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Understanding the Patient Safety Act

New statute has significant impact on medical malpractice litigation

In 2004, the New Jersey Legislature enacted the landmark Patient Safety Act, N.J.S.A. 26:2H-12.23. This statute mandates that hospitals disclose “serious preventable adverse events” to patients, and impacts the discoverability of the documents created solely to comply with the newly required investigation of such events. Every attorney handling a medical malpractice case must possess a comprehensive understanding of the application and limits of the Patient Safety Act.

The new statute’s legislative findings declared that preventable errors were “inherent in all systems,” and that “the great majority of medical errors result from systems problems, not individual incompetence.” The Legislature was determined to create a system that would allow for the detection and analysis of medical errors. The legislature acknowledged that “health care facilities and professionals must be held accountable for serious preventable adverse events,” but also that “punitive environments...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.” See N.J.S.A. 26:2H-12.24, *Findings, declarations relative to patient safety*.

The legislative solution was enactment of the Patient Safety Act. The statute focuses on three types of events: an “Adverse event,” defined as “an event that is a negative consequence of care that results in unintended injury or illness, which may or may not have been preventable”; a “Preventable event,” defined as “an event that could have been anticipated and prepared against, but occurs because of an error or other system failure”; and the “Serious preventable adverse event,” defined as “an adverse event that is a preventable event and results in death or loss of a body part, or disability or loss of bodily function lasting more than seven days or still present at the time of discharge from a health care facility.” See N.J.S.A. 26:2H-12.25, *Definitions relative to patient safety; plans; reports; documentation, notification of adverse events, etc.*

Significantly, the Patient Safety Act requires that every health care facility inform every patient affected by a “serious preventable adverse event or adverse event specifically related to an allergic reaction, 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.” *Id.* (Emphasis added.)

“The time, date, participants and content of the notification shall be documented in the patient’s medical record,” and the content of the notification “shall be determined in accordance with the rules and regulations of the commissioner.” The notice can be provided to a family member if disclosure “would seriously and adversely affect the patient’s health.” If an adult patient is not informed of a serious preventable adverse event or adverse event specifically related to an allergic reaction, the facility shall assure that the medical record includes a statement that provides the reason for not informing the patient. N.J.S.A. 26:2H-12.25(3)(d).

The statute requires each health care facility to create “a patient safety plan” which shall include the creation of a process designed to “reduce the probability of adverse events ... and ... 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, *Definitions relative to patient safety; plans; reports; documentation, notification of adverse events, etc.* The statute also requires health care facilities to report “every serious preventable adverse event that occurs in that facility” to the New Jersey Department of Health and Senior Services. N.J.S.A. 26:2H-12.25(3)(b).

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However, the statute provides that any documents "concerning serious preventable adverse events, near-misses, preventable events and adverse events that are otherwise not subject to mandatory reporting 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) considered a public record." *Id.* Furthermore, the information cannot be used in any "adverse employment action or in the evaluation of decisions made in relation to accreditation, certification, credentialing or licensing of an individual." *Id.* This provision does not apply where the health professional has "displayed recklessness, gross negligence or willful misconduct, or in which there is evidence, based on other similar cases known to the facility, of a pattern of significant substandard performance that resulted in serious preventable adverse events." N.J.S.A. 26:2H-12.25(3)(f). Similarly, the statute provides that:

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, and any document or oral statement that constitutes the disclosure provided to a patient or the patient's family member or guardian pursuant to subsection d. of this 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

subsection b. of this section. The provisions of this paragraph shall not be construed to limit a health care facility from taking disciplinary action against a health care professional in a case in which the professional has displayed recklessness, gross negligence or wilful misconduct, or in which there is evidence, based on other similar cases known to the facility, of a pattern of significant substandard performance that resulted in serious preventable adverse events. N.J.S.A. 26:2H-12.25(3)(g).

However, the statute states: "Notwithstanding the fact that documents, materials or information may have been considered in the process of self-critical analysis ... the provisions of this act shall not be construed to increase or decrease, in any way, the availability, discoverability, admissibility or use of any such documents, materials or information if obtained from any source or context other than those specified in this act." N.J.S.A. 26:2H-12.25(3)(h). (Emphasis added). Thus, a document created by or shared with any other committee or entity, including Sentinel Event Reports and all other Quality Improvement Programs that are required to be continued, are still discoverable, as was the case prior to the enactment of the Patient Safety Act. In fact, the statute actually cites a case to make the legislative intent clear. "Nothing in this act shall be construed 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." N.J.S.A. 26:2H-12.25(3)(k).

In *Christy v. Salem*, 366 N.J. Super. 535 (App. Div. 2004), the Appellate Division clarified the standards that govern disclosure of peer review materials. In *Christy*, the plaintiff claimed he was paralyzed from the neck down during the improper extubation of a breathing tube. The plaintiff obtained an order compelling production of a hospital's "peer

review committee report." The Appellate Division reviewed the report and observed that the first paragraph of the report was "purely factual material, apparently gleaned from the hospital report, while the remaining two paragraphs contain factual findings and opinions that are deliberative in nature." *Id.* at 539. The court also noted that certain portions of the last paragraph "could potentially lead to discovery of pertinent information." *Id.* In deciding that certain portions of the report were discoverable, the *Christy* panel explained that the analysis of this issue requires a "case-by-case balancing approach." *Christy* at 541.

After weighing the private interest of a patient seeking to pursue a malpractice claim against the public interest in permitting a hospital to improve the quality of care, the *Christy* court concluded that "patients have the right to know what treatment was received and what happened to them while in the hospital. See N.J.S.A. 26:2H-12.8c. Moreover, plaintiffs have the right to discover the location of critical information which would logically be expected to be in the possession of an adversary but is missing for some unexplained reason." *Christy* at 541. The Appellate Division therefore held that the plaintiff was certainly entitled to obtain the factual portions of the report. *Id.* at 543. The *Christy* panel further held that in some cases, even deliberative materials which may lead to the discovery of relevant evidence should be disclosed. *Id.* at 544. However, the court held that the balance of the information contained in the report, which it described as "opinions, analysis and findings of facts concerning the events that are the subject matter of plaintiff's case" was deemed protected from disclosure. *Id.*

The Patient Safety Act delicately balances the right of a severely injured patient to be informed about a serious preventable injury, while providing health-care professionals with a mechanism to freely discuss what went wrong without the fear of having that discussion repeated in a court of law. This statute will have a significant impact on medical malpractice litigation, and attorneys handling such cases are well advised to carefully review the Patient Safety Act. ■