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NEW JERSEY LEGISLATIVELY MANDATES AN ETHICAL RESPONSIBILITY

A. The statutory and regulatory scheme.

In 2004, the Legislature passed the Patient Safety Act, *N.J.S.A.* 26:2H-12.23 (PSA). This landmark legislation changed the way medical errors are dealt with in New Jersey by creating a legal duty to immediately disclose medical errors to patients who are harmed by them. *N.J.S.A.* 26:2H-12.25. There are few states in the nation that require this kind of disclosure. William M. Sage et al., *The Relational Regulatory Gap: A Pragmatic Information Policy For Patient Safety and Medical Malpractice,* 59 Vand. L. Rev. 1263 (2006) (noting that New Jersey was one of four states that recently passed legislation requiring patients to be informed when they were the victim of medical errors). Commentators have observed that the PSA has made the communication of healthcare errors a part of ordinary medical life. Edward A. Dauer, *Postscript on Health Care Dispute Resolution: Conflict Management And the Role of Culture,* 21 Ga. St.U. L.Rev. 1029, 1053 (2005).

Under the PSA, a patient must be informed no later than the end of the episode of care, or, if discovery occurs after the end of the episode of care, in a timely fashion, when the patient is a victim of "a serious preventable adverse event." *N.J.S.A.* 26:2H-12.25(d). A "serious preventable adverse event" is any adverse event that is preventable and results in death, loss of body part, or disability or loss of bodily function either lasting more than seven days, or that is still present at the time of discharge. *N.J.S.A.* 26:2H-12.25(a). In addition to requiring adverse events to be reported to the victims of medical malpractice, the Patient Safety Act also requires health care providers to report medical errors to the Department of Health and Human Services (the "Department"). *N.J.S.A.* 26:2H-12.25(c).

On January 24, 2008, the Department enacted regulations that gave teeth to the notification and reporting requirements of the Act. As of (a) March 3, 2008, for hospitals, (b) August 30, 2008, for ambulatory care facilities, home health care agencies and hospice providers, and (c) starting March 3, 2009, for nursing homes and assisted living facilities, health care providers have five business days after discovery of a serious preventable adverse event to notify the Department that a preventable adverse event has occurred. *N.J.A.C.* 8:43E-10.1, *N.J.A.C.* 8:43E-10.6(b). The notification requires the inclusion of specific categories of information, including: (a) the date and time the event occurred, (b) a brief description of the event, (c) a statement about the impact of the event on the health of the patient, (d) the date and time the facility became aware of the event, (e) how the event was discovered, (f) the immediate corrective actions to facility took to eliminate or reduce the adverse impact of the event on the patient, and (g) what steps were taken to prevent the occurrence of future similar events. *N.J.A.C.* 8:43E-10.6(c). Failure to comply with these reporting requirements results in a fine of $1,000 a day. *N.J.A.C.* 8:43E-3.4(14).

Medical providers have 24 hours after the discovery of a serious preventable adverse event to notify a patient that it has occurred. *N.J.A.C.* 8:43E-10.7(b). Patients are to be notified in person if they are still at the facility or by telephone or by certified mail if they are not. *N.J.A.C.* 8:43E-10.7(c). Disclosure to a patient must be accompanied by documentation in the patient's medical chart which indicates: (a) that the disclosure was made, (b) the time, date and individuals present when the disclosure was made and (c) the name of the person to whom the disclosure was made. *N.J.A.C.* 8:43E-10.7(f). Medical providers failing to disclose a serious preventable adverse event to a patient are subject to a fine of $1,000 if the

event was also not disclosed to the Department of Health and Senior Services, but $5,000 if they reported the event to department, *N.J.A.C.* 8:43E-3.4(15).

B. The Insufficiency of Existing Ethical Mandates to Disclose Medical Errors.

It is significant that when mandating the disclosure of medical errors under the PSA, New Jersey sought only to compel medical providers to do something already ethically required. Under the American Medical Association Code of Ethics, physicians have an ethical obligation to advise a patient when they commit consequential acts of medical malpractice when "a patient suffers significant medical complications that may have resulted from the physician's mistake or judgment." *Am. Med. Ass'n Code of Medical Ethics A-02 Edition, E-8.12 Patient Information*, 77. Similarly, the American College of Physicians Ethics Manual mandates disclosure of errors if disclosure of this information is "material to the patient's well-being." Lois Snyder & Cathy Leffler, *Ethics Manual, Fifth Editio*n, 142 Annals Internal Medicine 560, 563. Finally, the Joint Commissions on Accreditation of Health Care Organizations requires that patients be informed of unanticipated results that differ from the expected outcome in a significant way when a medical error occurs at a hospital. Joint Comm'n on Accreditation of Health Care Orgs., *Revisions to Joint Commission Standards in Support of Patient Safety and Medical/Health Care Error Reduction* 12 (2001).

Disclosure of medical errors is not only ethically mandated, literature supports that it is consistent with the fiduciary nature of the physician-patient relationship, since in most instances, disclosure of errors will be benefit a patient. C.J. Wusthoff, *Medical Mistakes and Disclosure: The Role of the Medical Student*, 286(9) Journal of the American Medical Association, 1080, 1081 (2001). Disclosure helps gain the cooperation of a patient who has been harmed by an error. *Id.* Further, understanding the cause of unexpected problems can relieve anxiety about recovery or complications. *Id.* Finally, some commentators have suggested that since patients need information about errors to make decisions about their medical care, disclosure of malpractice is part of a physician's duty to provide a patient with informed consent. Thomas H. Gallagher, Wendy Levinson, *Disclosing Medical Errors to Patients: a Status Report in 2007*, 177(3) Canadian Medical Association Journal 265 (2007).

In theory, physicians agree that they have an ethical obligation to disclose medical errors. One study suggests that between 70 and 90% of the physician population believes that doctors should disclose errors to patients. Kathleen M. Mazor et al., *Communicating with Patients about Medical Errors*, 164 Archives of Internal Medicine 1690, 1692 (2004). In another study, 97% of the faculty and resident population surveyed indicated that they would disclose medical errors that caused minor harm, and 93% indicated that they would disclose an error causing major harm. Lauris Kaldjian , et al. *Disclosing Medical Errors to Patients: Attitudes and Practices of Physicians and Trainees*, 22(7) J Gen Intern Med 988-96 (2007).

Regrettably, while physicians are ethically obligated to inform their patients of consequential medical malpractice and studies suggest they intellectually support this principle, theory has not translated into practice. A study revealed that only 24% of residents surveyed reported the medical errors they committed to their patients. Albert Wu, et al. *Do House Officers Learn From Their Mistakes?* 12 Quality & Safety Health Care 221, 224 (2003). Another study estimated that nationwide, physicians are only disclosing errors to patients about 1/3 of the time. Robert J. Blendon et al., *Views of Practicing Physicians and the Public on Medical Errors*, 347 New. Eng. J. Med. 1933, 1935 (2002) .

THE GENERAL IMPACT OF COMPULSORY ERROR REPORTING AND DISCLOSURE

A. Compulsory Error Reporting Will Make Significant Contributions to the Improvement of the Quality of Health Care Everywhere.

Mandatory disclosure of medical errors in New Jersey will provide invaluable information useful to medical providers everywhere. First, it will provide information about the scope of the medical malpractice problem. In November 1999, the Institute of Medicine, a branch of the National Academy of Sciences, declared that a threshold improvement in the quality of health care was needed because studies indicated that medical negligence committed in hospitals in the United States were killing more people annually than motor vehicle accidents, breast cancer and AIDS. Kohn LT, Corrigan JM, and Donaldson MS, *To Err Is Human: Building a Safer Health System,* National Academy Press pg. 26 (1999). (hereafter "To Err is Human"). As alarming as the statistics disclosed in the Executive Summary of this study were, it is significant that the analysis dealt only with deaths caused in hospitals. New Jersey's mandatory disclosure requirements apply not only to hospitals, but to all health care providers in the state. Not just deaths, but any preventable event that impacts a patient's health for more than seven days must be reported. Thus, mandatory disclosure of medical errors in New Jersey may provide the government and health care industry with the first accurate picture of the human and economic costs related to medical mistakes.

Beyond acquiring knowledge about the scope of the problem, analysis of the information generated from a statewide policy of compulsory error disclosure will provide the health care industry with the ability to analyze patterns in the data collected to see why system errors occur, and this will help determine what can be done to avoid or minimize certain problems. Surprisingly, such a systematic approach to dealing with medical errors is absent. In To Err is Human, the authors noted that the health care industry is at least a decade or more behind other high-risk industries in its attention to ensuring the basic safety of people it services. Id. at 5. The Institute of Medicine indicated that a multifaceted approach was needed to improve the quality of health care. Id. at 4. One of the changes it called for was mandatory reporting of serious adverse events so that these could be studied. Id. at 102. To date, the failure to disclose medical errors has undermined efforts to improve patient safety. Hebert PC, et al. Bioethics for Clinicians: 23. *Disclosure of Medical Error,* 164 CMAJ, 509-513 (2001); The Joint Commission on Accreditation of Healthcare Organizations, *Health Care at the Crossroads: Strategies for Improving the Medical Liability System and Preventing Patient Injury*, pg. 27 (2005). New Jersey's statewide compulsory error reporting requirement is one of the most significant first steps taken to correct this problem. Clearly, industry experts all over the world will be watching what New Jersey learns on this front.

B. Compulsory Error Disclosure Will Not Necessarily Result in an Increase in Medical Malpractice Filings in New Jersey.

There are few health care systems that enforce a policy of mandatory medical error disclosure. As a result, it is difficult to estimate how the PSA's compulsory error reporting requirements will impact medical malpractice filings in New Jersey. Nevertheless, studies in smaller systems where this was done demonstrate that the impact of mandatory disclosure on filings may be negligible and perhaps even positive. The Veterans Affairs Medical Center in Lexington, Kentucky, the University of Michigan Health System and a Colorado malpractice insurance company, COPIC, developed programs to fully disclose

medical errors while simultaneously attempting to compensate the victims of malpractice if warranted. *Disclosing Medical Errors to Patients: a Status Report in 2007*, *supra,* at 266. All of these organizations found that the number of malpractice claims filed either stayed the same or decreased. Id.; Christian J. Vercler, et al., *Communicating Errors*, 140 Cancer Treatment and Research, 195-213, 204 (2008).

Although seemingly counterintuitive, the idea that compulsory medical error disclosure may not yield more malpractice lawsuits is corroborated by studies that seek to ascertain what motivates patients to sue their doctors. Financial compensation is not the most common reason that people give for filing a medical malpractice lawsuit. In fact, it is fifth on the list, behind (1) a clear admission that a mistake was made, (2) a full explanation of the error, (3) a sincere apology, and (4) reassurances that things are being done so that the error is not repeated. Thomas Gallagher et al, *Patients' and Physicians' Attitudes Regarding the Disclosure of Medical Errors,* 289 JAMA 1001, 1004-1006 (2003). It may very well be that because the PSA's compulsory error reporting requirements will immediately satisfy the first four of the above desires, some potential lawsuits will not be filed.

-III-

THE PSA AND CHANGING THE CULTURE OF HEALTH CARE

An examination of the reasons why health care providers failed to meet their ethical obligation to disclose errors can shed light on how mandatory error reporting will change malpractice litigation because the same forces which discourage the reporting of medical mistakes when they occur likely discourage physicians from taking responsibility for mistakes after a lawsuit is filed.

Health care providers' failure to fulfill their ethical obligation to disclose medical errors is often blamed on the fear of potential medical malpractice lawsuits. Putting aside the question of whether avoiding being held financially responsible for a mistake is a valid basis to reject an ethical obligation to report it, scholarly articles addressing the subject of why physicians fail to disclose errors suggest motivations besides fear of lawsuits are at play. Notably, despite the fact that there are procedural safeguards in place to prevent statements made in M&M conferences from being used against a health care providers in medical malpractice cases, physicians are still reluctant to discuss medical mistakes in these forums, leading some commentators to conclude that legal liability does not inhibit the discussion of errors in these conferences as much as other factors, such as the social norms of medicine. Wei, Marlynn, *Doctors, Apologies and the law: An Analysis and Critique of Apology Laws*, 40(1) Journal of Health Law 107-59, 132 (2007).

Beyond M&M conferences, academics have noted that physicians do not disclose errors even when they are permitted to do so anonymously, without fear of retribution:

> *What is most striking is that even nonpunitive medical error reporting measures suffer from underreporting. Reporting systems at the federal and state level have attempted to build a database upon which providers can improve patient safety. Nevertheless, the detection and prevention of medical error continues to be plagued by under reporting of adverse events, even when the reports are anonymous, voluntary and confidential.*

Id. at 36. (2007).

Some have suggested that the culture of medicine, instilled in physicians beginning in medical school, is responsible for the widespread abandonment of the ethical obligation to disclose errors. Gallagher TH, Waterman AD et al. *US and Canadian Physicians' Attitudes and Experiences Regarding Disclosing Errors to Patients*, 166(15) Archives Internal Medicine 1605-1611. (2006). Similarly, it has been hypothesized that the failure to disclose errors is due to a "medical narcissism," which develops through doctors' "idealistic, perfectionist projection of themselves" which causes the mere acknowledgment of an error to be "so psychologically damaging to the physician's sense of self that he or she will go to great lengths to rationalize and obfuscate the facts of the error." Vercler CJ et al., *Communicating Errors,* 140 Cancer Treatment and Research 195-213, 206 (2008). (discussing Banja J.D., Medical Error and Medical Narcissism, Jones & Bartlet: Sudbury, MA (2005). According to this theory, a kind of preexisting narcissism drives individuals to become physicians in the first place, and a narcissistic inclination is then supported and encouraged through the medical education process, where residents are encouraged to strive for perfection. *Communicating Errors, supra,* at 206. Emotional detachment is simultaneously developed as a survival strategy, and the loss of empathy and the goal of perfection combine to present a major barrier to disclosure of mistakes. Id.

There are other aspects of the culture of medicine that contribute to the failure of physicians to disclose errors, including the desire of physicians to remain self-regulated. *Doctors, Apologies and the law: An Analysis and Critique of Apology Laws, supra,* at 146. Simply put, physicians resent being told how to treat their patients, especially by non-physicians. Id. Furthermore, disclosure of errors chips away at the mask of infallibility that physicians wear. Id. at 147. Infallibility supports two fundamental aspects of the physician-patient relationship. First, it buttresses the physician's position of authority in the relationship. Id. Second, it instills a sense of certainty in the physician's treatment recommendations. *Id.* at 148.

Physicians also resist the disclosure of errors because doing so creates worries about costs to reputation, loss of referrals and risk of litigation. Id. Finally, there are problems of analysis that contribute to physician's failure to disclose errors because there can be doubt about the cause of a particular outcome. *Communicating Errors, supra,* at 204.

"The culture of an organization is the nonverbal part of the ongoing conversation among the individuals who comprise the organization." Edward Dauer, *Postscript on Health Care Dispute Resolution: Conflict Management and the Role of Culture,* 21 Ga.St.U.L.Rev. 1029, 1044 (2005) (discussing Debra Gerardi, *The Culture of Health Care: How Professional and Organizational Cultures Impact Conflict Management,* 21 Ga.St.U.L.Rev. 857 (2005)). As one commentator observed, by compelling the disclosure and reporting of medical errors, the PSA is forcing a change in the culture of health care in New Jersey. Postscript on Health Care Dispute Resolution: Conflict Management and the Role of Culture, supra, at 1053. It stands to reason that this health care culture change will impact medical malpractice litigation.

-IV-

CONCLUSION

The PSA has provisions which prevent disclosures made pursuant to its terms from being used against medical providers in a malpractice case. Any documents submitted to the Department of Health and Human Services are not subject to discovery or admissible in evidence in a civil or criminal hearing. *N.J.S.A.* 26:2H-12.25(f)(1). Additionally, a statement by healthcare provider advising a patient that he is

the victim of a serious preventable adverse event are is not discoverable or admissible in evidence in a civil trial.

Although disclosure of a medical error under the PSA may not be brought to the attention of a jury in a medical malpractice case, it is a mistake to conclude that the compulsory immediate disclosure of a medical mistake will not impact medical malpractice litigation. Disclosure of a medical mistake under the PSA will require health care providers to immediately examine their actions and take responsibility for preventable adverse events of consequence. Not every serious preventable adverse event under the PSA will constitute a meritorious and viable medical malpractice claim. Nevertheless, every meritorious and viable medical malpractice case should meet the requirements of being a serious preventable adverse event under the PSA. Therefore, hereafter, in most medical malpractice cases, a defendant health care provider will have already examined his actions, concluded a mistake of consequence was made, and advised his patient and the state accordingly.

Failing to disclose medical error when they occur will often foreclose a physician from acknowledging the mistake in a subsequent lawsuit. *Doctors, Apologies and the law: An Analysis and Critique of Apology Laws, supra,* 110-111. At a minimum, if a plaintiff prevails, a defendant doctor can appear cold and unapologetic to the jury. Id. Furthermore, failing to honestly deal with a mistake at its outset can set the tone in a subsequent litigation, turning circumstances involving an honest error into a zero-sum credibility challenge, which unnecessarily escalates the stakes for everyone involved in the lawsuit.

Compulsory disclosure under the PSA should make medical malpractice cases less contentious because in many cases defendants will have already acknowledged and come to terms with the fact that they have committed a consequential mistake. Further, because the cultural and economic pressures that discourage disclosure and reporting of errors are some of the same forces that serve as obstacles to resolving a medical malpractice lawsuit, the PSA's compulsory error reporting requirements should obviate many unstated motivations medical malpractice defendants have for not taking responsibility for their actions throughout the course of a lawsuit.

In 2003, the American Arbitration Association (AAA) reported that out of the thousands of matters it handled throughout the United States, only 1 involved a claim of iatrogenic injury in a health care setting. Dauer, Edward A., *Postscript on Health Care Dispute Resolution: Conflict Management and the Role of Culture, supra,* at 1036. There is reason to believe that changes mandated by the PSA may make ADR a more useful tool for medical malpractice defendants.

If the changes in medical culture caused by compulsory error disclosure and reporting make medical malpractice cases in New Jersey less contentious, plaintiffs will not be the only beneficiaries. Ninety-five percent of physicians sued for malpractice report strong emotional responses related to that event, physical reactions or both. *Doctors, Apologies and the law: An Analysis and Critique of Apology Laws, supra,* at 139. Id. One half reported insomnia and a minority reported the manifestation of physical problems related to being sued for medical malpractice. Id. at 140.

Perhaps the PSA's error reporting and disclosure requirements will be just what the doctor ordered for patients and doctors who are unfortunate enough to have to go through a medical malpractice litigation. To be sure, many will be watching to see the impact this legislation has on the health care profession in New Jersey.