SYLLABUS

(This syllabus is not part of the opinion of the Court. It has been prepared by the Office of the Clerk for the convenience of the reader. It has been neither reviewed nor approved by the Supreme Court. Please note that, in the interest of brevity, portions of any opinion may not have been summarized.)

**C.A. v. Eric Bentolila, M.D. (A-32-12) (071702)**

**Argued February 3, 2014 -- Decided September 29, 2014**

**PATTERSON, J., writing for a majority of the Court.**

In this appeal, the Court considers whether a memorandum memorializing a round-table discussion by hospital staff investigating an adverse event is shielded from discovery under the Patient Safety Act, N.J.S.A. 26:2H-12.23 to -12.25.

The Patient Safety Act was enacted in 2004 to reduce the incidence of medical errors that may endanger patients in health care facilities. The Act imposed new requirements for evaluating and reporting adverse medical events, and created a statutory privilege shielding specific communications from discovery in litigation. The Act sought to encourage health care workers to candidly disclose their observations and concerns, and to promote self-critical evaluation by professional and administrative staff. Regulations detailing the requirements for complying with the Act were not promulgated until 2008.

Plaintiff Esther Applegrad was admitted to The Valley Hospital (Hospital) on May 26, 2007, in her forty-first week of pregnancy. Her daughter, C.A., was born later that same day. Plaintiffs contend that C.A. suffers from a serious brain injury that was caused by the negligent medical care she received at the Hospital during and after the birth. Defendants maintain that C.A.'s brain injury resulted from unpreventable birth complications.

Plaintiffs filed suit against the Hospital and the doctors and nurses involved in C.A.'s birth and care. They moved to compel production of the Hospital's investigative and peer review records relating to C.A.'s birth. Defendants urged the trial court to find that several of the Hospital's documents were privileged. Among those was the document at issue in this appeal, a memorandum dated June 1, 2007, and entitled "Director of Patient Safety Post-Incident Analysis," which was created following a "round-table" discussion among Hospital staff as part of an investigation of C.A.'s delivery and neonatal care. The document was designated for discovery purposes as "DV2." According to defendants, DV2 and other documents were absolutely privileged under the Patient Safety Act.

The trial court ultimately determined that although the Hospital did not strictly follow the requirements of the Patient Safety Act when it created DV2, it had substantially complied with the Act. It ruled that DV2 was privileged under the Patient Safety Act, and accordingly denied plaintiffs' motion to compel discovery of the document.

Plaintiffs filed a motion for leave to appeal with the Appellate Division. The Appellate Division granted the motion and held that the statutory privilege does not attach to documents created in a process in which "the specified procedures of the [Act] and the related regulations have not been observed." C.A. v. Bentolila, 428 N.J. Super. 115, 122 (App. Div. 2012). Applying the regulations adopted in 2008, after the creation of DV2, the panel concluded that DV2 was not created in full compliance with the processes and procedures of the Patient Safety Act, and ordered its disclosure. The judgment was stayed pending defendants' motion for leave to appeal to this Court. The Court granted the motion for leave to appeal. 213 N.J. 47 (2012).

**HELD**: The Hospital's evaluative process in this case conformed to the Patient Safety Act's requirements. The memorandum at issue is privileged, not subject to discovery, and should not be used for any purpose in this case.

1. New Jersey hospitals have been required to engage in self-evaluation and to maintain quality improvement programs since 1990. The Patient Safety Act was not intended to replace preexisting evaluative processes for hospitals. Instead, the Act pursues a distinct goal: to minimize adverse events deriving from system failures in a hospital or other health care facility. To that end, the Act mandates that health care facilities establish a patient

safety plan "for the purpose of improving the health and safety of patients at the facility." One of the plan's components is the establishment of "a patient safety committee." The Patient Safety Act did not specify the composition or operation of the patient safety committee, but left those details to be determined by regulation. The regulatory process was not completed until 2008, nearly four years after the Patient Safety Act became law. Thus, the structure and mission of the patient safety committee, now comprehensively prescribed by regulation, had yet to be specified when the Hospital prepared the document disputed in this case. (pp. 13-21)

2. The Legislature included in the Patient Safety Act a provision creating an absolute privilege. It reasoned that health care professionals and other facility staff are more likely to effectively assess adverse events in a confidential setting, in which an employee need not fear recrimination for disclosing his or her own medical error, or that of a colleague. Like its process requirements, the Patient Safety Act's privilege provisions were explained and refined by the regulations that followed. In the regulations that became effective in 2008, the standard for determining applicability of the privilege was expanded in two significant respects: first, to require that the documents, materials and information at issue be "exclusively" prepared in the setting of a qualifying self-critical analysis process, and second, to mandate that the self-critical analysis be conducted in accordance with one of three accompanying regulations. (pp. 21-28)

3. When DV2 was prepared on June 1, 2007, the only guidance to the Hospital and its staff was found in the Patient Safety Act. The discoverability of DV2 must therefore be determined in accordance with the Patient Safety Act itself, without imposing requirements that appeared for the first time in subsequent regulations. The Act shields from discovery documents, materials or information developed "as part of a process of self-critical analysis" and requires a safety plan that includes, at a minimum, four components: establishment of a patient safety committee; a process for teams of facility staff to conduct ongoing analysis and application of evidence-based patient safety practices; a process for teams of facility staff to conduct analyses of near-misses; and a process for the provision of ongoing patient safety training for facility personnel. (pp. 28-29)

4. The record supports the trial court's determination that the Hospital established all four of the components of the patient safety plan that are required by the statute. In addition, the record also supports the trial court's finding that DV2 was prepared "as part of a process of self-critical analysis" pursuant to the statute. Regardless of whether the Hospital's process would have satisfied the regulations that became effective at a later time, the Hospital met the only standard that governed it in 2007, the mandate of the Patient Safety Act itself. Health care facilities were not compelled to anticipate later regulations as a condition of the statutory privilege. (pp. 30-36)

The judgment of the Appellate Division is **REVERSED**, and the matter is **REMANDED** for proceedings consistent with this opinion.

**CUFF, P.J.A.D.** (temporarily assigned), **DISSENTING**, joined by **CHIEF JUSTICE RABNER** and **JUSTICE ALBIN**, expresses the view that the personnel involved in the Hospital's self-evaluation process were not representative of the facility's various disciplines and did not have the appropriate competencies as required under the Patient Safety Act. Therefore, that process did not comply with the Act and the memorandum should not be shielded from discovery.

**JUSTICES LaVECCHIA and FERNANDEZ-VINA and JUDGE RODRÍGUEZ (temporarily assigned) join in JUSTICE PATTERSON's opinion. JUDGE CUFF (temporarily assigned) filed a dissenting opinion in which CHIEF JUSTICE RABNER and JUSTICE ALBIN join.**

SUPREME COURT OF NEW JERSEY
A-32 September Term 2012
071702

C.A., a Minor, by Her Mother and Guardian ad Litem, ESTHER APPLEGRAD, ESTHER APPLEGRAD, Individually, and GEDALIA APPLEGRAD, Individually,

Plaintiffs-Respondents,

v.

ERIC BENTOLILA, M.D., and GITA PATEL, R.N.,

Defendants,

and

THE VALLEY HOSPITAL, KOURTNEY KACZMARSKI, R.N., MARY BROWN, R.T., and YIE-HSIEN CHU, M.D.,

Defendants-Appellants.

Argued November 6, 2013
Reargued February 3, 2014 – Decided September 29, 2014

On appeal from the Superior Court, Appellate Division, whose opinion is reported at 428 N.J. Super. 115 (2012).

Douglas S. Eakeley argued the cause for appellants (Lowenstein Sandler, Vasios, Kelly & Strollo, and Buckley Theroux Kline & Petraske, attorneys; Mr. Eakeley and Rowena M. Duran, of counsel; Mr. Eakeley, Ms. Duran, Natalie J. Kraner, Liad Levinson, Linda S. Fulop-Slaughter, Karla M. Donovan, and William G. Theroux, on the briefs).

Cynthia A. Walters argued the cause for respondents (Budd Larner, attorneys; Ms. Walters, Justin P. Van Dyke, and Donald P. Jacobs, on the briefs).

Ross A. Lewin argued the cause for amicus curiae New Jersey Hospital Association (Drinker Biddle & Reath, attorneys).

E. Drew Britcher argued the cause for amicus curiae New Jersey Association for Justice (Britcher, Leone & Roth, attorneys; Mr. Britcher and Kristen B. Miller, on the brief).

Susan J. Dougherty, Deputy Attorney General, submitted a letter in lieu of brief on behalf of amicus curiae Attorney General of New Jersey (John J. Hoffman, Acting Attorney General, attorney).

JUSTICE PATTERSON delivered the opinion of the Court.

In 2004, the Legislature enacted the Patient Safety Act to reduce the incidence of medical errors that may endanger patients in health care facilities. N.J.S.A. 26:2H-12.23 to -12.25. The Act imposed new requirements for evaluating and reporting of adverse events, and created a statutory privilege shielding specific communications from discovery in litigation. N.J.S.A. 26:2H-12.25(b), (c), (e), (g). The Act sought to encourage health care workers to candidly disclose their observations and concerns, and promote self-critical evaluation by professional and administrative staff.

The interlocutory appeal before the Court involves an early application of the Patient Safety Act. In the underlying

medical malpractice litigation, plaintiffs claim that the infant plaintiff, C.A., is permanently disabled because of injuries sustained during her birth on May 26, 2007, at The Valley Hospital (Hospital). Shortly after C.A.'s birth, a "round-table" discussion among Hospital staff was conducted as part of an investigation of her delivery and neonatal care. A hospital administrator prepared a memorandum memorializing the discussion. The parties dispute the discoverability of this document.

The trial court determined that because the Hospital had substantially complied with the Patient Safety Act in its investigation, the memorandum was subject to the Act's absolute privilege. The Appellate Division reversed the trial court's determination. C.A. v. Bentolila, 428 N.J. Super. 115, 122 (App. Div. 2012). It concluded that the process used by the Hospital and its staff in creating the memorandum did not meet the statute's requirements to shield the document from discovery. In its holding, the panel retroactively applied regulations that were adopted by the Department of Health and Senior Services (Department) after the preparation of the contested memorandum. It thus ordered the Hospital to produce the document in discovery.

We reverse. We construe the Patient Safety Act in light of its purpose to encourage health care workers to freely report

their observations and concerns related to patient safety in a confidential setting. Today, health care facilities are guided by detailed regulations that supplement the requirements of the Patient Safety Act. See N.J.A.C. 8:43E-10.1 to -10.11. Those regulations, however, did not exist when the document at issue was prepared. At the relevant time, the only prerequisite to the privilege was compliance with the terms of the Patient Safety Act itself. We hold that the Hospital's evaluative process in this case conformed to the Patient Safety Act's requirements, and that the memorandum at issue is therefore privileged.

Accordingly, we reverse the order requiring the Hospital to produce the disputed document.

I.

On May 26, 2007, plaintiff Esther Applegrad, in her forty-first week of pregnancy, was admitted to the Hospital after sustaining a spontaneous rupture of membranes the previous day.[1] She was treated by Eric Bentolila, M.D., the attending obstetrician. From the time that Applegrad arrived at the Hospital to the conclusion of the day shift at 7:00 p.m., the nurse primarily responsible for her care was Kourtney

[1] At this pretrial stage, the record before the Court regarding the medical care provided to Applegrad and the birth of C.A. is limited, and it appears that the parties substantially dispute many of the underlying facts.

Kaczmarski, R.N. Plaintiffs contend that Kaczmarski failed to ascertain that C.A. was in a breech position, and that the nurse's failure to note this complication prompted Dr. Bentolila to anticipate a vaginal delivery rather than a Caesarean section. They further allege that although Dr. Bentolila discovered C.A.'s breech presentation, he nonetheless decided to proceed with a vaginal delivery, thereby deviating from the applicable standard of care. Dr. Bentolila denied that he was negligent, and contended that he fully discussed the risks and benefits of both vaginal delivery and Caesarean section with Applegrad.

Plaintiffs allege that Dr. Bentolila ordered that the labor-inducing medication Pitocin be administered to Appelgrad, and that he later attempted to destroy the medical record indicating she was given Pitocin. They assert that in accordance with Dr. Bentolila's order, Kaczmarski began to administer Pitocin at approximately noon on the day of C.A.'s birth.

By evening, Applegrad was in the final stages of labor. Dr. Bentolila delivered C.A. at approximately 8:45 p.m. The newborn had an Apgar score of 2,[2] and her heart rate was recorded

[2] An Apgar score is an "evaluation of a newborn infant's physical status by assigning numerical values (0-2) to each of five criteria: heart rate, respiratory effort, muscle tone, response stimulation, and skin color; a score of 8-10 indicates the best

as faint. Following her birth, C.A. was intubated and transferred to the care of Yie-Hsien Chu, M.D., a pediatrician. Plaintiffs allege that Dr. Chu was negligent in her resuscitation of C.A. and for failing to immediately notify the attending anesthesiologist that the newborn's intubation tube was not functioning properly, which caused the infant to suffer an anoxic brain injury.

Plaintiffs claim that C.A. currently suffers from Hypoxic-Ischemic Encephalopathy and a seizure disorder resulting from the medical care that she received at the Hospital during and after her birth. Defendants maintain that C.A.'s brain injury resulted from unpreventable birth complications, that Applegrad received competent care during the birth, and that the infant was properly resuscitated.

This medical malpractice action was filed by Applegrad and her husband, Gedalia Applegrad, in the Law Division. Plaintiff named as defendants the Hospital, Dr. Bentolila, Dr. Chu, Nurse Kaczmarski, a second nurse, Gita Patel, R.N., and a respiratory therapist, Mary Brown, R.T.[3]

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possible condition." Stedman's Medical Dictionary 1735 (28th ed. 2006).

[3] The trial court dismissed plaintiffs' claims against Dr. Bentolila and Nurse Patel in 2009. The Hospital, Kaczmarski, Brown and Dr. Chu remain defendants in the case and are parties to this appeal.

The document dispute at the center of this case arose during pretrial discovery in the medical malpractice litigation. Plaintiffs moved to compel production of the Hospital's investigative and peer review records relating to C.A.'s birth. In their initial response to the motion, defendants did not rely upon the statutory privilege set forth in the Patient Safety Act. Instead, they urged the trial court to conduct the balancing test set forth by the Appellate Division in Christy v. Salem, 366 N.J. Super. 535, 541-45 (App. Div. 2004), and to find that several of the Hospital's documents were privileged in accordance with that standard.

Among the disputed documents that were the subject of plaintiffs' motion was a memorandum dated June 1, 2007, entitled "Director of Patient Safety Post-Incident Analysis." The document was designated for discovery purposes as "DV2." Along with five other documents, DV2 was submitted to the trial court for in camera review. The trial court initially proposed to review the document in accordance with the balancing test set forth by the Appellate Division in Christy. Notwithstanding its initial reliance upon the Christy test, the Hospital objected to the trial court's proposal, and claimed for the first time that the six documents at issue were absolutely privileged under N.J.S.A. 26:2H-12.25(g) of the Patient Safety Act. Following a further hearing, the trial court agreed with the Hospital's

position that the documents were privileged under the Act, and denied plaintiffs' motion to compel production of the documents.

Plaintiffs sought leave to appeal. An Appellate Division panel granted the motion, but later vacated its order and remanded to the trial court for further development of the record. On remand, defendants partly modified their position with respect to the documents at issue. They contended that only two documents, DV2 and a second memorandum, DV5, were subject to the Patient Safety Act's absolute privilege, and asserted that the remaining four documents should remain confidential on other grounds not at issue in this appeal.

The trial court conducted a seven-day evidentiary hearing. The Hospital presented the testimony of three witnesses: Kim Robles, the Hospital's Director of Quality Assessment Improvement and Regulatory Compliance; Michael Mutter, the Hospital's Director of Patient Safety and the author of DV2; and Linda Malkin, the Hospital's Director of Risk Management. The parties also submitted documentary evidence to the trial court.

The trial court made factual findings with respect to the Hospital's compliance with the Patient Safety Act and the process followed in the Hospital's investigation of C.A.'s birth and neonatal care. The trial court also made several observations about the purpose and preparation of the contested document, DV2. On the basis of those findings, the trial court

held that although the Hospital did not strictly follow the requirements of the Patient Safety Act when it created DV2, it had substantially complied with the Act. It ruled that DV2 was privileged under the Patient Safety Act, and accordingly denied plaintiffs' motion to compel discovery of the document. The court held, however, that the judge scheduled to preside over the medical malpractice trial should have a copy of the document in order to evaluate the credibility of witnesses who were participants in the round-table discussion.[4]

Plaintiffs filed a second motion for leave to appeal. After granting the motion, an Appellate Division panel affirmed in part and reversed in part the trial court's determination. C.A., supra, 428 N.J. Super. at 159. The panel construed the Act to confer an absolute privilege upon "post-event investigatory and analytic documents exclusively created in compliance with the [Act] and its associated regulations, and not created for some other statutory or licensure purpose." Id. at 122. It held, however, that the statutory privilege does not attach to documents created in a process in which "the specified procedures of the [Act] and the related regulations have not

[4] The trial court also made findings about the five other contested documents, and ruled on the discoverability of those documents in accordance with the standard set forth in Christy, supra, 366 N.J. Super. 535. Those findings are not pertinent to this appeal.

been observed," or to documents "generated for additional non-[Patient Safety Act] purposes." Ibid.

Applying the "exclusivity test" prescribed by N.J.A.C. 8:43E-10.9(b), a regulation adopted by the Department after the creation of DV2, the panel reasoned that a document must be exclusively created to comply with the Patient Safety Act -- and not for any other purpose -- in order to warrant the statutory privilege. Id. at 148-49. The panel further held that compliance with another regulation adopted after the preparation of DV2, N.J.A.C. 8:43E-10.4(d)(7), was essential for the application of the privilege. Id. at 153.

The panel concluded that DV2 was not created "in full compliance with the processes and procedures of the [Patient Safety Act]." Id. at 154. It noted that no physician participated in the round-table discussion, and that the findings recorded in the document were not presented to the Patient Safety Committee. Id. at 152-55. The panel ordered the disclosure of DV2, but stayed its judgment pending defendants' filing of a motion for leave to appeal in this Court. Id. at 159.[5]

[5] The panel also rejected plaintiffs' constitutional challenge to the Patient Safety Act, which was premised on the argument that the Legislature violated principles of the separation of powers doctrine when it created the evidentiary privilege under the Patient Safety Act without the involvement of the judicial

We granted defendants' motion for leave to appeal, which sought review of the portion of the Appellate Division's judgment that ordered the disclosure of DV2. 213 N.J. 47 (2012).

II.

Defendants argue that the Appellate Division improperly applied the administrative regulations adopted in 2008 to determine the discoverability of DV2, a document prepared before the regulations were adopted. They maintain that the Hospital satisfied the statutory standard that governed when DV2 was created. Defendants contend that the panel imposed requirements that are not found in the Act, such as the presence of a physician on the evaluating team and the involvement of the Patient Safety Committee in the evaluative process at issue. Defendants assert that the Appellate Division erred in holding that a document for which protection is sought must be exclusively created to comply with the Patient Safety Act. They maintain that the confidentiality provisions of the Act are not conditioned on strict adherence to every aspect of the statute.

Plaintiffs urge the Court to affirm the Appellate Division's determination. They argue that the panel properly held that the confidentiality provisions of the Patient Safety

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branch. C.A., supra, 428 N.J. Super. at 157-59. That determination is not challenged in this appeal.

Act are only available to facilities that conduct their investigations in strict compliance with the Act's terms. Plaintiffs contend that the panel correctly identified deficiencies in the process by which the Hospital created DV2. They maintain that although the "exclusivity test" invoked by the panel was set forth in the regulations adopted in 2008, it may also be inferred from the Act's statutory text, and should therefore provide the standard for this discovery dispute. In the alternative, plaintiffs argue that any change in the law that occurred with the adoption of the regulations was curative, and that the regulations should therefore apply retroactively.

Amicus curiae New Jersey Association for Justice (NJAJ) argues that the Legislature intended that any internal documents or communications generated by a health care facility should be protected only by the qualified privilege identified in Christy, not by any absolute privilege. NJAJ contends that the Hospital failed to comply with the Patient Safety Act's mandatory committee structure and that it violated the Act by failing to refer C.A.'s case to the Patient Safety Committee.

Amicus curiae New Jersey Hospital Association (NJHA) argues that the Patient Safety Act was intended to shield from discovery internal analyses generated in accordance with the Act, and that plaintiffs' argument that Christy governs the discoverability of such analyses would undermine the legislative

objective. It asserts that the panel improperly imposed conditions that were not articulated in the Patient Safety Act, and appeared only in regulations that had yet to take effect at the relevant time.[6]

III.

An appellate court applies "an abuse of discretion standard to decisions made by [the] trial courts relating to matters of discovery." Pomerantz Paper Corp. v. New Cmty. Corp., 207 N.J. 344, 371 (2011) (citing Bender v. Adelson, 187 N.J. 411, 428 (2006)). It "'generally defer[s] to a trial court's disposition of discovery matters unless the court has abused its discretion or its determination is based on a mistaken understanding of the applicable law.'" Ibid. (quoting Rivers v. LSC P'ship, 378 N.J. Super. 68, 80 (App. Div.), certif. denied, 185 N.J. 296 (2005)). However, we conduct a de novo review of the trial court's construction of a statute. In re Liquidation of Integrity Ins. Co., 193 N.J. 86, 94 (2007).

Our review of the trial court's interpretation of the Patient Safety Act is conducted in accordance with familiar rules of statutory construction. "The Legislature's intent is

[6] Pursuant to Rule 4:28-4, the Attorney General appeared in the trial court and the Appellate Division to defend the constitutionality of the Patient Safety Act. Because the constitutionality of the Act is not challenged before this Court, the Attorney General has declined to participate in this appeal.

the paramount goal when interpreting a statute and, generally, the best indicator of that intent is the statutory language." DiProspero v. Penn, 183 N.J. 477, 492 (2005). "When interpreting statutory language, the goal is to divine and effectuate the Legislature's intent." State v. Shelley, 205 N.J. 320, 323 (2011). Accordingly, "[t]he plain language of the statute is our starting point." Patel v. N.J. Motor Vehicle Comm'n, 200 N.J. 413, 418 (2009). In construing statutory language, "words and phrases shall be given their generally accepted meaning, unless that meaning is inconsistent with the clear intent of the Legislature or unless the statute provides a different meaning. Words in a statute should not be read in isolation." Shelton v. Restaurant.com, Inc., 214 N.J. 419, 440 (2013) (citing N.J.S.A. 1:1-1). "To accomplish that, we read the statutes in their entirety and construe 'each part or section . . . in connection with every other part or section to provide a harmonious whole.'" State v. Marquez, 202 N.J. 485, 499 (2010) (quoting Bedford v. Riello, 195 N.J. 210, 224 (2008) (alteration in original)). We consider the statute at the center of this case in accordance with these principles.

A.

The Patient Safety Act was not the first requirement imposed on New Jersey health care facilities to evaluate their practices in a confidential setting, and to report to regulatory

authorities. Since the adoption of N.J.A.C. 8:43G-27 in 1990, hospitals have been required to maintain a continuous quality improvement program. N.J.A.C. 8:43G-27.1 to -27.6.[7] That program must include a utilization review, a federally-mandated process by which a hospital reviews the physicians' practice of admitting and discharging patients, and the resources used to treat patients during hospital stays. 42 U.S.C.A. § 1395x et seq.; 42 C.F.R. § 482.30; see also Todd v. S. Jersey Hosp. Sys., 152 F.R.D. 676, 682 (D.N.J. 1993) (noting that utilization review is requirement of hospital's participation in Social Security and in certain other federal and state programs).

In addition, prior to the enactment of the Patient Safety Act, New Jersey hospitals were also permitted -- but not required -- to evaluate adverse events in accordance with

[7] Notably, N.J.A.C. 8:43G was enacted to replace N.J.A.C. 8:43B, a regulation that specifically mandated a peer review process. See N.J.A.C. 8:43B-6.1 et seq. (repealed 1990). That process required a hospital's medical staff to "identify problems that may exist in patient care and suggest appropriate action to correct those problems." Bundy v. Sinopoli, 243 N.J. Super. 563, 566 (Law Div. 1990); see N.J.A.C. 8:43B-6.1, -6.2 (repealed 1990). Although the current regulatory framework does "not specifically address[] the area of [p]eer [r]eview," it nevertheless "provide[s] a framework for the evaluation of the type and quality of care given to patients at hospitals." Bundy, supra, 243 N.J. Super. at 566; see, e.g., N.J.A.C. 8:43G-27.5(a) (obligating hospitals to engage in "an ongoing process of monitoring patient care" through a "criteria-based" evaluation "so that certain review actions are taken or triggered when specific quantified, predetermined levels of outcomes or potential problems are identified").

guidelines promulgated by the Joint Commission, a national accreditation body for health care organizations and programs. See Reyes v. Meadowlands Hosp. Med. Ctr., 355 N.J. Super. 226, 229-31 (Law Div. 2001) (noting that, pursuant to guidelines promulgated by Joint Commission, hospitals were asked to conduct root cause analyses of certain medical errors, called "Sentinel Events," "voluntarily, without compulsion under the accreditation process" and to report results to Joint Commission). The Joint Commission guidelines thus present a framework which a health care facility may use to investigate adverse events.

The Patient Safety Act was not intended to replace those preexisting evaluative processes in the health care setting; it specifically provides that it does not "eliminate or lessen a hospital's obligation under current law or regulation" to maintain "a continuous quality improvement program." N.J.S.A. 26:2H-12.25(b). Instead, the Act pursues a distinct goal: to minimize adverse events deriving from system failures in a hospital or other health care facility.[8] The sponsor's statement

[8] In enacting the Patient Safety Act, the Legislature responded in part to the revelation that Charles Cullen, a former nurse on staff at several New Jersey hospitals, "ha[d] professed to have killed at least 40 individuals under his care." Hearing on S. 557 Before the S. Health, Human Services and Senior Citizens Comm., 211th Leg. 2 (N.J. 2004) (Statement of Sen. Joseph F. Vitale, Chair). Following his April 29, 2004 guilty plea to the "murder of hospital patients in New Jersey and Pennsylvania,"

attached to the original bill stated that the Act's legislative objective was to

> [e]stablish[] a medical error reporting system for health care facilities that seeks to minimize the occurrence of errors, as well as to detect those that do occur, and to incorporate mechanisms to continually improve the performance of facilities to enhance patient safety by minimizing, to the greatest extent feasible, the harm to patients that results from the delivery system itself. In this regard, the [bill] establishes a system that both mandates the confidential disclosure to [the Department] or the Department of Human Services (DHS), in the case of State psychiatric hospitals, of the most serious preventable adverse events, and also encourages the voluntary, anonymous and confidential disclosure to the respective departments of less serious adverse events, as well as near-misses.
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> [S. 557 (Sponsor's Statement), 211th Leg. (2004).]

To that end, the Act mandates that health care facilities establish a patient safety plan "for the purpose of improving the health and safety of patients at the facility." N.J.S.A. 26:2H-12.25(b). One of that plan's components is the establishment of "a patient safety committee." N.J.S.A. 26:2H-12.25(b)(1). The Patient Safety Act did not specify the composition or operation of the Patient Safety Committee, but

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Charles Cullen is serving a sentence of life imprisonment. Taub v. Cullen, 373 N.J. Super. 435, 440 (Ch. Div. 2004).

left those details to be determined "by regulation." N.J.S.A. 26:2H-12.25(b)(1).

The regulatory process was completed in 2008, nearly four years after the Patient Safety Act became law.[9] The mandated composition and duties of a facility's patient safety committee were established with the adoption of N.J.A.C. 8:43E-10.4. That regulation compelled hospitals to establish a patient safety committee by June 1, 2008. N.J.A.C. 8:43E-10.4(a)(1). It requires that the committee be chaired by an individual selected by the facility's chief executive officer or administrator, and that individual committee members be assigned responsibilities "based on the relevance of their job responsibilities and professional experience." N.J.A.C. 8:43E-10.4(c). The regulation mandates that the patient safety committee report directly to the facility's chief executive officer and administrative head, that it meet at least quarterly, that it document its proceedings in minutes, and that it act independently of other committees. N.J.A.C. 8:43E-10.4(c)(4)-(7). Among other responsibilities, the committee must develop and periodically review and revise a written patient safety plan in accordance with N.J.A.C. 8:43E-10.5. N.J.A.C. 8:43E-10.4(d).

[9] The regulations adopted pursuant to the Patient Safety Act, N.J.A.C. 8:43E-10.1 to -10.11, became effective on March 3, 2008 as applied to general, special, psychiatric and rehabilitation hospitals. N.J.A.C. 8:43E-10.2.

The patient safety committee must also "[f]oster attitudes, beliefs and behaviors supporting open communication within the facility" by means of information systems detailed in the regulation, implement measures to minimize the risk of preventable adverse events, ensure timely reporting to regulators, and assemble an appropriate team to analyze root cause analyses of certain adverse events. N.J.A.C. 8:43E-10.4(d).

In short, the detailed requirements for the patient safety committee's composition, goals and process were not set forth in the Patient Safety Act itself, but were established by the regulations adopted nearly four years after the statute was enacted. The structure and mission of the patient safety committee, now comprehensively prescribed by regulation, had yet to be specified when the Hospital prepared the document disputed in this case.

A second important component of the Act is its mandate that each facility implement a procedure for the collaborative review of adverse events. As part of its patient safety plan, a facility must designate "teams of facility staff . . . comprised of personnel who are representative of the facility's various disciplines and have appropriate competencies," to analyze and apply "evidence-based patient safety practices," and thereby "reduce the probability of adverse events resulting from

exposure to the health care system." N.J.S.A. 26:2H-12.25(b)(2). Effective for general hospitals on March 3, 2008, a corresponding regulation, N.J.A.C. 8:43E-10.4(b)(2), supplemented the statutory requirement.

The Patient Safety Act also mandates that "serious preventable adverse event[s]" must be reported by health care facilities "in a form and manner established by the [C]ommissioner [of the Department]." N.J.S.A. 26:2H-12.25(a), (c).[10] Effective on March 3, 2008, for general hospitals, N.J.A.C. 8:43E-10.6 describes in detail the categories of events that will trigger the reporting requirement. N.J.A.C. 8:43E-10.6(e)-(j). That regulation specifies that a serious preventable adverse event occurring in a hospital must be disclosed to the Department within five business days of its discovery using the appropriate form. N.J.A.C. 8:43E-10.6(b), (c). It also gives detailed direction on the conduct and reporting of analyses of serious preventable adverse events -- guidance that was not set forth in the Patient Safety Act itself. N.J.A.C. 8:43E-10.6(k)-(m).[11]

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[10] The Act also encourages the anonymous reporting of adverse events that are not subject to mandatory reporting. N.J.S.A. 26:2H-12.25(e)(1).

[11] Other requirements that were set forth in general terms in the Patient Safety Act were further explained by subsequent regulations. The Patient Safety Act requires that teams of facility staff, comprised of personnel "who are representative of the facility's various disciplines and have appropriate

To further the legislative goal of minimizing system failures and enhancing patient care, the Patient Safety Act thus provided the basic framework for the analysis and reporting of serious adverse events occurring in health care facilities. The subsequent adoption of N.J.A.C. 8:43E-10.1 to -10.11 provided comprehensive guidance with respect to the necessary committee structure, evaluation methodology and process for reporting such events to regulators.

B.

The Legislature included in the Patient Safety Act a provision creating an absolute privilege. N.J.S.A. 26:2H-12.25(g). It reasoned that health care professionals and other facility staff are more likely to effectively assess adverse events in a confidential setting, in which an employee need not fear recrimination for disclosing his or her own medical error, or that of a colleague. As articulated in the statute's legislative findings,

> [t]o encourage disclosure of [adverse events and near-misses], . . . it is critical to create a non-punitive culture that focuses on

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competencies," analyze events that constitute "near-misses" -- occurrences "that could have resulted in an adverse event but the adverse event was prevented." N.J.S.A. 26:2H-12.25(a), (b)(3). That requirement was refined by N.J.A.C. 8:43E-10.5(a)(3). The Patient Safety Act also requires "a process for the provision of ongoing patient safety training for facility personnel," N.J.S.A. 26:2H-12.25(b)(4), and the details of that process are prescribed in N.J.A.C. 8:43E-10.5(a)(5).

> improving processes rather than assigning blame. Health care facilities and professionals must be held accountable for serious preventable adverse events; however, punitive environments are not particularly effective in promoting accountability and increasing patient safety, and may be a deterrent to the exchange of information required to reduce the opportunity for errors to occur in the complex systems of care delivery. Fear of sanctions induces health care professionals and organizations to be silent about adverse events, resulting in serious under-reporting.
>
> [N.J.S.A. 26:2H-12.24(e).]

The Legislature thus recognized the pivotal role of confidentiality in promoting open and effective evaluation and reporting.

The Patient Safety Act was drafted in a setting in which other evaluative processes conducted by health care facilities were completely or partially privileged from disclosure by statute or case law. In New Jersey, the utilization review process is subject to a statutory privilege against disclosure. See N.J.S.A. 2A:84A-22.8 (stating that, subject to certain exceptions, "[i]nformation and data secured by and in the possession of utilization review committees established by any certified hospital or extended care facility in the performance of their duties shall not be revealed or disclosed in any manner or under any circumstances by any member of such committee").

In Christy, supra, the Appellate Division addressed the privilege protecting documents memorializing a health care facility's peer review process. 366 N.J. Super. at 537. There, a medical malpractice plaintiff sought discovery of a report created by the defendant hospital's "peer review committee" regarding the plaintiff's care. Id. at 538. Noting the absence of a statutory privilege governing peer review materials, the Appellate Division conducted a balancing test of the competing interests at issue -- the "plaintiff's right to discover information concerning his care and treatment" for purposes of his litigation and the "public interest to improve the quality of care and help to ensure that inappropriate procedures, if found, are not used on future patients." Id. at 541. Relying on Payton v. N.J. Turnpike Auth., 148 N.J. 524 (1997), the Appellate Division ordered the disclosure of the "purely factual" contents of the peer review report, but shielded from discovery "evaluative and deliberative materials" within the report that contained the hospital's "opinions, analysis, and findings of fact concerning the events that [were] the subject matter of [the] plaintiff's case." Id. at 543-45. The panel thus concluded that "peer review" materials should be evaluated case by case to determine the existence and scope of a privilege. Ibid. Like the statutory privilege that governs the utilization review component of continuous improvement programs,

the common law privilege governing documents generated in a peer review process exists to promote open discussion of medical errors.

In enacting the Patient Safety Act, the Legislature considered the extent to which the statute's confidentiality provisions would shield documents from disclosure in litigation and other settings. As explained by Clifton R. Lacy, M.D., then Commissioner of the Department, in his testimony before the Senate Health, Human Services and Senior Citizens Committee in support of Senate Bill 557, the proposed Act "strikes the right balance between acknowledging and learning from errors, and also holding people accountable. It shields self-critical analysis from discovery, but maintains discoverable all that is now discoverable." Hearing on S. 557 Before the S. Health, Human Services and Senior Citizens Comm., 211th Leg. 6 (N.J. 2004) (Statement of Clifton R. Lacy, M.D.). Asked to elaborate on that statement, Commissioner Lacy testified:

> [W]hat I meant when I said that everything that's currently discoverable remains discoverable -- [w]hat this shields is, multidisciplinary teams get together and sit and analyze and digest and try to find out what are the root causes, why did this error occur, and what safety precautions can we put into place -- redundancy, scrutiny -- whatever is necessary -- computerization. Find out the causes, find the fix to prevent not just this error, but every error like this kind in the future. Everything that's currently discoverable -- the medical record, the test

> results, deposition of witnesses -- all that continues to be exactly as it is now. What this legislation shields is that self-critical analysis, the next step of analyzing -- of getting the team of nurses, physicians, pharmacists, these interdisciplinary groups -- to digest and find those root causes. That's protected. And the reporting of those things to our Department is protected.
>
> [Hearing on S. 557 Before the S. Health, Human Services and Senior Citizens Comm., 211th Leg. 12-13 (N.J. 2004) (Statement of Clifton R. Lacy, M.D.).][12]

The Act attaches a privilege to specific information generated by health care facilities in two distinct processes: the reporting of adverse events to regulators, and the investigative process that may or may not lead to such reporting. Pursuant to N.J.S.A. 26:2H-12.25(f), "[a]ny documents, materials or information received by" the Department from a health care facility pursuant to the statute's two reporting provisions, N.J.S.A. 26:2H-12.25(c) and -12.25(e), "that are otherwise not subject to mandatory reporting pursuant to [N.J.S.A. 26:2H-12.25(c)], shall not be . . . subject to discovery or admissible as evidence or otherwise disclosed in

[12] Prior to the passage of the Patient Safety Act, the Senate Bill was amended to confirm that the Act was not intended "to increase or decrease the discoverability, in accordance with Christy v. Salem . . . of any documents, materials or information if obtained from any source or context other than those specified in this act." S. Bill No. 557 (Mar. 4, 2004).

any civil, criminal, or administrative action or proceeding." N.J.S.A. 26:2H-12.25(f)(1).[13]

Similarly, N.J.S.A. 26:2H-12.25(g)(1) protects communications generated in the setting of self-critical analysis:

> Any documents, materials or information developed by a health care facility as part of a process of self-critical analysis conducted pursuant to subsection b. of this section concerning preventable events, near-misses and adverse events, including serious preventable adverse events . . . shall not be:
>
> > (1) subject to discovery or admissible as evidence or otherwise disclosed in any civil, criminal or administrative action or proceeding.

N.J.S.A. 26:2H-12.25(g) thus shields certain documents, materials and information developed by a health care facility as it investigates and evaluates adverse events.

Like its process requirements, the Patient Safety Act's privilege provisions were explained and refined by the regulations that followed. Effective March 3, 2008, as applied to the Hospital, N.J.A.C. 8:43E-10.9(b)(1) requires that a

[13] The same section of the Act provides that such reporting documents, materials and information shall not be "considered a public record under [N.J.S.A. 47:1A-1]," N.J.S.A. 26:2H-12.25(f)(2), and addresses the use of such information in adverse employment actions and in the evaluation of certain "accreditation, certification, credentialing or licensing" decisions, as defined in the statute. N.J.S.A. 26:2H-12.25(f)(3).

document be "exclusively" developed in the setting of self-critical analysis as defined by three other regulations, N.J.A.C. 8:43E-10.4, 10.5 and 10.6, in order to warrant the statutory privilege:

> Documents, materials and information (including [root cause analyses] and minutes of meetings) developed by a health care facility exclusively during the process of self-critical analysis, in accordance with [N.J.A.C.] 8:43E-10.4, 10.5 or 10.6 concerning preventable events, near-misses and adverse events, including serious preventable adverse events . . . shall not be:
>
> > (1) Subject to discovery or admissible as evidence or otherwise disclosed in any civil, criminal or administrative action or proceeding.
>
> [(emphasis added).]

Thus, pursuant to N.J.A.C. 8:43-10.9, which now governs New Jersey health care facilities, the statutory privilege applies only to documents, materials and information developed exclusively during self-critical analysis conducted during one of three specific processes: the operations of the patient or resident safety committee pursuant to N.J.A.C. 8:43E-10.4, the components of a patient or resident safety plan as prescribed by N.J.A.C. 8:43E-10.5, or reporting to regulators under N.J.A.C. 8:43E-10.6. N.J.A.C. 8:43E-10.9(b). In the regulations that became effective in 2008, the statutory standard was expanded upon in two significant respects: first, to require that the

documents, materials and information at issue be "exclusively" prepared in the setting of a qualifying self-critical analysis process, and second, to mandate that the self-critical analysis be conducted in accordance with one of three accompanying regulations as a prerequisite for the privilege to attach, N.J.A.C. 8:43E-10.4, -10.5 and -10.6. N.J.A.C. 8:43E-10.9(b). Under the statutory and regulatory framework in place today, medical and administrative professionals are on notice of the exact procedures that they must follow in order to ensure the confidentiality of information pursuant to the Patient Safety Act.

IV.

This case did not arise in the setting of the detailed regulatory scheme that now exists. Although the Patient Safety Act had been passed when DV2 was written, the implementing regulations had yet to be adopted at that time; they would not govern the Hospital until March 3, 2008. N.J.A.C. 8:43E-10.2(a)(9). Moreover, health care facilities were given an additional 180 days from the regulations' effective date to "[d]evelop a written patient or resident safety plan for the facility" in compliance with the regulations. N.J.A.C. 8:43E-10.4(d)(1). When DV2 was prepared on June 1, 2007, the only guidance to the Hospital and its staff was found in the Patient Safety Act. The discoverability of DV2 must therefore be

determined in accordance with the Patient Safety Act itself, without imposing requirements that appeared for the first time in subsequent regulations.

The Act focuses upon the process that generated the communication for which a health care facility claims privilege. N.J.S.A. 26:2H-12.25(g) shields from discovery documents, materials or information developed "as part of a process of self-critical analysis conducted pursuant to" N.J.S.A. 26:2H-12.25(b). N.J.S.A. 26:2H-12.25(b) requires that a patient safety plan include, "at a minimum," four components: the establishment of "a patient safety committee," N.J.S.A. 26:2H-12.25(b)(1); "a process for teams of facility staff . . . to conduct ongoing analysis and application of evidence-based patient safety practices" to reduce the risk of adverse events, N.J.S.A. 26:2H-12.25(b)(2); "a process for teams of facility staff . . . to conduct analyses of near-misses," N.J.S.A. 26:2H-12.25(b)(3); and "a process for the provision of ongoing patient safety training for facility personnel," N.J.S.A. 26:2H-12.25(b)(4). Accordingly, the discoverability of DV2 turns on whether the document was developed in the setting of a "process of self-critical analysis," conducted as part of a patient safety plan that meets the four components of N.J.S.A. 26:2H-12.25(b). N.J.S.A. 26:2H-12.25(g).

The record supports the trial court's determination that the Hospital had established such a patient safety plan. It confirms that the Hospital satisfied the first aspect of such a plan, the establishment of a patient safety committee in compliance with N.J.S.A. 26:2H-12.25(b)(1). As the trial court found, the Hospital's Patient Safety Committee consisted of sixteen members and was chaired by Mitchell Rubenstein, M.D., the Chief Medical Officer of the Hospital. The Patient Safety Committee was determined to be a "stand-alone, decision making committee" with "independent decision-making" authority. Nothing in N.J.S.A. 26:2H-12.25(b)(1) requires that the Patient Safety Committee conduct every aspect of factfinding in accordance with the Patient Safety Act. That Committee was in operation when DV2 was prepared in June 2007. The Hospital therefore met this component of the statutory mandate.

The Hospital also complied with N.J.S.A. 26:2H-12.25(b)(2) and (3). Those provisions require facilities to establish "teams of facility staff" that "are comprised of personnel who are representative of the facility's various disciplines and have appropriate competencies" to analyze patient safety practices and near-misses. The Patient Safety Act did not require that physicians, nurses, administrators, or any other category of facility staff play a role in a given committee, and it did not specify the procedure for the meeting of a team

following a potentially reportable adverse event. Instead, the statute requires only that each facility appoint teams of staff, comprised of members with competencies representative of the facility's various disciplines. N.J.S.A. 26:2H-12.25(b)(2), (3).

The Hospital met that standard. As the trial court determined, after the Patient Safety Act became effective, it was Mutter's practice, as Director of Patient Safety, to conduct round-table discussions with professionals from various disciplines, as required by the Act. Mutter would commence each round-table meeting by stating that the discussion was held as an exercise in self-critical analysis, in accordance with the Patient Safety Act.

Finally, as evidenced by its Performance Improvement Plan, the Hospital had implemented "a process for the provision of ongoing patient safety training for facility personnel," in compliance with N.J.S.A. 26:2H-12.25(b)(4). Consequently, the Hospital's patient safety plan satisfied all of the statutory requirements of the Patient Safety Act.

As it establishes the Hospital's general compliance with the Patient Safety Act, the record also supports the trial court's finding that DV2 was prepared "as part of a process of self-critical analysis" pursuant to N.J.S.A. 26:2H-12.25(b). As the trial court noted, Mutter recorded in DV2 that the document

memorializing the meeting was created pursuant to the Patient Safety Act. The team of facility staff that reviewed C.A.'s case included Mutter, in his role as the Director of Patient Safety, along with obstetrical nursing management and educators, and the nurses involved in the care of Applegrad and her child. As the trial court found, Mutter assured the participants in the round-table discussion that their disclosures would be kept confidential, and inquired about the medical treatment administered to Applegrad and C.A. during and following the birth. Following the meeting that was memorialized in DV2, Mutter separately discussed C.A.'s case with Robles and Malkin. All three individuals agreed that C.A.'s birth and neonatal care did not give rise to a reportable event for purposes of N.J.S.A. 26:2H-25(c) of the Patient Safety Act, or a "Sentinel Event" that would warrant a root cause analysis under the Joint Commission standards. The round-table discussion that led to the creation of DV2 was part of an investigation into whether the incident under review was a serious preventable adverse event that should be reported to the Department under N.J.S.A. 26:2H-12.25(c).

Moreover, the self-critical analysis required by N.J.S.A. 26:2H-12.25(b) entails not only the decision-making that leads to the reporting of an adverse event, but also the development and collection of information necessary for that determination.

See N.J.S.A. 26:2H-12.25(g)(2) (identifying "development, collection, reporting or storage of information" as components of process of self-critical analysis under N.J.S.A. 26:2H-12.25(b)).

Notwithstanding the detailed requirements later implemented by regulation, the "round-table" evaluative process initiated by the Hospital under Mutter's oversight satisfied the statutory mandate.[14] DV2 was "developed . . . as part of a process of self-critical analysis conducted pursuant to [N.J.S.A. 26:2H-12.25(b)]," as required by N.J.S.A. 26:2H-12.25(g). Regardless of whether the Hospital's process would have satisfied the regulations that became effective at a later time, the Hospital met the only standard that governed it in 2007, the mandate of the Patient Safety Act itself.

Our dissenting colleagues do not share the Appellate Division's view that this case is governed by the regulatory requirements of N.J.A.C. 8:43E-10.6, which were not yet in effect when the Hospital prepared DV2. Nor do they contend that

[14] Contrary to the suggestion of the Appellate Division panel, the Hospital's conclusion that the event was not reportable does not abrogate the statutory privilege. Nothing in N.J.S.A. 26:2H-12.25(g) limits the privilege to settings in which the incident is ultimately determined to be subject to mandatory reporting under N.J.S.A. 26:2H-12.25(c). The Patient Safety Act's privilege is not constrained to cases in which the deliberative process concludes with a determination that the case is reportable under N.J.S.A. 26:2H-12.25(c).

the Hospital's Patient Safety Committee was not established in accordance with N.J.S.A. 26:2H-12(b)(1). Instead, our dissenting colleagues argue that the Hospital failed to comply with the requirement of N.J.S.A. 26:2H-12(b)(2) and (3) that "teams of facility staff . . . comprised of personnel who are representative of the facility's various disciplines and have appropriate competencies," analyze evidence-based safety practices and near-misses. Post at ____ (slip op. at 1-2, 6-8, 11-12). Contrary to the suggestion of the dissent, however, the round-table discussion that generated DV2 was not confined to Mutter, Robles and Malkin. Instead, that discussion included a broader team of Hospital staff, including the obstetrical nurses directly involved in the care of C.A. and her mother, as well as nursing managers and nursing educators. The Hospital complied with the PSA's mandate that this case be analyzed by a qualified team of its staff.

Our dissenting colleagues further contend that the Hospital's process fell short of compliance with the PSA because the record does not establish that the review conducted by Mutter, Robles and Malkin was conducted with the knowledge of the Patient Safety Committee of which the three administrators were members. Post at ____ (slip op. at 7-8). However, nowhere in the PSA did the Legislature define the relationship between the Patient Safety Committee, which was generally mandated by

N.J.S.A. 26:2H-12.25(b)(1) with details to be "prescribed by regulation," and the teams envisioned by N.J.S.A. 26:2H-12.25(b)(2) and (3). The Patient Safety Committee's conduct of its analytical function, and its reporting structure, would later be set forth in detail in N.J.A.C. 8:43E-10.4, but the regulatory requirements had yet to be imposed at the relevant time.

In sum, the Patient Safety Act exists to promote thorough and candid discussions of events occurring in health care facilities, and thereby to protect the safety of patients. In the interim period between the enactment of the Act and the adoption of its implementing regulations, health care facilities were required to follow the Patient Safety Act, which serves the important public policy goal of promoting open discussions of adverse events. Those facilities were not compelled to anticipate later regulations as a condition of the statutory privilege. In this case, the Hospital complied with the requirements governing the application of that privilege. DV2 memorialized part of a confidential process of self-critical analysis, as prescribed by N.J.S.A. 26:2H-12.25(b).

Accordingly, pursuant to N.J.S.A. 26:2H-12.25(g), DV2 is not subject to discovery, and should not be used for any purpose in this case, including its use as a resource for the judge trying the case. N.J.S.A. 26:2H-12.25(g) shields only DV2,

consistent with the narrow construction generally afforded to privileges under our law, and does not protect otherwise discoverable information concerning C.A.'s birth and neonatal treatment. See State v. J.G., 201 N.J. 369, 383 (2010); Stempler v. Speidell, 100 N.J. 368, 375 (1985); State v. Dyal, 97 N.J. 229, 237 (1984).

V.

The judgment of the Appellate Division is reversed, and the matter is remanded for further proceedings in accordance with this opinion.

JUSTICES LaVECCHIA and FERNANDEZ-VINA and JUDGE RODRÍGUEZ (temporarily assigned) join in JUSTICE PATTERSON's opinion. JUDGE CUFF (temporarily assigned) filed a separate, dissenting opinion in which CHIEF JUSTICE RABNER and JUSTICE ALBIN join.

SUPREME COURT OF NEW JERSEY
A-32 September Term 2012
071702

C.A., a Minor, by Her Mother and Guardian ad Litem, ESTHER APPLEGRAD, ESTHER APPLEGRAD, Individually, and GEDALIA APPLEGRAD, Individually,

Plaintiffs-Respondents,

v.

ERIC BENTOLILA, M.D., and GITA PATEL, R.N.,

Defendants,

and

THE VALLEY HOSPITAL, KOURTNEY KACZMARSKI, R.N., MARY BROWN, R.T., and YIE-HSIEN CHU, M.D.,

Defendants-Appellants.

JUDGE CUFF (temporarily assigned), dissenting.

A newborn suffered catastrophic injuries during the birthing process at The Valley Hospital (Hospital). The Patient Safety Act, N.J.S.A. 26:2H-12.23 to -12.25(k), mandated that the Hospital create a patient safety committee to investigate such adverse events as occurred in this case. The composition of that committee should have been "representative of the facility's various disciplines and have appropriate competencies." N.J.S.A. 26:2H-12.25(b). Yet the Hospital

committee that reviewed the tragic event was comprised of three administrators, none of whom was a physician, much less one specializing in obstetrics.

The Patient Safety Act guarantees that documents developed during a patient safety committee inquiry, such as interview notes, are privileged and not subject to discovery. This interlocutory appeal presents a narrow issue concerning whether information generated by Hospital personnel reviewing the events preceding and immediately following this birth is subject to the privilege conferred on any document or information generated as part of a process of self-critical analysis conducted pursuant to the Act. The majority holds that the evaluative process utilized by the Hospital conformed to the requirements of the Patient Safety Act and the memorandum at issue in this appeal is privileged. The committee that conducted the inquiry here, however, was not a patient safety committee as envisioned by the Act. Having failed to satisfy the conditions established in the Act, the Hospital cannot invoke the absolute privilege accorded by the statute. For that reason, I part with the majority and would hold that no privilege attaches to interview notes generated by a committee not in compliance with the Patient Safety Act.

It is not necessary to recount the facts and procedural history recited by the majority. It is also unnecessary to

recount the events that precipitated enactment of the Patient Safety Act and its relationship to other processes that hospitals are permitted to utilize to evaluate adverse events. The focus of this dissent is founded on the process employed in this case and my conclusion that the process did not conform to that contemplated by the Legislature as a pre-condition for invocation of the statutory privilege.

N.J.S.A. 26:2H-12.25(g) provides that any documents or information developed by a health care facility in accordance with the process outlined by the Act shall not be subject to discovery, or used in any civil, criminal or administrative action or proceeding, an adverse employment action, or the valuation of credentialing, accreditation, certification or licensure of any individual. The statute provides:

> Any documents, material, or information developed by a health care facility as part of a process of self-critical analysis conducted pursuant to [N.J.S.A. 26:2H-12.25(b)] of this section concerning preventable events, near-misses, and adverse events, including serious preventable adverse events, and any document or oral statement that constitutes the disclosure provided to a patient or the patient's family member or guardian pursuant to [N.J.S.A. 26:2H-12.25(d)] of the section, shall not be:
>
> (1) subject to discovery or admissible as evidence or otherwise disclosed in any civil, criminal, or administrative action or proceeding; or

> (2) used in an adverse employment action or in the evaluation of decisions made in relation to accreditation, certification, credentialing, or licensing of an individual, which is based on the individual's participation in the development, collection, reporting, or storage of information in accordance with [N.J.S.A. 26:2H-12.25(b)].
>
> [N.J.S.A. 26:2H-12.25(g).]

In short, a hospital named as a defendant in a medical negligence action may withhold possibly relevant and probative information and documents developed during a Patient Safety Act self-critical analysis pursuant to the privilege conferred by that statute on such information and documents.

By the terms of the statute, the privilege does not attach to the information and documents generated during a Patient Safety Act self-critical analysis unless the hospital has followed the procedure outlined in the statute. First, the hospital must develop and implement a patient safety plan. N.J.S.A. 26:2H-12.25(b). The purpose of the plan is to improve the "health and safety of patients at the facility." Ibid. Then, the Act proceeds to outline the minimum features of the patient safety plan requiring

> (2) a process for teams of facility staff, which teams are comprised of personnel who are representative of the facility's various disciplines and have appropriate competencies, to conduct ongoing analysis and application of evidence-based patient safety practices in order to reduce the probability of adverse events resulting from exposure to

> the health care system across a range of diseases and procedures; [and]
>
> (3) a process for teams of facility staff, which teams are comprised of personnel who are representative of the facility's various disciplines and have appropriate competencies, to conduct analyses of near-misses, with particular attention to serious preventable adverse events and adverse events.
>
> [N.J.S.A. 26:2H-12.25(b)(2) and (3).]

The Act also contemplates the enactment of regulations,[15] N.J.S.A. 26:2H-12.25(b)(1), and a process for ongoing patient safety training for hospital personnel, N.J.S.A. 26:2H-12.25(b)(4).

The majority asserts that the review conducted by the Hospital complied with the Patient Safety Act. Ante at ____ (slip op. at 33). It notes that the Legislature enacted the Act shortly before C.A.'s birth and that the review at issue occurred long before the Department of Health issued its regulations in 2008. Ante at ___ (slip op. at 28). It concludes that the Hospital did no less than reasonably possible given the lack of direction provided by the Legislature. Accordingly, the majority determines that the Hospital's efforts permit it to invoke the statutory privilege afforded to self-critical analysis of adverse events. Ante at ___ (slip op. at 30).

[15] See N.J.A.C. 8:43E-10.1 to -10.10, effective March 3, 2008.

The Patient Safety Act, however, cannot be characterized as a vague declaration of public policy with little or no guidance to the administrative agency charged with its administration or the health care facilities required to follow the law, which can decide to invoke the privilege conferred by the statute. The patient safety plan must outline a process to conduct an ongoing analysis of patient safety practices and to apply those practices such that adverse events "resulting from exposure to the health care system across a range of diseases and procedures" are reduced. N.J.S.A. 26:2H-12.25(b)(2). The patient safety plan must also include a process to conduct analyses of "near-misses, with particular attention to serious preventable adverse events and adverse events." N.J.S.A. 26:2H-12.25(b)(3).

Importantly, the Patient Safety Act does more than prescribe the development and implementation of a process. Sections 12.25(b)(2) and (3) also prescribe the personnel who are to be engaged in the process. The process to analyze and implement patient safety practices and the process to analyze near-misses and serious preventable adverse events and adverse events are to be conducted by "teams of facility staff" comprised of "personnel who are representative of the facility's various disciplines and have appropriate competencies" to

conduct the analyses required by the Act. N.J.S.A. 26:2H-12.25(b)(2).

Here, the record reveals that at the time of C.A.'s birth, the Hospital had a Patient Safety Committee (Committee) comprised of sixteen members. The Chief Medical Officer, an employee of the Hospital, chaired the Committee. Other non-employee physicians with staff privileges at the Hospital were members of the Committee. Michael Mutter, Director of Patient Safety, was a member of this Committee.

Following C.A.'s birth, Kim Robles, Director of Quality Assessment Improvement and Regulatory Compliance, received a referral from the Quality Assurance Coordinator. She referred the matter to Linda Malkin, Director of Risk Management, who referred the matter to Mutter to conduct an investigation to determine whether the circumstances of C.A.'s birth and her condition were a preventable event that should be reported to the Department of Health. Mutter convened a roundtable discussion composed of persons designated by the manager of the Labor and Delivery Unit. During this discussion, Mutter sought to identify a process failure and led the discussion by posing open-ended questions to the participants. All in attendance were encouraged to participate. In the end, Mutter concluded that the circumstances of the labor and delivery were attributable to medical complications rather than a failure of

process. Therefore, he concluded that events attendant to C.A.'s birth were not a reportable event and he forwarded his recommendation to Malkin. She consulted Robles, who concurred.

The matter was not reviewed by the Committee. In fact, the record does not reflect that the Committee was aware of the Mutter roundtable discussion and report or the concurrence of Robles and Malkin. The record also does not reveal whether the Committee ever knew that a patient safety review of this incident under its auspices ever occurred. In other words, the purported Patient Safety Act review was conducted by one member of the Committee, who reported his roundtable findings to another member of the Committee, and a third member of the Committee concurred.

Although relevant evidence is presumed to be discoverable, it is well-established that the presumption can be overcome by an applicable evidentiary privilege. Such a privilege excludes relevant evidence from the factfinder's consideration and therefore "'contravene[s] the fundamental principle that the public . . . has a right to every man's evidence.'" State v. Szemple, 135 N.J. 406, 413 (1994) (quoting Trammel v. United States, 445 U.S. 40, 50, 100 S. Ct. 906, 912, 63 L. Ed. 2d 186, 195 (1980) (internal quotation marks omitted)). As a result, this Court has repeatedly instructed that any privilege must be narrowly construed so as to protect the judicial system's

fundamental goal of securing just results. See, e.g., State v. J.G., 201 N.J. 369, 372 (2010) ("[C]ourts sensibly accommodate privileges to the 'aim of a just result[.]'" (quoting State v. Briley, 53 N.J. 498, 506 (1969))); Kinsella v. Kinsella, 150 N.J. 276, 294 (1997) (noting that privileges are generally construed narrowly in favor of admitting relevant evidence; privilege against compelled disclosure "'runs counter to the fundamental theory of our judicial system that the fullest disclosure of the facts will best lead to the truth.'" (quoting In re Selser, 15 N.J. 393, 405 (1954))).

Privileges are disfavored as obstacles to this Court's "desire to attain truth through the adversarial process[.]" Payton v. N.J. Tpk. Auth., 148 N.J. 524, 539 (1997); see also State v. Mauti, 208 N.J. 519, 531 (2012). Despite a presumption against the creation of new privileges, Payton, supra, 148 N.J. at 546, the Legislature is free to do so in situations where the social policy in support of nondisclosure is weightier than the evidence it renders unavailable. In accordance with these guiding principles, a statutory privilege will shield evidence from compelled disclosure only when, "in the particular area concerned, it serves a more important public interest than the need for full disclosure." State in Interest of C., 165 N.J. Super. 131, 136 (App. Div. 1979) (citing Briley, supra, 53 N.J. at 506).

Until today, cognizant of the disfavored status of privileges, New Jersey has refused to recognize a broad privilege for information generated by an organization engaged in self-critical analysis. See Payton, supra, 148 N.J. at 547-48 (holding employer's internal investigation of sexual harassment complaint akin to other confidential information and therefore not privileged). The Patient Safety Act, which affords an absolute privilege to information and documents generated pursuant to a self-critical analysis conducted by a healthcare facility in accordance with the requirements of that statute, N.J.S.A. 26:2H-12.25(b), embodies a narrow exception to this rule.

In drafting the Patient Safety Act, the Legislature devoted a separate subsection to the policies and procedures a healthcare facility must follow in order to claim a privilege with regard to the results of a self-critical analysis. These requirements include developing a patient safety plan, which must include a patient safety committee, ongoing patient safety training for facility personnel, and processes for conducting ongoing analysis of "evidence-based patient safety practices" and "near misses [or] serious preventable adverse events and adverse events." N.J.S.A. 26:2H-12:25(b). The presence of these conditions clearly indicates that the Legislature did not intend the Act's privilege to apply universally to any self-

critical analysis conducted by a healthcare facility, but rather to a carefully circumscribed self-critical analysis conducted in accordance with the statute. Like all relevant evidence, such information would be discoverable unless the healthcare facility abided by the specific requirements to invoke the privilege.

The Legislature's decision to carefully circumscribe the circumstances under which this privilege may be invoked accords with the disfavored status of privileges and the principles of broad discovery envisioned by the New Jersey Rules of Evidence. The Patient Safety Act requires more than the existence of a hospital committee that bears the name "Patient Safety Committee." The committee must be "comprised of personnel who are representative" of the hospital's "various disciplines." N.J.S.A. 26:2H-12.25(b)(2) (emphasis added). Thus, the Act requires more than a reference to one member of a committee and consultation with two other members. Yet that is all this record establishes. This record does not even permit a finding that the Hospital's existing Patient Safety Committee knew that the so-called self-critical analysis contemplated by the Act and purportedly conducted by Mutter, Malkin, and Noble was conducted under its auspices. Furthermore, the focus of the Mutter, Malkin, and Noble effort seems to have concentrated more on whether the Hospital should report the birth event to the Department of Health rather than identifying any internal

process that may have caused or contributed to the circumstances surrounding C.A.'s birth. The record requires me to conclude that the discussion led by Mutter falls well short of the process envisioned by the Patient Safety Act. I, therefore, respectfully disagree with the majority's decision to shield the document at issue from discovery. The privilege created by the Act cannot apply when a healthcare organization fails to abide by the requirements of that statute.

I would affirm the Appellate Division. Therefore, I respectfully dissent.

CHIEF JUSTICE RABNER and JUSTICE ALBIN join in this opinion.

SUPREME COURT OF NEW JERSEY

NO. A-32 SEPTEMBER TERM 2012

ON APPEAL FROM Appellate Division, Superior Court

C.A., a Minor, by Her Mother
And Guardian Ad Litem, ESTHER
APPLEGRAD, ESTHER APPLEGRAD,
Individually, and GEDALIA
APPLEGRAD, Individually,

Plaintiffs-Respondents,

v.

ERIC BENTOLILA, M.D., and
GITA PATEL, R.N.,

Defendants,

and

THE VALLEY HOSPITAL, KOURTNEY
KACZMARSKI, R.N., MARY BROWN,
R.T., and YIE-HSIEN CHU, M.D.,

Defendants-Appellants.

DECIDED September 29, 2014

Chief Justice Rabner PRESIDING

OPINION BY Justice Patterson

CONCURRING/DISSENTING OPINION BY

DISSENTING OPINION BY Judge Cuff

| CHECKLIST | REVERSE/REMAND | AFFIRM |
|---|---|---|
| CHIEF JUSTICE RABNER | | X |
| JUSTICE LaVECCHIA | X | |
| JUSTICE ALBIN | | X |
| JUSTICE PATTERSON | X | |
| JUSTICE FERNANDEZ-VINA | X | |
| JUDGE RODRÍGUEZ (t/a) | X | |
| JUDGE CUFF (t/a) | | X |
| | 4 | 3 |