 4. It should be noted, however, that the reliability of the Health Grades study has been called into question for a number of reasons. See Maxine M. Harrington, *Revisiting Medical Error: Five Years After the IOM Report, Have Reporting Systems Made a Measurable Difference?*, 15 HEALTH MATRIX 329, 346-48 (2005).

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examine the risks of non-confidentiality and contrast these risks with the rationales for disclosure. Finally, Part IV will argue that the use of incident reports should be limited to their intended purposes—that of research by a hospital into its processes for the purposes of improvement and satisfaction of regulatory requirements, and preparation for litigation—and not an additional tool for use by plaintiffs seeking redress. Therefore, federal legislation must go farther to protect all incident reports, including those that must be submitted to state departments of health.

II. THE HISTORY AND CONTEMPORARY STATUS OF QUALITY ASSURANCE ANALYSIS

A. Confidentiality in the Quality Assurance Process

Quality assurance is the term used for a healthcare provider's review of its systems to improve patient safety and care.⁹ The confidentiality of quality assurance review in the healthcare industry has a robust, if inconsistent, history. Confidentiality is granted to quality assurance activities on the premise that without such a promise, providers are less likely to participate or be truthful when participating in the quality assurance process.¹⁰ Without truthful and open participation, there can be no genuine improvement.

Many industries, including healthcare, recognize that employees are more willing to report errors if they know that their reports will remain confidential.¹¹ It is recognized that the “mere fear of litigation due to disclosure of data is the greatest barrier to reporting.”¹² In addition to an apprehension of litigation, disclosure spurs a fear of both reputational damage and professional sanctions.¹³ To further the quality assurance process, which entails making sure less focus is placed on those responsible and more is directed toward solutions, the trust of the potential reporters must be earned. Dependable confidentiality goes far in earning such trust.

Since regulating health care has typically been the province of the states,¹⁴ state law governs the confidentiality of medical peer review and quality assurance committees, as well as the reports and activities of those committees.¹⁵ State legislatures

9. Dollar, *supra* note 5, at 264–66.

10. *Id.* at 279–80.

11. See, e.g., Dayna C. Nicholson & Lynsey A. Mitchel, *A Medical Error Happened: Now What? The Implications for Medical Errors Heat Up*, 10 J. HEALTH CARE COMPLIANCE 5 (2008) (describing the oft-cited model of aviation safety and improvements).

12. Harrington, *supra* note 8, at 353 (citing MIMI MARCHEV, NAT'L ACAD. FOR ST. HEALTH POL'Y, MED. MALPRACTICE AND MED. ERROR DISCLOSURE: BALANCING FACTS AND FEARS 2 (2003), http://www.nashp.org/Files/Medical_Malpractice_and_Medical_Error_Disclosure.pdf).

13. Patient Safety and Quality Improvement, 73 Fed. Reg. at 8113.

14. QUALITY INTERAGENCY COORDINATION TASK FORCE, DOING WHAT COUNTS FOR PATIENT SAFETY: FEDERAL ACTIONS TO REDUCE MEDICAL ERRORS AND THEIR IMPACT 10 (2000), <http://www.quic.gov/Report/errors6.pdf>; see also Duggin, *supra* note 1, at 329.

15. See generally AM. HEALTH LAWYERS ASS'N, PUBLIC INTEREST COLLOQUIUM, MINIMIZING MEDICAL ERRORS: LEGAL ISSUES IN THE DEBATE ON IMPROVING PATIENT SAFETY (2003); Duggin, *supra* note 1, at 329–30.

that enact laws granting confidentiality to the quality assurance process within hospitals seem to have accepted the concept that people may be more likely to disclose errors if they are assured of confidentiality.¹⁶ Many states also provide confidentiality to the discussions and reports of committees internal to healthcare providers whose job it is to review these quality assurance processes.¹⁷ Most often healthcare providers, in many cases hospitals, have a medical peer review committee to look after the medical staff as well as a type of quality assurance committee to monitor quality of care.¹⁸

Medical peer review is the process through which hospitals credential (grant privileges to) and evaluate the physicians who work for them.¹⁹ To be credentialed to practice and treat patients at a hospital, a physician must provide the hospital with, among other things, proof of his or her qualifications and competence, both initially and then on a regular basis over the course of his or her tenure.²⁰ Should the physician's qualifications or competence be called into question, the peer review committee will review the physician's behavior and recommend measures to discipline or assist the physician.²¹ For example, if a physician shows up to work intoxicated, the peer review committee has the authority to investigate the physician's reported behavior.²² The peer review committee has the power to suspend that physician or even revoke his or her hospital privileges.²³ Healthcare providers may also have quality assurance committees, which are responsible for risk management processes, such as investi-

16. See, e.g., *Logue v. Velez*, 92 N.Y.2d 13, 16–18 (1998).

17. See, e.g., N.Y. EDUC. LAW § 6527(3).

18. See, e.g., Health Care Quality Improvement Act of 1986, 42 U.S.C. § 11101–11152 (2000).

19. See Steven Suydam, et al., *Patient Safety Data Sharing and Protection from Legal Discovery*, 3 ADVANCES IN PATIENT SAFETY: FROM RESEARCH TO IMPLEMENTATION 361, 365 (2005).

20. See Katharine Van Tassel, *Hospital Peer Review Standards and Due Process: Moving From Tort Doctrine Toward Contract Principles Based on Clinical Practice Guidelines*, 36 SETON HALL L. REV. 1179, 1190 (2006) (citing CREDENTIALING & PEER REVIEW PRACTICE GROUP OF THE AM. HEALTH LAWYER'S ASS'N, PEER REVIEW GUIDEBOOK (3d ed. 2003)). Physicians who seek to be credentialed at a hospital may have to provide additional information, such as disclosure of any conflicts of interest or evidence of good physical health. Requirements vary from institution to institution. For a good overview of these requirements as well as problems that physicians encounter with peer review committees, which in part led to the passage of the Health Care Quality Improvement Act of 1986, see Pauline Martin Rosen, *Medical Staff Peer Review: Qualifying the Qualified Privilege Provision*, 27 LOY. L.A. L. REV. 357 (1993).

21. Van Tassel, *supra* note 20, at 1190.

22. See *id.* at 1190–91.

23. *Id.* If a physician's privileges are revoked, the physician cannot see patients at that hospital until the privileges are reinstated. The physician is not precluded from seeking patients at another practice where he or she has privileges and that is independent of the hospital. However, for behavior that compels a revocation of privileges, there may be a concurrent state board of medicine investigation that may ultimately determine whether the physician may keep his or her license to practice medicine. *Id.* For examples of types of reporting and investigations beyond those initiated by hospital peer review committees, see the Health Care Quality Improvement Act of 1986, 42 U.S.C. §§ 11131–11137.

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gating accidents and other events that occur within the hospital.²⁴ These committees are found in particular at skilled nursing facilities and other places that treat Medicare and Medicaid patients.²⁵ These committees as a whole, not just at skilled nursing facilities, are responsible for recommending changes to processes that have not been working or that present a risk to patients.²⁶

The purpose of providing protection for these processes is to ensure that the reviewers can perform their functions objectively and effectively.²⁷ The state has an interest in improving medical care—whether by monitoring and disciplining physicians, reporting incidents, or improving hospital systems.²⁸ States therefore provide for the protection of peer review and quality assurance committee records by statute, although each state is different and protection in one state is by no means the same as protection in another.²⁹ For example, in one state the final outcome of a peer review hearing may be the only aspect of the review process that is kept confidential, while in another state the entire process is protected from disclosure.³⁰ In addition,

24. Dollar, *supra* note 5, at 279–84.

25. Healy et al., *supra* note 5, at 613. Quality assurance committees at skilled nursing facilities already play a more significant role as the federal government has entered into Corporate Integrity Agreements with several of these facilities to address quality issues within the institutions—such agreements are normally associated with the federal government's attempt to improve an institution's billing issues. *Id.* at 611–61.

26. For a government-mandated implementation of a quality assurance committee, see U.S. DEP'T OF HEALTH AND HUMAN SERV., CORP. INTEGRITY AGREEMENT BETWEEN OFFICE OF INSPECTOR GEN. OF THE DEP'T OF HEALTH AND HUMAN SERV. AND GREEN VALLEY PAVILION ET AL. 3 (May 2007), available at http://oig.hhs.gov/fraud/cia/agreements/green_valley_pavilion_05012007.pdf (mandating creation of a Quality Assurance Compliance Committee “to address issues concerning quality of care at Green Acres’ nursing homes” and a Quality Assurance Monitoring Committee to, among other things “review the adequacy of Green Acres’ system of internal controls, quality assurance monitoring, and patient care”).

27. See, e.g., *Logue*, 92 N.Y.2d at 16–18. In *Logue*, the New York Court of Appeals reviewed the legislative history behind two New York statutes that provide confidentiality to peer review and quality assurance proceedings, finding that “[t]he purpose of the discovery exclusion is to ‘enhance objectivity of the review process’ and to assure that medical review committees ‘may frankly and objectively analyze the quality of health services rendered’ by hospitals.” *Id.* at 17 (quoting Mem. of Assembly Rules Comm., Bill Jacket, L. 1971, ch. 990, at 6).

28. See Duggin, *supra* note 1, at 329–30.

29. Bryan A. Liang, *The Adverse Event of Unaddressed Medical Error: Identifying and Filling the Holes in the Health-Care and Legal Systems*, 29 J.L. MED. & ETHICS 346, 352 (2001) (“[S]tate-based peer review statutes are quite variable in their coverage. Some state statutes cover some information; others, little; still others, only information generated by particular providers, such as hospitals, while ignoring other provider forms, such as managed care organizations.”); see also David H. Johnson & David W. Shapiro, *The Institute of Medicine Report on Reducing Medical Error and Its Implications for Healthcare Providers and Attorneys*, 12 HEALTH LAW. 1, 7–8 (2000) (“Unfortunately for confidentiality, these [peer review privilege] statutes vary considerably in their reach and strength. Overall, this makes them a problematic source of legal protection for error data The treatment of incident reports within an institution, for example, varies by state.”). See generally Bryan A. Liang & Steven D. Small, *Communicating About Care: Addressing Federal-State Issues in Peer Review and Mediation to Promote Patient Safety*, 3 HOUS. J. HEALTH L. & POLY 219 (2003).

30. Dollar, *supra* note 5, at 283–84.

as with the example of attorney-client privilege discussed below, disclosure of the information with a third party during the peer review or quality assurance process may constitute waiver of confidentiality. This can hamper the sharing of quality of care information between healthcare institutions that seek to learn from each other's mistakes.³¹

Statute is not the only means by which quality of care information may be protected. If quality of care information is sought by an adversary during discovery, providers may also rely on evidentiary privileges to protect the information. The attorney-client and attorney work-product privileges may be invoked when the hospital's attorneys have participated in the internal investigation of an incident and in drafting an incident report.³² These privileges may be asserted concurrently with the assertion of statutory peer review or quality assurance privilege and confidentiality.

Attorney-client privilege protects conversations between attorney and client. The purpose of attorney-client privilege is to "encourage full and frank communication between attorneys and their clients and thereby promote broader public interests in the observance of law and administration of justice."³³ When such communication is guaranteed to remain confidential, a client may feel free to be completely honest with his or her attorney, which allows the attorney to provide the best possible advice. When the client is a hospital, attorney-client privilege becomes a more complicated issue, because the hospital is a corporation and acts through its agents.³⁴ The question then becomes: to whom does this privilege apply?³⁵ To determine whose communications with an attorney are covered by the corporate attorney-client privilege, courts have developed various tests, such as the control group test and the subject matter test.³⁶ In the control group test, the agents of the corporations who were covered under the corporate attorney-client privilege were management-level employees or officers representing the corporation who sought legal advice from counsel on behalf of the corporation.³⁷ The Supreme Court rejected the control group test in *Upjohn Co. v. United States*, recognizing that the privilege existed not just for an attorney to provide legal advice to the corporation but for an attorney to

31. Suydam, *supra* note 19, at 362 ("One potential problem with such [regional safety consortia comprised of member healthcare institutions] . . . was that free exchange of information between institutions may render such information vulnerable to discovery by plaintiffs . . . by implied waiver of any peer review privilege that might exist . . .").

32. See generally Dollar, *supra* note 5.

33. *Upjohn Co. v. United States*, 449 U.S. 383, 389 (1981).

34. For an extensive examination and discussion of the corporate attorney-client privilege, see Vincent C. Alexander, *The Corporate Attorney-Client Privilege: A Study of the Participants*, 63 ST. JOHN'S L. REV. 191 (1989).

35. See generally Grace M. Giesel, *The Legal Advice Requirement of the Attorney-Client Privilege: A Special Problem for In-House Counsel and Outside Attorneys Representing Corporations*, 48 MERCER L. REV. 1169 (1997).

36. *Id.*

37. *Upjohn*, 449 U.S. at 391-93.

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receive information about the problem facing the corporation.³⁸ The Supreme Court declined to establish an alternative test at that time.³⁹ Another test, the subject matter test proposed in *Samaritan Foundation v. Goodfarb*, protects conversations between an attorney and those employees, whether management or not, who had something to do with the subject matter of the incident which led to the attorney's involvement.⁴⁰ Whether in an individual context or in the corporate context, attorney-client privilege can easily be waived by disclosure—purposeful or inadvertent—to a third party.

Attorney work-product privilege protects an attorney's notes and other materials created in anticipation of litigation, including an attorney's thoughts and strategies.⁴¹ One author of a law review article described attorney work product as follows: “[N]otes and other documents prepared by or for the organization's attorneys as a result of an internal investigation are protected, but only if the work is done in anticipation of litigation.”⁴² As recognized in the Federal Rules of Civil Procedure, these materials are unavailable to an adverse party in litigation, except in cases of undue hardship.⁴³ Thus, it appears that attorney work-product privilege is not as broad as attorney-client privilege because of the condition that it only covers material created in anticipation of litigation.⁴⁴

Problems can arise for hospitals when they attempt to use these evidentiary privileges to shield incident reports from disclosure during litigation. Examples of some problems include: cases in which the hospital has provided an incident report to a third party, such as an insurer or regulator;⁴⁵ cases in which in-house hospital counsel “wears more than one hat” in the organization and the court finds that in preparing the incident report, counsel was acting in the capacity of business management, not counsel;⁴⁶ and cases in which a hospital's policy is to create a report for each incident,

38. *Id.* at 390.

39. *Id.* at 396–97.

40. 862 P.2d 870, 875 (Ariz. 1993) (citing *Harper & Row Publishers, Inc. v. Decker*, 423 F.2d 487 (7th Cir. 1970), *aff'd by an equally divided court*, 400 U.S. 348 (1971)).

41. *Hickman v. Taylor*, 329 U.S. 495 (1947).

42. Gabriel Imperato, *Internal Investigations, Government Investigations, Whistleblower Concerns: Techniques to Protect Your Health Care Organization*, 51 ALA. L. REV. 205, 215–16 (1999).

43. *In re Qwest Comm'n Int'l, Inc.*, 450 F.3d 1179, 1186 (10th Cir. 2006) (citing FED. R. CIV. P. 26(b)(3)).

44. *See generally* Imperato, *supra* note 42, at 212–19.

45. *See* Liang, *supra* note 29, at 353 (“[E]rror and safety information must often be disclosed to third parties. For example, information about errors resulting in an adverse event must be reported to a particular state agency in roughly two dozen or so states and to JCAHO under its Sentinel Event Policy.”); Dollar, *supra* note 5, at 259 (“The attorney-client privilege does not consistently protect incident reports because they are prepared for other persons, such as liability insurers and hospital risk managers and quality committees, as well as for the attorney.”).

46. Greg Radinsky, *The Compliance Officer Conundrum: Assessing Privilege Issues in a Health Care Setting*, 5 DEPAUL J. HEALTH CARE L. 1, 2–3 (2002). It should be noted that currently this conflict arises more within the context of counsel who are also compliance officers at healthcare institutions. Compliance

and the court finds a report to have been created in the ordinary course of business rather than in anticipation of litigation.⁴⁷ One researcher has expressed the concern that, if others in management either direct the creation of or receive such reports, a court may find that the privileges do not apply because the reports were not created at the behest of counsel.⁴⁸ In addition, the collaborative sharing of error reports among hospitals for the purpose of enhancing each other's knowledge and processes may also waive the privilege because they are third parties.⁴⁹ Overall, "[i]n the context of internal investigations, counsel often cannot rely with total confidence on the most frequently invoked protections—the attorney-client privilege and the work-product doctrine."⁵⁰ This inability to rely on well-established confidentiality protections creates a serious impediment to accurate and thorough reporting, because hospitals and physicians will be reluctant to fully disclose if they believe their reports will end up in the hands of an adverse party.

The self-evaluative privilege is another privilege meant to protect a hospital's quality assurance review procedures.⁵¹ The self-evaluative privilege is similar to statutory quality assurance privileges in that it is meant to shield internal review analysis.⁵² To qualify for the privilege, the information must have come from critical self-analysis, there must be public interest in having the practitioners engage in the self-analysis, and that self-analysis would stop if the information were discovered.⁵³

officers at healthcare institutions generally are responsible for ensuring that hospital bills, as well as Medicare and Medicaid claims, are accurate and correct, and that there has been no fraud. However, compliance programs for quality assurance have begun to make their way into the healthcare industry, beginning with skilled nursing facilities as the federal government implements new quality assurance compliance programs in these institutions with particularly vulnerable populations. Healy et al., *supra* note 5, at 611–12. Therefore, this potential problem may become a more widespread issue if quality assurance compliance programs move into other federally funded healthcare institutions, such as hospitals. To this end, the Centers for Medicare & Medicaid Services has "begun to utilize quality factors as a basis for reimbursement decisions; the wave of the future is non-payment for medical care related to an adverse event." Nicholson & Mitchel, *supra* note 11, at 5.

47. Dollar, *supra* note 5, at 279 ("When the reports serve more than one purpose, even if both purposes serve important policies, the privilege is uncertain.").
48. *Id.* at 274 ("Some courts have ruled that incident reports are not confidential communications because they are made under the direction of the hospital's internal administration, not just the attorney, and the reports are delivered to hospital administrators and insurers.").
49. See generally Colin P. Marks, *Corporate Investigations, Attorney-Client Privilege, and Selective Waiver: Is a Half-Privilege Worth Having at All?*, 30 SEATTLE U. L. REV. 155, 163–65 (2006) (describing how attorney-client privilege is more easily waived than the work-product privilege, though both may be waived by disclosure to a third party).
50. Thomas F. O'Neil & Adam H. Charnes, *The Embryonic Self-Evaluative Privilege: A Primer for Health Care Lawyers*, 5 ANNALS HEALTH L. 33, 34 (1996).
51. See Dollar, *supra* note 5.
52. Healy et al., *supra* note 5, at 628–29 (referencing *Bredice v. Doctor's Hosp., Inc.*, 50 F.R.D. 249 (D.D.C. 1970), *aff'd*, 479 F.2d 920 (D.C. Cir. 1973), in which the court found that the public interest in allowing hospitals to investigate a patient's death outweighed disclosure).
53. Imperato, *supra* note 42, at 216–17 (quoting Thomas F. O'Neil & Adam H. Charnes, *The Embryonic Self-Evaluative Privilege: A Primer for Health Care Lawyers*, 5 ANNALS HEALTH L. 33, 37 (1996)).

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When reporting is not required and the review process is voluntary, researchers caution that even then “those portions of a written report that compile, organize, and present all pertinent underlying facts nonetheless may well be disgorged, providing opposing parties with an easy road map for proving their claims, as well as admissions of a party opponent that are extremely useful during litigation.”⁵⁴ Despite its potential utility and similarity to statutory quality assurance privileges, courts have not universally accepted this privilege.⁵⁵

Finally, there is selective waiver—the disclosure of confidential, privilege-protected information to a third party, such as a government regulator, with the understanding that the disclosure should not be construed as full waiver.⁵⁶ Sometimes the selective waiver doctrine is invoked if voluntary disclosure has been made under a confidentiality agreement with an investigating government agency.⁵⁷ In situations where the government is investigating fraud or billing claims, a hospital may attempt to demonstrate its cooperativeness with the government by waiving its privileges and disclosing confidential information in the hopes of receiving a reduction in penalties, but is not willing to share the confidential information with other interested persons not party to the agreement.⁵⁸ The difficulty with selective waiver is that it is contractual and cannot bind third parties, so courts have found waiver, no matter under what agreement, to be complete.⁵⁹ Healthcare providers considering whether to self-disclose to the government should not count on the doctrine of selective waiver to keep their incident reports confidential.⁶⁰ Healthcare providers, therefore, may have statutory protection for quality of care information as well as potential coverage by evidentiary privileges.

54. O’Neil & Charnes, *supra* note 50, at 39.

55. See Healy et al., *supra* note 5, at 628–31.

56. Marks, *supra* note 49, at 165.

57. See, e.g., *In re HCA/Columbia Healthcare Corp. Billing Practices Litig.*, 293 F.3d 289 (6th Cir. 2002).

58. Duggin, *supra* note 1, at 313 (“The selective waiver conflict pits individuals and entities who have voluntarily disclosed otherwise privileged materials to law enforcement authorities against third-party litigants seeking access to these materials in related civil litigation . . .”).

59. *Id.* at 315–16.

60. See *In re Qwest Comm’n Int’l, Inc.*, 450 F.3d at 1186–94 (providing an overview of the state of the law surrounding selective waiver in various circuits, and in the process, clarifying Tenth Circuit law in this area by rejecting the selective waiver in all contexts). Selective waiver in the context of attorney-client privilege has been adopted by the Eighth Circuit, but has been rejected by the D.C. Circuit, as well as the First, Second, Third, Fourth, and Sixth Circuits. *Id.* at 1186–88. In the context of attorney work product, the Fourth Circuit has adopted selective waiver in regards to opinion work product but rejected it with regard to non-opinion work product, and the First, Third, Sixth, and Eighth Circuits have rejected selected waiver for non-opinion work product. *Id.* at 1190–91. Further, the state of the law is unclear in the D.C. Circuit which has upheld, without providing analysis, a district court finding that the work-product doctrine had not been waived, but has in other circumstances rejected selective waiver of work-product protection. *Id.*

New federal legislation will also provide additional protections to certain quality assurance material.⁶¹ The PSQIA “creates a new and strong federal privilege for patient safety work product, preempting state laws governing civil or administrative procedures that would require the disclosure of information by a healthcare provider to a certified PSO [Patient Safety Organization].”⁶² The legislation provides an incentive to providers to voluntarily report errors and other incidents by protecting all disclosures made to PSOs that are certified with, and governed by, the Agency for Healthcare Research and Quality.⁶³ The act also sets out that patient safety material disclosed to a PSO, or in specific other permitted circumstances, continues to be protected and there is no waiver because of this disclosure to a third party.⁶⁴ Quality of care information that is not reported to a PSO is not protected. The preamble to the proposed regulations, published in February 2008, stresses that “[p]roviders or PSOs that have a documented patient safety evaluation system will have substantial proof to support claims of privilege and confidentiality when resisting requests for production of, or subpoenas for, information constituting patient safety work product”⁶⁵

The legislation seems promising, but the PSQIA will not solve all of a provider’s reporting disclosure problems while widely differing state policy concurrently exists,⁶⁶ and it does not protect disclosures made to state regulatory agencies.⁶⁷ This means that if a copy of an incident report made for the purpose of reporting to a state

61. Patient Safety and Quality Improvement Act of 2005 § 299b-22. The Act reads in pertinent part: 42 USC 299b-22: PRIVILEGE AND CONFIDENTIALITY PROTECTIONS.

(a) Privilege.—Notwithstanding any other provision of Federal, State, or local law, and subject to subsection (c), patient safety work product shall be privileged and shall not be—(1) subject to a Federal, State, or local civil, criminal, or administrative subpoena or order, including in a Federal, State, or local civil or administrative disciplinary proceeding against a provider; (2) subject to discovery in connection with a Federal, State, or local civil, criminal, or administrative proceeding, including in a Federal, State, or local civil or administrative disciplinary proceeding against a provider; (3) subject to disclosure pursuant to section 552 of title 5, United States Code (commonly known as the Freedom of Information Act) or any other similar Federal, State, or local law; (4) admitted as evidence in any Federal, State, or local governmental civil proceeding, criminal proceeding, administrative rulemaking proceeding, or administrative adjudicatory proceeding, including any such proceeding against a provider

Id.

62. Barry R. Furrow, *Regulating Patient Safety: Toward a Federal Model of Medical Error Reduction*, 12 WIDENER L. REV. 1, 17 (2005).

63. *See id.*

64. *See* Charles M. Key, *A Review of the Patient Safety and Quality Improvement Act of 2005*, 18 HEALTH LAW. 20, 21 (2005).

65. Patient Safety and Quality Improvement, 73 Fed. Reg. at 8120.

66. *See, e.g.*, Melissa Morgan Hawkins, *Amendments 7 and 8 Update: Legislation Enabling the Patient’s Right to Know Act and Three Strikes Rule*, 25 TRIAL ADVOC. Q. 7, 11 (2006) (noting the unknown impact that PSQIA’s regulations will have on relevant Florida law).

67. Patient Safety and Quality Improvement, 73 Fed. Reg. at 8123. In addition, the regulations make clear that regulatory and accrediting agencies may not be certified as PSOs. *Id.* at 8120, 8126–32.

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agency is submitted to a PSO, only the copy submitted to the PSO is protected by the federal privilege and confidentiality provisions.⁶⁸ The proposed regulations set out that any entity that provides regulatory oversight, such as accreditation or licensure, may not be certified as a PSO because of the need to reassure providers that patient safety reporting to PSOs will not be punitive.⁶⁹

Healthcare providers must actually report in order to be protected: “the mere assembling for the purpose of reporting medical errors or other quality information programs is not enough to trigger protection.”⁷⁰ Those records compiled for internal risk management efforts and to report to external regulators will not be considered patient safety work product, so reports composed for purposes internal to the hospital, as well as mandatory reports made to state agencies, may still be accessible.⁷¹ In addition, encouraging providers to report will require convincing them that the report material will always be protected, which is no easy task when experiences in certain states, or certain courts, have shown them otherwise.⁷² For example, Florida’s recent constitutional amendment opens up *all* incident reports to the public, not just those created after the date of the amendment.⁷³

B. Mandatory Incident Reporting in Florida and New York

An incident report is, in broad terms, the product of an internal investigation by a hospital into an event outside of the hospital’s normal occurrences.⁷⁴ Incident reporting is defined by the National Patient Safety Foundation as “a process used to document occurrences that are not consistent with routine hospital operation or care.”⁷⁵ The reporting and the investigation may be mandated by a state or federal regulatory agency.⁷⁶

68. *Id.* at 8123.

69. *Id.* at 8126–27.

70. Ice Miller LLP, *Survey of Recent Developments in Health Law*, 39 IND. L. REV. 1051, 1077 (2006).

71. *See* Patient Safety and Quality Improvement, 73 Fed. Reg. at 8121.

72. *See* Key, *supra* note 64, at 22 (“Only time, and the inevitable challenges, will tell whether the privilege is as sound as it seems . . .”).

73. *See, e.g.*, North Broward Hosp. Dist. v. Kroll, 940 So. 2d 1281 (Fla. Dist. Ct. App. 2006). *But see* Michota v. Bayfront Med. Ctr., Inc., No. 04-1057-CI-19, 2005 WL 900771 (Fla. Cir. Ct. 2005) (holding that Amendment 7 is not retroactive).

74. Dollar, *supra* note 5, at 263 (citing JOHN F. MONAGLE, RISK MANAGEMENT: A GUIDE FOR HEALTH CARE PROFESSIONALS 29 (1985)).

75. NATIONAL PATIENT SAFETY FOUNDATION, PATIENT SAFETY DEFINITIONS, (citing NATIONAL PATIENT SAFETY FOUNDATION, LESSONS IN PATIENT SAFETY (L.A. Zipperer & S. Cushman eds., 2001)), <http://npsf.org/rc/mp/definitions.php> (last visited Sept. 18, 2008).

76. *See* Duggin, *supra* note 1, at 329–32.

An incident report serves two purposes.⁷⁷ One purpose is to “prepare for potential litigation.”⁷⁸ The second purpose is to analyze the incident and its circumstances with the goal of changing or implementing a process to avoid the occurrence of a similar event in the future.⁷⁹ After an incident occurs, such as when a patient is given the wrong medication, a statute usually determines whether it must be reported.⁸⁰ The investigation into and reporting of the incident generally will be led by a member of the entity’s risk management or compliance team.⁸¹

Examples of incidents that may need to be reported include instances of medical equipment failure, fire, medication mix-up, surgery on the wrong part of a patient’s body or surgery on the wrong patient.⁸² An incident that almost occurs but is averted is labeled a near miss.⁸³ Near misses are less frequently required to be reported, although some researchers argue that they are just, if not more, important in helping providers understand a system’s weaknesses.⁸⁴

Within the healthcare industry, such occurrences are known by different names, such as incidents, adverse events, or sentinel events. Often, the choice of label used depends upon the regulatory context, and there are many regulators within the healthcare industry with individual definitions of incident, resulting in no universal agreement about what, exactly, an incident entails. For example, the National Patient Safety Foundation, a non-profit organization dedicated to improving the safety of patients, lists definitions currently used by institutions—*adverse event* is defined nine ways, *accident* two ways, and *error* seven ways.⁸⁵ The Joint Commission for the Accreditation of Healthcare Organizations, also known as the Joint Commission or JCAHO, an independent organization that accredits healthcare organizations, refers to serious incidents as sentinel events within the context of its reporting

77. Dollar, *supra* note 5, at 259.

78. *Id.*

79. *See id.*

80. *See generally* Furrow, *supra* note 62, at 12; Lucian L. Leape, *Reporting of Adverse Events*, 347 NEW ENG. J. MED. 1633 (2002).

81. This will vary depending upon the organizational structure of the institution.

82. *See, e.g.*, N.Y. PUB. HEALTH LAW § 2805-1 (McKinney 2007).

83. Near misses are often reported along with actual incidents in voluntary reporting systems. COMMITTEE ON QUALITY OF HEALTH CARE IN AMERICA, INSTITUTE OF MEDICINE, *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* 87 (Linda T. Kohn et al., eds., 2000) [hereinafter *TO ERR IS HUMAN*] (“When voluntary systems focus on the analysis of ‘near misses’, their aim is to identify and remedy vulnerabilities in systems before the occurrence of harm.”); *see also* Ellen Flink et al., *Lessons Learned from the Evolution of Mandatory Adverse Event Reporting Systems*, in 3 *ADVANCES IN PATIENT SAFETY: FROM RESEARCH TO IMPLEMENTATION* 135, 147 (2005) (“Near misses are a vital part of voluntary reporting systems.”).

84. Liang, *supra* note 29, at 357–58.

85. National Patient Safety Foundation, Patient Safety Definitions, <http://www.npsf.org/rc/mp/definitions.php> (last visited Sept. 18, 2008).

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policy.⁸⁶ One researcher sums up the vast variety of definitions—and the subtle implications in choice of terms—as follows:

Much lies between the two extremes of blame-free accident and deliberate harm, and this is reflected by the myriad terms competing to describe the phenomenon of error in medicine: accidents, mishaps, mistakes, errors, negligence, failures, incompetence, misconduct, malpractice, deficient or substandard care, adverse or untoward events and the concept of iatrogenic harm all appear in the literature. In addition, particularly serious incidents may warrant the label disaster.⁸⁷

While this wealth of terminology could be viewed as simply a little extra work for a provider's quality assurance committee, it is more complicated than that. How an incident is defined can determine what needs to be reported to regulatory authorities and what is—or should be—protected from discovery in a medical malpractice claim.⁸⁸ The proposed PSQIA regulations acknowledge this problem, which becomes particularly keen when providers from different states—and hence different regulatory regimes—report to a single PSO. In the draft regulations, therefore, the Department of Health and Human Services actively seeks input in compiling a standard list of incidents that should be reported.⁸⁹

In an environment with many regulators, there may be many different entities to which a hospital must report the occurrence of an incident, as “[s]tate and federal legislatures, state and federal administrative agencies, industry accrediting, professional and peer review organizations, courts and litigants, and purchaser organizations are all active regulators of patient safety today.”⁹⁰ In at least twenty states, including Florida and New York, state law requires that incidents be reported to the state government.⁹¹ Like the variations found in the definitions of the word incident, these reporting systems are not all the same and do not require that the same events be

86. JOINT COMM'N, SENTINEL EVENT POLICY AND PROCEDURES, July 2007, *available at* http://www.jointcommission.org/NR/rdonlyres/F84F9DC6-A5DA-490F-A91F-A9FCE26347C4/0/SE_chapter_july07.pdf. JCAHO defines a sentinel event as “an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase ‘or the risk thereof’ includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.” *Id.* JCAHO does not consider all medical errors to rise to the level of a sentinel event. *Id.*

87. Oliver Quick, *Outing Medical Errors: Questions of Trust and Responsibility*, 14 MED. L. REV. 22, 24 (2006).

88. The difficulty with defining error, and the different definitions according to the regulatory context, can lead to problems in disclosure because what may be considered a reportable incident by one state or accreditation organization may not be considered as such by another. For a discussion of the problems of defining and researching medical error, see Harrington, *supra* note 8.

89. Patient Safety and Quality Improvement, 73 Fed. Reg. at 8128–29.

90. Mello et al., *supra* note 1, at 403.

91. See AMERICAN HEALTH LAWYERS ASSOCIATION, PUBLIC INTEREST COLLOQUIUM, MINIMIZING MEDICAL ERRORS: LEGAL ISSUES IN THE DEBATE ON IMPROVING PATIENT SAFETY 14 (2003); Leape, *supra* note 80.

reported.⁹² In addition, some researchers point out that “[t]here is also a lack of uniformity among regulators regarding the degree of protection reports should receive from legal discovery and public scrutiny, creating uncertainty that especially affects multistate hospital chains.”⁹³ Therefore, a provider that maintains hospitals in even two states has a much larger workload with potentially greater levels of uncertainty.

Such differences in confidentiality levels are apparent when comparing incident data across the nation, and such differences risk hindering the progress in improvement of patient care. This disparity in state practice is evidenced by comparing Florida and New York, two states in which incident reporting by hospitals is required.

1. *Florida*

In Florida, hospitals must report incidents that result in patient injury to the Florida Agency for Health Care Administration.⁹⁴ Florida law requires hospitals to report categories of patient injuries in two types of reports.⁹⁵ One, the Annual Report, requires a hospital to list all patient injuries that occurred over the course of a year, the employees or contractors involved in the injuries, and all malpractice claims against it.⁹⁶ A second report, the Code Fifteen Report, gives an account to the Agency for Health Care Administration of injuries that result in patient “death, brain or spinal damage, surgery unrelated to the patient’s diagnosis, surgery to repair damage from a planned surgery, surgery to remove foreign objects, wrong site surgery, wrong patient surgery, and wrong surgical procedure.”⁹⁷ Formerly, there was a third report, the Twenty-four Hour Report, which reported the above listed injuries to the agency within one day of the occurrence and serves as a preliminary notification to the state that an incident has occurred.⁹⁸ Until 2004, these incident reports were protected from disclosure as identified attorney work product⁹⁹ and also exempted from public disclosure by statute.¹⁰⁰

92. Although beyond the scope of this note, this patchwork of requirements, aside from creating confusion and complexity, can lead to additional costs for healthcare systems that maintain hospitals in more than one state. *See* Mello et al., *supra* note 1, at 409.

93. *Id.* at 409 (citation omitted).

94. FLA. STAT. ANN. § 395.0197 (West 2006).

95. *Id.*

96. *Id.*

97. AGENCY FOR HEALTH CARE ADMIN., DIV. OF MANAGED CARE AND HEALTH QUALITY, MANDATORY SERIOUS PATIENT INJURY REPORTING: SUMMARY REPORT HOSPITALS AND AMBULATORY SURGICAL CENTERS (1999), available at http://www.fdhc.state.fl.us/mchq/health_facility_regulation/Risk/documents/1999_A_C_1999%20Annual%20Report%20Summary.pdf.

98. *Id.*

99. *Bay Medical Ctr. v. Sapp*, 535 So. 2d 308 (Fla. Dist. Ct. App. 1988).

100. FLA. STAT. ANN. § 395.0198 (West 2003) (repealed 2003).

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In 2004, Florida citizens voted to adopt a constitutional amendment that requires Florida hospitals to provide patients, upon their request, with access to any incident reports created by the hospitals in response to adverse incidents.¹⁰¹ The amendment does not limit disclosure to incident reports related to the requesting patient's injury. Rather, the hospital must provide *any* incident report to *any* patient.¹⁰² Amendment 7 states, “[i]n addition to any other similar rights provided herein or by general law, 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.”¹⁰³ “Patient” is defined by the amendment as “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.”¹⁰⁴ The amendment does not specify that the patient must seek only those records relating to that patient's treatment, although it does require hospitals to redact patient identifying information when disclosing incident reports to others.¹⁰⁵

Enabling legislation, passed one year after the amendment was ratified, attempted to limit the reach of the amendment by stating that incident reports created prior to the passage of the amendment were not available for disclosure because they were created under confidential circumstances.¹⁰⁶ The legislation also attempted to define “patient” more narrowly with regard to patient access to incident records.¹⁰⁷ Florida courts have held the enabling legislation unconstitutional.¹⁰⁸ Currently, any incident report created after the passage of the constitutional amendment is open to access by the patient involved, or by patients who may have experienced a similar incident, and it is likely that any incident report created before the amendment will also be accessible to those patients, and in reality, to the general public.¹⁰⁹

Hospitals in Florida therefore have little state protection for their incident reports. In *Notami Hospital of Florida, Inc. v. Bowen*, each of the plaintiffs in three

101. FLA. CONST. art. X, § 25.

102. *See, e.g.*, Morton Plant Hosp. Ass'n v. Shahbas *ex. rel.* Shahbas, 960 So. 2d 820, 825 (Fla. Dist. Ct. App. 2007) (“[T]he Shahbases, as previous patients, are entitled to any of the hospital's records relating to any adverse medical incident. There is no requirement that the records discoverable under Amendment 7 be relevant to any pending litigation.”).

103. FLA. CONST. art. X, § 25(a).

104. *Id.* at (c)(2).

105. *Id.* at § 25; James C. Sawran & Robert C. Weill, *Amendment 7: Will the Patient's Right to Know Come at Too High a Price?*, 24 TRIAL ADVOC. Q. 7, 11 (2005).

106. FLA. STAT. ANN. § 381.028 (West 2007 & Supp. 2008).

107. *Id.* at (7)(a) (“Pursuant to s. 25, Art. X of the State Constitution, the adverse medical incident records to which a patient is granted access are those of the facility or provider of which he or she is a patient and which pertain to any adverse medical incident affecting the patient or any other patient *which involves the same or substantially similar condition, treatment, or diagnosis as that of the patient requesting access.*” (emphasis added)).

108. *See* Notami Hosp. of Fla., Inc. v. Bowen, 927 So. 2d 139, 145 (Fla. Dist. Ct. App. 2006).

109. *See* Sawran & Weill, *supra* note 105, at 11.

medical malpractice cases consolidated for trial requested that the hospital produce peer review, risk management, and credentialing documents.¹¹⁰ When the trial court ordered the hospital to produce the documents, the hospital petitioned for a writ of certiorari.¹¹¹ The appellate court denied the writ, stating that “the Hospital does not have a vested right in maintaining the confidentiality of adverse medical incidents [because t]he Hospital’s ‘right’ is no more than an expectation that previously existing statutory law would not change.”¹¹² The appellate court held that the enabling legislation, section 381.028 of the Florida Statutes, “impermissibly restricts rights expressly granted under the Constitution.”¹¹³

More research must be done to know whether Florida’s mandatory incident reporting, coupled with the newfound public access to those reports, has had any effect on the level of reporting actually done by hospitals. In Florida’s Agency for Health Care Administration’s March 2007 Risk Management and Patient Safety Newsletter, the agency reported that 710 incidents were reported from 282 licensed hospitals.¹¹⁴ One hundred and two of those did not file any incident reports in two of the last three years.¹¹⁵ It seems unlikely that those 102 hospitals did not have any reportable incidents during that time period. In any event, as compared to other states with published data, like New York, this level of mandatory reporting is very low.¹¹⁶

The PSQIA provides a privilege and confidentiality provision that protects patient safety work product from discovery.¹¹⁷ While the federal legislation is clear that it preempts state law, it is also clear that it only protects specific data, not any state-mandated reporting, and so will not provide any additional protection for the two aforementioned reports that hospitals *must* file with Florida’s Department of Health.¹¹⁸

2. *New York*

New York presents a very different side of the debate. State law mandates that hospitals report any incidents that, among other things, did or could have harmed or

110. 927 So. 2d 139, 141–42 (Fla. Dist. Ct. App. 2006), *aff’d in part per curiam*, Florida Hosp. Waterman, Inc., v. Buster, 984 So. 2d 478 (Fla. 2008) (holding that Amendment 7 is self-executing, retroactive, and applies to records that existed before its passage; those sections of 381.028 that conflict with the amendment are unconstitutional and severed from the statute).

111. *Id.* at 141.

112. *Id.* at 143–44.

113. *Id.* at 143.

114. See RISK MGMT. AND PATIENT SAFETY NEWSL. (Agency for Healthcare Administration, Tallahassee, FL), March 2007, at 1, *available at* http://www.fdhc.state.fl.us/MCHQ/Health_Facility_Regulation/Risk/documents/march_2007_RM_newsletter.pdf.

115. *Id.*

116. See Flink et al., *supra* note 83.

117. Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. § 299b-22; *see also* Patient Safety and Quality Improvement, 73 Fed. Reg. at 8140–56.

118. Patient Safety and Quality Improvement, 73 Fed. Reg. at 8121.

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killed a patient. Specifically, Public Health Law section 2805-l says, “All hospitals . . . shall be required to report incidents . . . to the [Department of Health] in a manner and within time periods as may be specified by regulation of the department.”¹¹⁹ The statute lists the types of incidents required to be reported, including patient death or bodily function impairment not related to the patient’s illness, hospital fires, equipment malfunctions, poisonings, strikes, disasters not originating within the hospital, and the termination of hospital services such as heat, laundry, food, or rodent control.¹²⁰ Incident reporting is mandatory in New York: hospitals that do not report adverse events to the New York Patient Occurrence Reporting and Tracking System (“NYPORTS”) may be publicly sanctioned.¹²¹

After less than successful attempts with other reporting methods, including a paper-based method, New York created a secure electronic reporting system, NYPORTS, to simplify the reporting process.¹²² Two other New York statutes, Public Health Law section 2805-m and Education Law section 6527, provide for the confidentiality of the reports entered into the NYPORTS system. Public Health Law section 2805-m states that “reports required to be submitted pursuant to [statutory requirements] shall be kept confidential and shall not be released except to the department.”¹²³ It also provides an additional layer of protection by specifying that the reports may not be accessed from the Department of Health through use of the New York freedom of information law.¹²⁴ In addition, Education Law section 6527 states that “records relating to performance of a medical or a quality assurance review function” are generally exempt from disclosure.¹²⁵

For the most part, the statutory confidentiality provisions that protect these mandatory reports work to both encourage providers to comply with the reporting requirements and to protect providers in litigation.¹²⁶ For example, the First

119. N.Y. PUB. HEALTH LAW § 2805-l(1) (McKinney 2007 & Supp. 2008).

120. *Id.* at § 2805-l(2).

121. N.Y.S. DEP’T OF HEALTH, OFFICE OF HEALTH SYSTEMS MGMT., N.Y. PATIENT OCCURRENCE REPORTING AND TRACKING SYSTEM REPORT 3–6 (2000–2001). Compliance with the reporting requirements is monitored through “overall hospital surveillance activities” which include chart reviews by an outside independent agency. *Id.*

122. Flink et al., *supra* note 83, at 137–38.

123. N.Y. PUB. HEALTH LAW § 2805-m(1) (McKinney 2007).

124. N.Y. PUB. HEALTH LAW § 2805-m.

125. N.Y. EDUC. LAW § 6527(3); *see, e.g.*, Orner v. Mt. Sinai Hosp., 761 N.Y.S.2d 603, 606–07 (1st Dep’t 2003).

126. *See, e.g.*, Shapiro v. Central General Hosp., Inc., 673 N.Y.S.2d 724 (2d Dep’t 1998). A comparison between the number of reports submitted to the NYPORTS mandatory reporting system and those submitted to the JCAHO voluntary reporting system reveals that considerably more incidents are reported when the reporting is mandatory. Flink et al., *supra* note 83, at 142. Flink determined that between January 1995 and December 2003, 2,405 events were reported to JCAHO (176 of these were from New York hospitals) while during 1998 and December 2003 the NYPORTS system received 11,028 reports. *Id.* JCAHO has published Sentinel Event Statistics as of December 31, 2007 on its website. The total number of sentinel events reviewed by JCAHO between January 1995 and December

Department has emphasized that, although the confidentiality provisions may make things harder for a particular plaintiff, the plaintiff's hardship is outweighed by the benefit the public receives "by encouraging open and candid discussion."¹²⁷ Despite this, there are still some cases in which a hospital's incident report is ordered released to the plaintiffs in a medical malpractice action. In most of these cases, disclosure is ordered because the report was found to have been prepared in the ordinary course of business,¹²⁸ because it was not prepared pursuant to the quality assurance privilege,¹²⁹ or because the privilege was waived by the involvement of a third party.¹³⁰

Confidentiality may be defeated if a hospital cannot prove that it prepared its incident reports in accordance with statute. For example, in *Marte v. Brooklyn Hospital Center*, the hospital did not establish that the documents were prepared pursuant to Public Health Law section 2805-l or Education Law section 6527(3).¹³¹ Specifically, the court said that, "[a] review of the . . . [h]ospital's motion for a protective order and the attached documents does not reveal any statement by the Hospital that it actually prepared any committee review incident reports for the Department of Health as required under Public Health Law § 2805-l."¹³² The court also said that "[r]ecords generated at the behest of a quality assurance committee for

31, 2007 is listed as 4,817. See The Joint Commission, Sentinel Event Statistics: As of December 31, 2007, http://www.jointcommission.org/NR/rdonlyres/D7836542-A372-4F93-8BD7-DDD11D43E484/0/se_stats_063007.pdf. It is important to keep in mind that, although New York and JCAHO vary in their reporting requirements and so do not require hospitals to always report the same incidents, JCAHO is a national accreditation agency, drawing reports from hospitals in every state, while the NYPORTS statistics derive only from hospitals in New York. One researcher, comparing data from different state agencies, including New York, Utah, Florida, and Colorado, to data from JCAHO in an earlier time period, noted that part of the discrepancy between numbers is in part due to the difference in definition of error and adverse event. Harrington, *supra* note 8, at 362–66.

127. *Brathwaite v. State*, 623 N.Y.S.2d 228, 235 (1st Dep't 1995). See also *Finnegan v. State*, 686 N.Y.S.2d 589, 591–94 (N.Y. Ct. Cl. 1999) (comprehensive review of the differences in the appellate departments over the scope of the privilege).

128. *Williams v. Brookhaven Memorial Hosp. Med. Ctr., Inc.*, No. 03–6201, 2006 WL 2559527, at *1–2 (Sup. Ct. Suffolk County July 26, 2006) ("Here, the reports in question are not assessing the care provided . . . It further appears that the reports were made in the regular course of business pursuant to 10 NYCRR § 405.8(b)(1).").

129. See, e.g., *Feig v. Lenox Hill Hosp.*, 636 N.Y.S.2d 971 (Sup. Ct. N.Y. County 1995) *appeal dismissed*, 653 N.Y.S.2d 782 (1st Dep't 1997) (holding that under the education law, hospital could not keep confidential documents prepared by a private agency the hospital had hired to investigate an incident); *Berggren v. Saint Vincent's Catholic Med. Ctr. of N.Y., Inc.*, No. 10129/04, 2004 WL 2903641, at *1 (Sup. Ct. Richmond County Dec. 13, 2004) (holding that an incident report about chair that collapsed under patient while he sat in the waiting room not privileged). But see *People v. N.Y. City Health and Hosps. Corp.* (*In re Grand Jury Subpoena Duces Tecum*), 709 N.Y.S.2d 513, 514 (1st Dep't 2000) (upholding that since defendant was not a hospital as defined under Public Health Law § 2808(1) its peer review and quality assurance records could not be privileged; yet the court also upheld that documents prepared by an "independent professional standards review firm" were privileged under Education Law § 6527(3)).

130. See, e.g., *Feig*, 636 N.Y.S.2d 971. But see *N.Y. City Health and Hosp. Corp.*, 709 N.Y.S.2d 513.

131. 779 N.Y.S.2d 82, 86 (2d Dep't 2004).

132. *Id.* at 87 (citing *Matter of Subpoena Duces Tecum to Doe*, 99 N.Y.2d 434 (2003)).

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quality assurance purposes, including compilations, studies or comparisons derived from multiple records, should be privileged, whereas records simply duplicated by the committee are not necessarily privileged.”¹³³ This analysis is not clear, as the court does not explain in further detail how it determined that the reports were not prepared for the Department of Health as required by statute.

In *Williams v. Brookhaven Memorial Hospital Medical Center*, the Supreme Court of Suffolk County found that incident reports that are “multi-motivated,” meaning those that report errors pursuant to statute as well as in the regular course of business, and that do not contain any review of quality of care, are not covered under the privilege.¹³⁴ Part of the purpose of incident reporting is to assess quality of care. If a hospital does not assess its care but simply reports an incident because it is supposed to, it does not get the benefit of the privilege. It can also be argued that if there is no quality assurance review analysis within the incident report, there is nothing in the report that needs to be kept confidential anyway, as the facts underlying the incident are discoverable and any error impacting the patient should have been recorded in the patient’s medical record.

In addition, New York courts are clear that a document does not fall under the privilege simply because it was used or reviewed by a quality assurance committee. For example, in *Spradley v. Pergament Home Centers*, the Second Department noted that “merely because documents are placed in a quality assurance file does not ‘per se render these documents privileged from disclosure under the Education Law § 6527(3).’”¹³⁵ Hospitals cannot hide incriminating records by claiming a blanket quality assurance privilege. Providers would be well advised to clearly label any incident reports to ensure that there is no mistaking reports for other documents that happen to be in a quality assurance committee’s file.

III. THE RISKS OF NON-CONFIDENTIALITY

A number of factors have chiseled away at the confidentiality that should be given to incident reports. These factors include the Institute of Medicine’s 1999 report on the prevalence of medical error in the American healthcare system,¹³⁶ the plaintiffs’ bar,¹³⁷ and public outcry demanding accountability and improved error reporting systems in the healthcare industry.¹³⁸ One researcher notes that shortly after the Institute of Medicine (“IOM”) released its 1999 report on medical errors, *To Err Is Human*, a national magazine published an article with a sensationalist

133. *Id.* at 88.

134. No. 03-6201, 2006 WL 2559527, at *1 (Sup. Ct. Suffolk County July 26, 2006); *see also* Crawford v. Lahiri, 673 N.Y.S.2d 189 (2d Dep’t 1998); *Sonsini v. Memorial Hosp. for Cancer and Diseases*, 693 N.Y.S.2d 17 (1st Dep’t 1999) (upholding that maintenance log for mammography machine not considered quality assurance material).

135. 689 N.Y.S.2d 517 (2d Dep’t 1999) (quoting *Heitman v. Mango*, 654 N.Y.S.2d 413 (2d Dep’t 1997)).

136. *TO ERR IS HUMAN*, *supra* note 83.

137. Pegalis, *supra* note 8, at 1063–65; Liang, *supra* note 29, at 348–50.

138. *See* Duggin, *supra* note 1, at 342.

headline drawing attention to doctors and their “deadly mistakes.”¹³⁹ The researcher also noted that following the article, plaintiffs’ attorneys often (incorrectly) referred to the IOM’s statistics as evidence that doctors are committing malpractice at break-neck speed, so they should be sued more often, not less.¹⁴⁰

The IOM’s 1999 report recommended that the United States implement a national, mandatory reporting system.¹⁴¹ Proponents of mandatory incident reporting explain that analyzing the incidents increases patient safety by requiring hospitals to analyze the root of the problem and implement processes to prevent the problem from happening again.¹⁴² By making incident reporting mandatory, providers are forced to evaluate the failings in their systems. Not all reporting systems are mandatory, and voluntary reporting systems, like that of JCAHO, tend to have lower numbers of providers reporting.¹⁴³ A hospital does not have to report to JCAHO because a hospital does not have to be accredited by JCAHO to treat patients, although most hospitals prefer to take on the extra responsibility to appear more reliable and trustworthy.¹⁴⁴ But because both the accreditation and the reporting are voluntary, there is less at stake for a hospital that is non-compliant with JCAHO. However, even in mandatory reporting systems, reporting levels may be low because providers may decide to risk sanctions instead of disclosure. This may have contributed to the low numbers that Florida reports.¹⁴⁵

Many proponents also think that the reports should be shared with other hospitals and healthcare institutions, because while “[t]he primary purpose of reporting is to learn from experience,” sharing the reports with other institutions enables those institutions to also learn from another’s experience and implement their own preventative measures.¹⁴⁶ By seeing where others have gone wrong, hospitals have the opportunity to correct the same or similar problems in their systems and processes

139. Harrington, *supra* note 8, at 343–44 (citing Michael D. Lemonick, *Doctors’ Deadly Mistakes*, TIME, Dec. 13, 1999, at 74).

140. *Id.*

141. TO ERR IS HUMAN, *supra* note 83, at 9. In 1999, the IOM published its ground-breaking report, *To Err Is Human*, in which its authors noted that at least 44,000 and possibly as many as 98,000 Americans die each year because of medical errors. *Id.* at 26. The IOM, a non-governmental organization associated with the National Academy of Sciences, provides advice to the federal government on such issues as health and medical issues, among others. See Institute of Medicine of the National Academies, <http://www.iom.edu> (last visited Oct. 10, 2008).

142. Flink et al., *supra* note 83, at 144.

143. Furrow, *supra* note 62, at 14 (“The third problem [of three problems with the JCAHO disclosure standard] is, lacking real regulatory muscle, the level of actual disclosure of errors has been very low.”).

144. See Joint Comm’n, Accreditation Programs—Hospitals, <http://www.joint-commission.org> (last visited Sept. 18, 2008) (“The Joint Commission has been accrediting hospitals for more than 50 years. Its accreditation is a nationwide seal of approval that indicates a hospital meets high performance standards.”).

145. See RISK MGMT. AND PATIENT SAFETY NEWSL., *supra* note 114, at 1.

146. Leape, *supra* note 80.

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before the same mistakes happen in their institutions.¹⁴⁷ The PSQIA takes a new step toward a national reporting system and in ensuring confidentiality to those analyses of incidents reported into its system. But the PSQIA does not protect incident reports made for other purposes.¹⁴⁸ Ultimately, the problem is that neither mandatory nor voluntary reporting can or will work effectively until full privilege is restored to incident reports.

While some physicians and professional medical associations oppose mandatory reporting,¹⁴⁹ the public thinks mandatory reporting improves accountability.¹⁵⁰ But beyond simply wanting incidents to be reported, the public wants *access* to those reports: “62 to 73 percent of Americans believe that healthcare providers should be required to make this information [uncovered during investigations] publicly available.”¹⁵¹ The fact that a high percentage of the public may want these reports can play directly into the fears of providers, which can lead to less thorough reporting, and ultimately defeats the goals of the reporting—accountability and quality improvement.¹⁵²

Several arguments urge the disclosure of incident reports, the first being the interest of the injured plaintiff. In the course of litigating a malpractice case, a patient will use, among other things, his medical chart to prove that a provider did not perform to a reasonable standard of care.¹⁵³ But if the medical chart does not contain the information the patient seeks, such as notations regarding an error or an indication of a deviation from the standard of care, and given evidence that doctors

147. See OFFICE OF HEALTH SYSTEMS MGMT., N.Y.S. DEP'T OF HEALTH, N.Y. PATIENT OCCURRENCE REPORTING AND TRACKING SYSTEM REPORT 2000/2001 6 (July 2003), http://www.health.state.ny.us/nysdoh/hospital/nyports/annual_report/2000-2001/pdf/2000-2001_annual_report.pdf (explaining the database of reported adverse events in NY: “While the identity of individual hospitals in the comparative groups is not disclosed, the comparative database is a useful tool in support of hospital quality improvement activities”).

148. Patient Safety and Quality Improvement, 73 Fed. Reg. at 8121 (“[I]nformation that is collected to comply with external obligations is not patient safety work product. Such activities may include: State incident reporting requirements . . .”).

149. See Troyen A. Brennan, *The Institute of Medicine Report on Medical Errors—Could It Do Harm?*, 342 NEW ENG. J. MED. 1123 (2000); Michelle Harper & Robert L. Helmreich, *Identifying Barriers to the Success of a Reporting System*, in 3 ADVANCES IN PATIENT SAFETY: FROM RESEARCH TO IMPLEMENTATION 167, 172 (2005).

150. Flink et al., *supra* note 83, at 148.

151. Leape, *supra* note 80 (citing THE KAISER FAMILY FOUND., NATIONAL SURVEY ON AMERICANS AS HEALTH CARE CONSUMERS (Agency for Healthcare Research and Quality, Washington, D.C., December 2000)).

152. Although not directly on point in this note, it should be noted that there is a prevalence of “shame and blame” within the medical industry that points fingers at individuals; this environment has further perpetuated providers’ fears of being singled out. However, the IOM report and a number of scholars have concluded that error in the medical industry is more often the result of a system’s failure than attributable to individuals. See, e.g., Liang & Small, *supra* note 29, at 222–26.

153. See, e.g., Talavera *ex rel.* Rios v. N.Y. City Health and Hosps. Corp., 851 N.Y.S.2d 189, 190 (1st Dep’t 2008) (“Plaintiffs submitted affirmations from a physician establishing that the medical records, on their face, evince that defendant failed to provide proper care to plaintiffs . . .”).

sometimes do not fully complete their patients' medical records, it is not unreasonable for the patient to wonder whether the provider has neglected to include the relevant information in his chart.¹⁵⁴ The patient may then seek other documents from the hospital in order to make his or her case, arguing a substantial need for the information and undue hardship without it. An incident report would be ideal for this purpose, as it may contain a description of the event, the actor(s) involved, and an analysis of what happened.¹⁵⁵ It is possible that such an analysis may contain references or comparisons to earlier, similar incidents as well.

A second argument for disclosure of incident reports is that the public has a right to know which hospitals are *safe* and what its hospitals are doing wrong.¹⁵⁶ Patients are consumers, and to be reasonably informed consumers, they should have all of the facts about the hospitals with which they entrust their safety and well-being.¹⁵⁷ A patient cannot make an informed decision without having all of the facts at hand.¹⁵⁸ Public access to incident report information, such as that in Florida, gives the public greater control over its quality of care and allows the public to make independent, more educated decisions when selecting among healthcare providers.

It is therefore not surprising that providers think that if they participate in or share information recorded in incident reports, they risk: 1) being sued;¹⁵⁹ 2) irreparable damage to their professional reputations;¹⁶⁰ and 3) professional sanctions.¹⁶¹ Providers also worry that error or incident information shared within a confidential environment—i.e., with another institution for collaborative or educational purposes—will waive any applicable privileges and be discoverable.¹⁶² Sometimes, these worries mean that they do not share error information within their own institution.¹⁶³ It may seem safer to the providers not to say anything at all.

The fear of litigation from incident report disclosure has been described as overblown, with some researchers arguing that there has not been a demonstrated link

154. See Lori Andrews, *Studying Medical Error in Situ: Implications for Malpractice Law and Policy*, 54 DEPAUL L. REV. 357, 362 (2005).

155. Dollar, *supra* note 5, at 266–67.

156. See Laura A. Chernitsky, Note, *Constitutional Arguments in Favor of Modifying the HCQIA to Allow the Dissemination of Physician Information to Healthcare Consumers*, 63 WASH. & LEE L. REV. 737, 755–56 (2006).

157. Other researchers have found, however, that patients either do not use quality comparisons or find the information on provider quality of care information not useful. Mello et al., *supra* note 1, at 392–93 (citing the six different studies).

158. On the other side of this argument, this information is already out there, although it is scattered and would undoubtedly be time-consuming for consumers to find and understand. Chernitsky, *supra* note 156, at 742–44.

159. See, e.g., Brennan, *supra* note 149.

160. Patient Safety and Quality Improvement, 73 Fed. Reg. at 8113.

161. *Id.*

162. See discussion *supra* Part II.A.

163. See Andrews, *supra* note 154.

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between reporting and litigation.¹⁶⁴ However, one researcher writes that a plaintiff's law firm received over \$100 million in contingency fees over the course of five years by using quality of care information gleaned from nursing homes.¹⁶⁵ Another researcher points out that immediately after Florida's constitutional amendment took effect, "several plaintiffs' lawyers sent hospitals requests for the disclosure of documents that were created in confidence Plaintiffs' attorneys were using the passage of Amendment 7 as a cast-net to fish for cases."¹⁶⁶

Even just the worry of litigation is enough to keep providers from engaging fully in the incident reporting process.¹⁶⁷ One researcher hypothesizes that "this trend by the courts to compel discovery of hospital incident reports will discourage health care providers from making immediate, full disclosure; rather, health care providers will likely report only minimal factual descriptions of accidents already contained in the patient's chart."¹⁶⁸ A national study of risk managers in 2002, performed in response to JCAHO's implementation of a sentinel event policy, revealed that "[r]eluctance to disclose preventable harms was twice as likely to occur at hospitals having major concerns about the malpractice implications of disclosure."¹⁶⁹ The study examined why there was little reporting and found the reasons to be "failure to recognize that an error occurred, liability worries, concerns about job security . . . and concerns about personal and professional reputation."¹⁷⁰ Other studies of error reporting show that many errors and near misses are never actually reported.¹⁷¹ Providers may choose not to disclose a near miss or minor incident to an affected patient, preferring to avoid any chance of litigation and damage to reputation under the rationale that the patient was not harmed, and does not need to know.¹⁷² Some

164. Leape, *supra* note 80; *see also* Rae M. Lamb et al., *Hospital Disclosure Practices: Results of a National Survey*, 22 HEALTH AFFAIRS 73, 80 (2003) ("A different, and increasingly prominent, twist on the malpractice issue is that clinicians' and hospital's perceptions about litigation risk may be worse than the reality.").

165. Healy et al., *supra* note 5, at 618.

166. Hawkins, *supra* note 66, at 7–8.

167. In her note, Dollar cites to an older study of Ohio hospitals in which the hospital staff had compiled incident reports for only half of the incidents that resulted in legal action against the hospital. Dollar, *supra* note 5, at 286 (citing Gladys Duran, *Positive Use of Incident Reports*, 53 HOSPS. 60, 60 (1979)). Additional research should be done in this area to determine whether there has been any improvement in incident report completion.

168. Dollar, *supra* note 5, at 260.

169. Lamb et al., *supra* note 164, at 73. The study found that "fear of medical malpractice litigation was still the most commonly cited institutional barrier to developing and implementing disclosure policies, followed by staff opposition." *Id.* at 76.

170. Furrow, *supra* note 62, at 29.

171. *Id.* (noting "[o]ne study found that twenty-nine percent of observed errors were not reported").

172. *See* Pegalis, *supra* note 8, at 1072 (citing Thomas H. Gallagher et al., *Choosing Your Words Carefully: How Physicians Would Disclose Harmful Medical Errors to Patients*, 166 ARCHIVES INTERNAL MED. 1585, 1585 (2006)). *But see* AM. MEDICAL ASS'N, CODE OF MEDICAL ETHICS: CURRENT OPINIONS WITH ANNOTATIONS, 2006–2007, 242 (2006) ("An expression of concern need not be an admission of

other researchers have found that providers are more inclined to tell patients about the little things.¹⁷³ This lack of reporting may not be improved despite the protections that will arise with the implementation of the PSQIA, particularly in states that have mandatory reporting requirements. This is because providers, concerned with confidentiality and afraid of the implications of full disclosure, may continue to divulge only the barest facts or will not report at all, lending little value in the new federal reporting system. A reporting system can only be effective if its providers feel protected.

Studies have found that providers would be more motivated to report if the reports were protected from discovery.¹⁷⁴ Protecting the confidentiality of the reporting system is one of five critical elements identified by researchers at the New York Department of Health for a successful mandatory reporting system.¹⁷⁵ While many experts in the field disagree on how to improve the quality of care patients receive in hospitals, “quality experts almost universally agree that an important predicate to quality improvement is for providers themselves to identify medical errors and other quality problems through data analysis and the generation of self-critical quality of care information.”¹⁷⁶ Confidentiality must be a part of the providers’ internal review process. It is safe to surmise that without this protection, whether or not there is a legitimate basis for providers’ fears, reports will lack any useful mental impressions or thorough analysis, containing only the same bare facts that can be found in the medical record. Absent as well will be the opportunity to learn any lasting, meaningful lesson about the error—why it happened, and how another can be prevented, perhaps at a different hospital across the country.

The problem of the unprotected incident report looms particularly large in states where providers must report, and especially for healthcare systems that provide care in more than one state.¹⁷⁷ Hospitals are often already required by the state in which they are licensed to report adverse events. And to be accredited by independent organizations, such as JCAHO, they must also analyze and report incidents.¹⁷⁸ In

responsibility. When patient harm has been caused by an error, physicians should offer a general explanation . . . Such communication is fundamental to the trust that underlies the patient-physician relationship, and may help reduce the risk of liability.”).

173. *See, e.g.*, Andrews, *supra* note 154, at 361.

174. Harper & Helmreich, *supra* note 149, at 177.

175. Flink et al., *supra* note 83, at 149. The four other elements are: 1) collaborative system development with the stakeholders; 2) clear reporting criteria; 3) continual training; and 4) creating a stakeholder advisory group. *Id.*

176. Healy et al., *supra* note 5, at 596.

177. Some physician researchers argue for fewer regulators as one solution. “Pluralistic regulation is a choice, not an inevitability. In other industries in which safety is a concern, we have limited the number of regulators.” Mello et al., *supra* note 1, at 403. While not the central focus of this note, it would likely be easier to mandate the confidentiality of incident reports if the number of regulators was limited. Other researchers advocate for a national agency to collect all of the error information. *See* Liang, *supra* note 29, at 357.

178. *See, e.g.*, JCAHO, *supra* note 86.

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addition, hospital risk management departments and quality assurance committees review and analyze incidents in an attempt to improve hospital processes and prevent errors from happening in the future.¹⁷⁹ Thorough, thoughtful, and self-critical incident reporting is essential for the hospital and, in particular, for its patients.¹⁸⁰ Hospitals may feel they are risking a great deal by opening up their analysis to regulators, and perhaps even their own internal quality improvement staff, for fear that the public, knowing those reports are there, will seek the information.¹⁸¹ These fears, and continued encroachment on confidentiality such as Florida's constitutional amendment, will lead to bare-bones reporting without thorough analysis.

Incident reports, particularly those analyzing systems' breakdowns and root causes of incidents, may also make life much easier for a plaintiff's attorney.¹⁸² The reports explain what went wrong, why, list the hospital employees involved, and may discuss or compare the reported incident with previous ones. If a plaintiff's attorney can access the incident report, much of that attorney's work is already done.¹⁸³ Incident reports provide a vehicle for the hospitals to improve their quality of care, to learn from others' mistakes, and for the states to assist in improving rates of errors. They are not meant to give a plaintiff a leg up in settlement negotiations, or at trial, but a lack of confidentiality leads them to be used for this purpose.¹⁸⁴

In states where providers are required to report incidents, loss of privilege, or lack of privilege to begin with, is especially a problem.¹⁸⁵ In these states, because of the mandate to file incident reports after certain events, courts may view the reports

179. See Dollar, *supra* note 5; Healy et al., *supra* note 5.

180. See Dollar, *supra* note 5, at 264 (explaining why incident reporting is important); Duggin, *supra* note 1, at 346 (expressing the concern that with loss of attorney-client privilege, less will be committed to writing, with adverse consequences).

181. Duggin, *supra* note 1, at 341 (“[F]ear that materials generated in the course of quality reviews will end up in the hands of prosecutors or civil plaintiffs undoubtedly diminishes the enthusiasm for the review process.”).

182. See Dollar, *supra* note 5, at 291–92.

183. See, e.g., *Florida Hosp. Waterman, Inc. v. Buster*, 984 So. 2d 478 (Fla. 2008) (*per curiam*) (Wells, J., concurring in part and dissenting in part). The dissent notes that it is fundamentally unfair to allow into evidence records of hospital investigations that were previously protected by statute. *Id.* at 495. However, the majority opinion found that to disallow access to records of adverse incidents created before the passage of the amendment would defeat the purpose of the amendment and “a patient would never actually gain the access plainly promised by the amendment.” *Id.* at 489–90. “Clearly, one of the primary purposes of the amendment is to provide a patient contemplating treatment by a medical provider access to that provider’s past history of adverse incidents.” *Id.* at 490 n.6.

184. There has been some consideration as to whether the tort system provides a method of improving patient safety at hospitals. However, some researchers find that relying on the tort system to improve safety is ill-advised:

[The tort system’s] ability to set new standards for patient safety is circumscribed by the continued reliance of most states’ courts on medical custom to set the standard of care . . . [a]t best, it is a regulator of last resort, seeking to make whole those who have suffered injuries that other forms of regulation have tried and failed to prevent.

Mello et al., *supra* note 1, at 418.

185. See, e.g., discussion *supra* Part III.A.

as part of the business operations of a hospital and not subject to a particular privilege.¹⁸⁶ Arguably, incident reports are not created in the ordinary course of business, as healthcare providers are not generally in the business of injuring people.¹⁸⁷ Yet, this argument does not always hold up at trial.¹⁸⁸

Overall, the continued lack of protection for incident reports detracts from the quality of our health care, perpetuates the shame-and-blame culture of medical error, and can unfairly prejudice the defendant provider in litigation. In addition, such potential disclosure of incident reports ultimately endangers everyone who uses the healthcare system.

IV. RETHINKING THE INCIDENT REPORT

There is a fundamental misunderstanding of the purpose of incident reports that has pervaded our medical and legal systems. Incident reports do not provide anything new to an investigation except opportunity for the plaintiff. They are, and should remain, a tool for the hospitals to improve the quality of their care. Making hospital incident reports discoverable only impedes the quality assurance function they are meant to serve. Error reporting and quality improvement have reached a stalemate. Incident reports must be taken out of the equation completely in order to propel the healthcare industry beyond its current stagnant relationship with medical error. While the PSQIA is a start, federal legislation must go further in providing a broad protection to all incident reports, including those required to be reported to state regulators, and preempt state law that says otherwise.

One study identifies three primary reasons why quality of care information should be kept confidential: 1) providers who review their quality of care usually provide better care; 2) lack of confidentiality is a disincentive to providers to review their care; and 3) healthcare providers are already subject to sanctions by state and federal governments when their care is substandard.¹⁸⁹ The key to understanding why incident reports should be kept confidential in litigation, whether or not they are disclosed within a particular community for the purpose of quality improvement, lies in remembering that the underlying facts of the adverse event are discoverable, as is the affected patient's medical record.¹⁹⁰ It is the responsibility of the physicians

186. *See, e.g.*, *Williams v. Brookhaven Memorial Hosp. Med. Ctr., Inc.*, No. 03–6201, 2006 WL 2559527, at *1 (Sup. Ct. Suffolk County July 26, 2006).

187. While it can be argued that it should be regular procedure for a hospital to analyze its procedures after an incident, this regular procedure should not be considered within the hospital's ordinary course of business because its business is providing health care; incidents are often unique and unpredictable.

188. *See, e.g.*, *Williams*, 2006 WL 2559527, at *2 (“It further appears that the reports were made in the regular course of business pursuant to 10 NYCRR § 405.8(b)(1).”).

189. Healy et al., *supra* note 5, at 600–01.

190. *See, e.g.*, FED. R. EVID. 803(6). Thus, it is the patient's medical record and not the incident report that should be deemed part of the health provider's regular course of business, though both may be kept as such. And in fact, much information about a provider's quality of care is already required to be made available to the public, including the results of a state agency's review of a facility and information on providers who have violated the law. Healy et al., *supra* note 5, at 614–15.

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and other caregivers to note any mistakes along with everything else in the patient's record,¹⁹¹ and "most states have statutory penalties for inaccurate, incomplete, or falsified hospital records."¹⁹² The proposed regulations for the PSQIA underscore this by specifically defining a patient's medical record and other information that goes into the record as not patient safety work product.¹⁹³

An incident report is not a set of new facts, or a repository for those facts a guilt-ridden doctor would like to keep hidden from the patient. On the contrary, an incident report is a hospital's analysis of a problem and a compilation of the findings of the hospital's investigation into the matter, described so that the hospital can learn from its mistakes.¹⁹⁴ If done well, an incident report is a candid, thorough examination of what went wrong.¹⁹⁵ The incident report is the hospital's research into its processes and is for the benefit of the hospital—and all of the hospital's patients. But because of this candid research into previous occurrences, staff behavior, and equipment performance, incident reports can be a gold mine for a patient's attorney.¹⁹⁶ The hospital can be penalized for attempting to prevent future harm. By allowing discovery of incident reports—documents meant for self-evaluation and fulfillment of regulatory requirements—the quality of our health care is endangered.¹⁹⁷

While the patient's attorney absolutely should not be barred from discovering the facts, the patient's attorney should be denied access to what essentially amount to arguments made for it by the defendant.¹⁹⁸ The hospital should not be required to present the patient with his or her case. Likewise, incident reports should not be

191. Pegalis, *supra* note 8, at 1070–72.

192. Dollar, *supra* note 5, at 262–63. See also N.Y. EDUC. LAW § 6530(32) (McKinney 2002), which deems "[f]ailing to maintain a record for each patient which accurately reflects the evaluation and treatment of the patient" professional misconduct. A physician found guilty of misconduct can be subjected to any number of penalties, including up to a \$10,000 fine for each instance of misconduct and revocation of the provider's license." N.Y. PUB. HEALTH LAW § 230-a (McKinney 2001 & Supp 2008); *see, e.g., Saunders v. Admin. Review Bd. for Prof'l Med. Conduct*, 695 N.Y.S.2d 778 (3d Dep't 1999) (upholding suspension of a doctor's medical license for inadequate medical records, deceptive advertising, and ordering unnecessary medical tests). In Florida, failing to keep legible medical records that justify the course of treatment is grounds for disciplinary action. FLA. STAT. ANN. § 458.331(1)(m) (West 2007). It should be noted that complete medical records are also important for hospitals that participate in the Medicare program. *See, e.g., Jeff Sinaiko et al., Emerging Issues in Physician Documentation and Compliance: All of the Old, More of the New*, 9 J. HEALTH CARE COMPLIANCE 5 (2007).

193. Patient Safety and Quality Improvement, 73 Fed. Reg. at 8173.

194. *See, e.g., JCAHO, supra* note 86 (describing root cause analysis requirements for analyzing sentinel events).

195. *See id.*

196. *See* Healy et al., *supra* note 5, at 618–19.

197. Dollar, *supra* note 5, at 267.

198. *See* QUALITY INTERAGENCY COORDINATION TASK FORCE, *supra* note 14, at 5 ("[I]ndividuals should have access to information leading up to and including the occurrence of a preventable error that caused their serious injury or the death of a family member. However . . . subsequent 'root-cause' analyses undertaken to determine the internal shortcomings of the hospital's delivery system should not be subject to discovery in litigation . . .").

discoverable in litigation because the relevant information they provide should be duplicative of what is already recorded in the patient's chart. Further, any changes to processes or systems recommended in the report cannot be introduced as evidence of wrongdoing because such recommendations may be considered remedial action, and as such cannot be introduced to show liability.¹⁹⁹

As discussed above, hospital incident reports are the hospital's analysis of a problem. Using the facts of the incident, the hospital is able to analyze what went wrong in the hopes of improving its quality of care. These facts are also available to the plaintiff because they are found in the patient's medical chart and record.²⁰⁰ There is no need to give the plaintiff's attorney access to a document that reiterates facts already available and that may lay out the plaintiff's case, to the detriment of the defense and the general public.

Yet patients and their attorneys should be reassured that hospitals cannot use the incident report as a hiding place for facts that a hospital does not wish plaintiffs to learn.²⁰¹ And in fact, model legislation proposed by researchers thirteen years ago emphasizes that hospitals should not include facts in the incident report that cannot be found in the medical and other records of the hospital accessible by the plaintiff.²⁰² This is echoed in the PSQIA. In the proposed regulations, the following is excluded from the definition of patient safety work product: "a patient's original medical record, billing and discharge information, or any or any other original information that is collected, maintained, or developed separately, or exists separately from, a patient safety evaluation system."²⁰³

Providers also face serious sanctions for not completing patients' charts on a timely basis.²⁰⁴ To more effectively counter bad physician behavior and to give injured patients what they need to be made whole, attention should focus not on accessing incident reports, but on sanctioning providers who do not complete their patients' charts accurately and on a timely basis. To aid chart completion, other provider staff who notice the incomplete chart should be encouraged to report noncompliance, perhaps with education about labor laws prohibiting retaliation and access to an anonymous hotline.²⁰⁵ There can be no excuse for not completing a

199. FED. R. EVID. 407; *see also* Johnson & Shapiro, *supra* note 29, at 7–8 (describing states' evidence rules on remedial action).

200. *See* Dollar, *supra* note 5.

201. *See id.* at 262–63 (citing WILLIAM H. ROACH, JR. ET AL., *MEDICAL RECORDS AND THE LAW* 15, Appendix B (1985); JANINE FIESTA, *THE LAW AND LIABILITY: A GUIDE FOR NURSES* 173–93 (2 ed. 1988)).

202. *See generally* Dollar, *supra* note 5; Healy et al., *supra* note 5.

203. Patient Safety and Quality Improvement, 73 Fed. Reg. at 8120.

204. *See, e.g.*, Gray v. Jaeger, 794 N.Y.S.2d 324 (1st Dep't 2005) (upholding an order to strike defendant physician's answer, as his failure to keep medical records was negligent and precluded plaintiff from presenting *prima facie* case); Ruggiero v. State Dep't of Health, 643 N.Y.S.2d 698 (3d Dep't 1996) (upholding the revocation of license for physician who kept a filthy office, mixed food and medication in refrigerator, and relied on memory, not paper records, when treating patients).

205. *See, e.g.*, N.Y. LAB. LAW § 741 (McKinney 2002 & Supp. 2008).

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patient's chart accurately and expeditiously. Providers cannot hide the facts of a course of treatment, even if they might like to. And while it may be true in some cases that a patient may bear an undue burden in proving his or her case without benefit of the incident report, in those cases, the court must review the incident report in-camera to determine what, if anything, should be released to the plaintiff. Recognizing that incident reports may only be discoverable when medical charts are not accurately completed may provide additional incentive to providers to ensure charts are complete.

In addition, although some defense attorneys may disagree, providers must be forthright with their patients. It may be, but is not always true, that a patient does not need access to the incident report to know something went wrong with his or her procedure.²⁰⁶ The Joint Commission and many institutions already require that mistakes be disclosed to patients even if the patient would have been unaware.²⁰⁷ Where state law does not mandate disclosure, a physician's code of ethics does: "Hospitals, physicians, or nurses have no moral or legal rights to withhold information from patients. Full disclosure is not an option; it is an ethical imperative."²⁰⁸ Some hospitals have instituted full disclosure and apology policies, gambling on the theory that affected patients will be less likely to sue if they are dealt with honestly and sincerely.²⁰⁹ It is worth noting that defense attorneys generally greet such policies with skepticism.²¹⁰ The patient must be told of the error, and will have the ability to access the medical chart if he or she decides to take further action. Informing the patient of an error is without question difficult for the provider, but disclosure to the patient is necessary so that the provider may appropriately be held liable if the patient has been harmed.²¹¹ However, the fact that a provider made an error does not give the patient license to delve into the provider's quality assurance work. If the patient is given that

206. This is not true for near miss incidents in which an error almost happens but is averted, either intentionally or not. It is unfortunate, although perhaps not entirely surprising, that some studies have found that doctors routinely do not report errors to patients. See, e.g., Andrews, *supra* note 154, at 370–71.

207. Farrow, *supra* note 62, at 12–14; Pegalis, *supra* note 8, at 1071; Jonathan R. Cohen, *Apology and Organizations: Exploring an Example from Medical Practice*, 27 *FORDHAM URB. L.J.* 1447, 1452 (2000).

208. Pegalis, *supra* note 8, at 1072 (quoting Lucian Leape, *Forward to DISCLOSING MEDICAL ERRORS: A GUIDE TO AN EFFECTIVE EXPLANATION AND APOLOGY*, v–vi (Joint Commission Res. 2007)); see also AMERICAN MEDICAL ASSOCIATION, *CODE OF MEDICAL ETHICS: CURRENT OPINIONS WITH ANNOTATIONS, 2006–2007*, 242 (2006). Aside from being an ethical imperative, it is essential to keep patients informed to provide dignified and informed care. Peter A. Clark, *Medication Errors in Family Practice, in Hospitals and After Discharge from the Hospital: An Ethical Analysis*, 32 *J.L. MED. & ETHICS* 349, 354 (2004) (arguing that a mandatory reporting system is a way to ensure the autonomy and dignity of patients).

209. See, e.g., Lamb et al., *supra* note 164; see also Cohen, *supra* note 207 (reviewing risks and benefits of apology).

210. See Cohen, *supra* note 207, at 1458.

211. Clearly, this view portrays the ideal. See Andrews, *supra* note 154, at 362 (noting that "some physicians in the [author's] study indicated that they did not include information about errors in the patient's chart because they wanted to avoid litigation").

access, our cycle of medical error will undoubtedly continue. Patients must unequivocally be denied access to the incident report; medical record completion and disclosure must be strictly enforced.

Much is made of the fact that hospitals ought to report to enhance accountability and to improve quality of care.²¹² By creating a data repository where errors can be analyzed, hospitals will be better able to examine their mistakes as well as to learn from the mistakes of others. And at least twenty states already require hospitals to report incidents, thereby improving accountability, particularly when hospitals that fail to report are subject to sanctions.²¹³ But reporting for its educational and regulatory value can easily be confused with reporting for punitive purposes. Attempts to use the incident report for something other than its intended purpose of quality assurance ignores the fact that hospitals cannot keep the evidence of an error to themselves and hinders vital quality assurance activities.²¹⁴ Hospitals must provide the plaintiff with access to the facts underlying the case, but they must be allowed to keep their quality of care information confidential.

In court, hospitals argue against disclosure of incident reports, citing attorney-client privilege because they were confidential communications between attorney and client, and attorney work product privilege as they were prepared in anticipation of litigation.²¹⁵ Making such an argument also does not halve the dual purpose of the incident report (preparation for litigation and quality assurance) to one; in other words, simply because the providers argue that the reports were prepared in anticipation of litigation does not mean that they were not also prepared for quality assurance purposes internal to the hospital. It is problematic that incident reports get tied up in litigation when their purpose ought to be for the hospital to conduct research on its own failings, and to improve.

To improve the state of medical care, the hospital must not just be held accountable or found liable. Simply sanctioning or suing a hospital does little to further the quality of care for the rest of the patients, because to adequately understand the mistake and protect future patients, the hospital must perform a thorough self-evaluation that includes honestly analyzing its mistakes.²¹⁶ That analysis should be kept confidential.

212. *See generally* TO ERR IS HUMAN, *supra* note 83; QUALITY INTERAGENCY COORDINATION TASK FORCE, *supra* note 14.

213. *See, e.g.*, Leape, *supra* note 80.

214. Further research needs to be done to compare actual quality of health care in states that give access to incident reports as opposed to states that keep incident reports confidential. More thorough analysis of reporting statistics, as well as whether errors are repeated, can shed light on whether allowing access to incident reports hinders the improvement of health care to more patients than the one affected by the error. While it is generally assumed that the mandatory collection of error data (or collection of error data in general) improves the overall quality and safety of hospital care, recent studies have put this into question. Liang, *supra* note 29, at 348.

215. *See, e.g.*, Flynn v. Univ. Hospital, Inc., 876 N.E.2d 1300 (Ohio Ct. App. 2007).

216. Dollar, *supra* note 5.

MAKING THE PLAINTIFF'S BAR EARN ITS KEEP

As the Department of Health and Human Services completes its promulgation of the PSQIA regulations,²¹⁷ it will likely take into consideration the incident report's dual purposes of reporting and self-analysis.²¹⁸ Much of the impetus for the PSQIA was a recognition that to encourage providers to report an error, there needed to be assurance that the reports would be kept confidential.²¹⁹ The proposed regulations address this by proposing civil money penalties of up to \$10,000 for breach of confidentiality provisions by disclosing patient safety work product to third parties.²²⁰ Ultimately, though, it seems that the PSQIA will not go far enough, as hospitals in some states, such as those in Florida, need protection for all of their incident reporting activities and not just those that are reported to the PSO. In addition, in states that require providers to report, reporting to yet another agency will likely be burdensome, particularly when the incentive of confidentiality does not help where help is needed. The federal law needs a broader preemption to be able to include all hospitals in all states, and to actually have some measure of success. This could arguably take management of health away from the state, but would improve health care for the country as a whole, and, like the Employee Retirement Income Security Act of 1974 does for employers, would ultimately simplify things for hospital systems.²²¹ Instead of having to worry about several different layers of reporting they could worry about one.²²² Physician licensing and hospital accountability could still remain under state law, but reporting of incidents should be directly and only to the federal government, which could then relay relevant information to states with recommendations for sanctions but without disclosure of the report itself. Nothing should be withheld from the patient except the hospital's own self-evaluation.

V. CONCLUSION

Medical errors continue to occur despite increased public awareness and pressure from parts of society to improve the healthcare delivery system. However, improvement cannot be made until providers feel confident that reporting errors will not lead to increased liability. One step towards achieving this improvement is the reimagining of incident reports—documents that compile the results of a hospital's investigation into what went wrong—from something other than a tool for a plaintiff's attorney. Instead, they should be thought of as what they actually are: research

217. Patient Safety and Quality Improvement, 73 Fed. Reg. at 8112. The proposed rules were released on February 12, 2008, for a period of public comment.

218. The Office of Civil Rights within the Department of Health and Human Services was given the authority to promulgate regulations under the PSQIA in May 2006. *See* 71 Fed. Reg. 28701, 28701–28702 (May 17, 2006).

219. *See* Furrow, *supra* note 62, at 17.

220. Patient Safety and Quality Improvement, 73 Fed. Reg. at 8113.

221. 29 U.S.C. § 1144 (2000 & Supp. 2005).

222. *See, e.g.*, Furrow, *supra* note 62, at 18 (“State mandatory reporting systems . . . may also cause inconsistencies and result in confusing procedures and inaccurate data, or not data collected at all.”).

for the hospital into its own failings so that it can improve, and so that ultimately all healthcare consumers may benefit from this reflective, self-evaluative process.