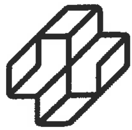

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Brugaletta v. Garcia – The New Jersey Supreme Court's Most Recent Decision on the Patient Safety Act

Paul E. Dwyer

by Paul E. Dwyer, Esq. and John Zen Jackson, Esq.

John Zen Jackson

I. INTRODUCTION

The New Jersey Supreme Court recently issued an important decision, *Brugaletta v. Garcia,* relating to the Patient Safety Act *N.J.S.A.* 26:2H-12.23-.25 ("PSA")[1]. A thorough understanding of the opinion is crucial for any hospital attorney, patient safety executive or medical malpractice practitioner. Although the opinion addresses many aspects of the PSA, the decision may be winnowed down to five central holdings.

1) When a claim of privilege is properly made and challenged, the trial court is required to perform an *in camera* review of the materials in question and issue specific rulings regarding the privilege.[2]
2) When a party claims the privilege under the PSA, the trial court's only inquiry is whether the hospital performed its self-critical analysis in compliance with the procedures found under the PSA and its associated regulations.[3]
3) Once the privilege is established, a trial court cannot order any version of the privileged document to be produced, even in a redacted form, nor can a trial court order that a Serious Preventable Adverse Event ("SPAE") be reported to the Department of Health.[4]
4) If the privileged information is available from a source other than those enumerated in the statute, it is subject to discovery from that source.[5]
5) When pertinent, discoverable information is located in voluminous documents, the trial court may order the producing party to create a narrative for the requesting party, specifying where particular information can be found, though such an order should not be issued routinely.[6]

Each of these holdings is discussed below:

II. PATIENT HEALTH AND SAFETY MOVES TO THE FOREFRONT OF PUBLIC CONCERNS

In 2000, the Institute of Medicine ("IOM") published its landmark study *To Err is Human.*[7] Extrapolating from prior independent studies, the IOM concluded that between 44,000 and 98,000 hospital patients die annually from preventable adverse events.[8]

Spurred by these alarming figures, Congress passed the Patient Safety and Quality Improvement Act in 2005.[9] New Jersey had passed its own Patient Safety Act a year earlier.[10] Both statutes sought to reduce these tragic incidents by creating a privileged non-punitive learning environment which would encourage healthcare providers to engage in self-critical analysis believed to be the key to improving patient safety and the quality of healthcare.[11]

III. CASE FACTS AND PROCEDUREAL HISTORY

Although numerous state courts and several federal courts have decided cases under the federal act,[12] the New Jersey Supreme Court addressed the parameters of this state's act for only the second time earlier this year.

In *Brugaletta v. Garcia,[13]* plaintiff presented to defendant Chilton Memorial Hospital's emergency room (hereinafter, "the Hospital") complaining of a week's fever with abdominal and body pains. She was diagnosed with pneumonia and admitted to the hospital. Further examination revealed a pelvic abscess due to a ruptured appendix. Her physician then determined that the plaintiff was developing necrotizing fasciitis in her thigh muscles and right buttock due to the abscess draining around a nerve, necessitating multiple surgeries. Plaintiff's fever dissipated and her abdominal pain subsided, but her leg pain worsened. Upon discharge three weeks after her admission, plaintiff reported having residual pain and injuries to her legs and buttocks, later claiming that they were permanent.

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Two years after her admission, plaintiff brought a medical malpractice action against the Hospital and her treating physicians.

During the course of discovery, plaintiff served interrogatories upon the Hospital requesting copies of any statements regarding the lawsuit and the circumstances surrounding their creation. In response, the Hospital disclosed in a privilege log that it possessed two reports regarding the incident and claimed that the reports were privileged under the New Jersey Patient Safety Act.[14]

Plaintiff moved to compel the production of the privileged documents. The Hospital cross-moved for a protective order, providing the certification of a physician administrator that the two incident reports were prepared "for the sole purpose of complying with the requirements of the PSA" and that the reports were provided to the Patient Safety Committee but no other committee.[15]

After argument and an *in camera* review, the trial court ordered the production of a redacted version of one of the incident reports, marked DCP-2.[16] The trial court went on to hold that the plaintiff had suffered an SPAE, as that term is defined under the PSA, which it had failed to report to the Department of Health as mandated by the statute.[17] Therefore, the Hospital was ordered to report. Further, the trial court held that where a healthcare provider fails to report an SPAE in an "arbitrary and capricious" manner, it loses its privileges under the PSA.[18] The court ruled that the Hospital had not acted arbitrarily and capriciously, so it did not forfeit its privileges.[19] The court redacted from DCP-2 those portions providing a self-critical analysis, but ordered the factual portion disclosed. The trial court stayed its own order so that the parties could exercise their appellate rights.

The Appellate Division reversed,[20] holding that the only precondition to preserve the privilege was that the Hospital perform its self-critical analysis in conformance with the PSA and its associated regulations.[21] The Appellate Division also ruled that the trial court had erred in finding that an SPAE had occurred because its determination was unsupported by expert opinion.[22]

The Supreme Court took up the appeal.

IV. THE NEW JERSEY SUPREME COURT'S DECISION

A. GENERAL PRINCIPLES OF THE PSA

The New Jersey Supreme Court noted that the Legislature sought to reduce adverse events "by fostering a non-punitive, confidential environment in which healthcare facilities can review internal practices and policies and report problems without fear of recrimination while simultaneously being held accountable."[23] The PSA requires healthcare facilities to create patient safety committees of qualified professionals to perform self-critical analyses, create evidence-based plans to increase patient safety, and to provide continual training to hospital personnel regarding patient safety. The Court held that once the committee is made aware of an SPAE, it is required to (i) perform a root cause analysis to identify the causes of the adverse event and take corrective action, and (ii) report the event to the Department of Health and the patient.[24] Failure to report can subject the healthcare facility to administrative monetary penalties.[25]

The statute makes the report to the Department of Health and "[a]ny documents, materials, or information developed by a healthcare facility as part of the process of self-critical analysis" privileged.[26] The Court held that the privilege envelopes the healthcare facility's entire self-critical analysis process, including deliberations and decisions.[27] The privilege precludes admission of the material into evidence in any civil, criminal, or administrative action.[28] The privilege attaches, however, only to documents, materials or information created "exclusively during the process of self-critical analysis."[29] Such material may, however, be discoverable if obtained in "any ... context other than those specified" under the statute.[30]

The sole condition to the application of the statute's privileges is that the healthcare facility conducted its self-critical analysis in conformance with the procedures delineated in the PSA and its associated regulations.[31]

B. PROCEDURES TO BE FOLLOWED BY THE TRIAL COURT WHEN A PRIVILEGE IS CLAIMED AND CHALLENGED UNDER THE PSA

The Supreme Court then turned to the ruling of the trial court. The Court held that where a party claims privilege and describes the general nature of the privileged information, such as appears in a privilege log, and its adversary challenges the assertions, it is incumbent upon the trial court to conduct an *in camera* review of the material and "make specific rulings as to the applicability" of the privilege.[32]

The Court further held that the trial court erred in even considering whether the Hospital correctly determined that an SPAE had occurred. "The Legislature inserted no role for a trial court to play in reviewing the SPAE determination made by a patient safety committee of a healthcare facility."[33] Further, the trial court erred in requiring production of the redacted incident report and ordering the Hospital to report the event to the Department of Health.[34] The PSA vests oversight of the patient safety process in the Department of Health and enforcement powers with the Commissioner of Health.[35]

The Court, in turn, vacated the trial court and Appellate Division's opinions as they related to the standard to be applied in determining whether an SPAE had occurred.[36]

Ultimately, the Court held that a trial court cannot order the discovery of a document created during the self-critical analy-

sis process, even in a redacted form.[37] Nor can a trial court consider the healthcare facility's determination of whether an SPAE occurred.[38] The trial court is prohibited from ordering the disclosure of an event to the Department of Health.[39]

C. THE PRODUCING PARTY MAY BE ORDERED TO CREATE A NARRATIVE SPECIFYING WHERE INFORMATION CAN BE FOUND IN VOLUMINOUS DOCUMENTS WHEN EQUITY DICTATES

The Court went on to hold that the Patient Safety Act privilege does not protect information otherwise discoverable. Within the "thousands of pages" of medical records disclosed by the Hospital to the plaintiff, "there are notations ... that, when read together, reveal the nature of the events underlying the divergent Serious Preventable Adverse Event determinations of the committee and the trial court."[40] The pertinent information was found in nine of approximately 4,500 pages of medical records produced.[41]

Although such a solution should not be "routinely" ordered, the Court held that under these circumstances, where the pertinent information is scattered in a few pages of voluminous records produced, the Hospital should be ordered to provide a "narrative" that "specifies for the requesting party where responsive information can be found."[42] Where a party, more familiar with its records and recordkeeping practices than its adversary, produces a mass of documents within which discrete information is located necessary to respond fully to a discovery request, a balancing of the equities mandates that the producing party provide a narrative directing the requesting party to the places within the record where the pertinent information is located.

V. CONCLUSION

Privileges are narrowly construed. The battle over privilege under the Patient Safety Act is won or lost when the patient safety plan is completed and the Patient Safety Committee is established and functioning. The Court was quite clear that the only way to establish and maintain the privilege is to adhere to the strictures of the statute and corresponding regulations.

The party asserting the privilege is obligated to prove all its elements. Any medical malpractice defense attorney must be prepared to muster the evidence necessary to maintain the privilege.

In the case of the Patient Safety Act, however, the privilege is established when the appropriate material is developed in accordance with procedures set forth in the statute. And then no court or other administrative body can order its disclosure.

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Footnotes

[1] *234 N.J. 225* (2018).
[2] *Id.* at 235.
[3] *Id.* at 247.
[4] *Id.* at 249.
[5] *Id.* at 246-247.
[6] *Id.* at 256.
[7] L. Kohn, J. Corrigan, M. Donaldson, ed., *To Err Is Human: Building A Safer Health System,* Institute of Medicine, National Academy Press (2000).
[8] *Id.* at 31.
[9] 42 *U.S.C.* § 299-b (21) *et seq.*
[10] *N.J.S.A.* 26:2H-12.23 – .25.
[11] 73 *Fed. Reg.* 70732 (November 23, 2008); *N.J.S.A.* 26:2H-12.24 e. and f.
[12] *Charles v. Southern Baptist Hospital of Florida, 209 So.3d 1199 (Fla. 2017); Baptist Hospital Richmond, Inc. v. Clouse, 497 S.W.3d 759 (Ky. 2016); Daley v. Teruel, 2018 Ill. App. (1st) 170891 (Ill. App. 1st Dist. 2018); University of Kentucky v. Bunnell, 532 S.W.3d 658 (Ky. App. Ct. 2017); Dunn v. Dunn, 163 F.Supp. 3d 1196 (M.D. Ala. 2016); Department of Financial and Professional Regulation v. Walgreen Company, 970 N.E.2d 552 (Ill. App. 2nd Dist. 2012).*
[13] 234 *N.J.* 225 (2018).
[14] *Id.* at 233-234. The hospital claimed a litany of privileges including those under Peer Review and Improvement Act 42 *U.S.C.* § 11101 *et seq.;* the Patient Safety Act, *N.J.S.A.* 2A:84A-22.8; the healthcare Quality Improvement Act, 42 *U.S.C.* § 11101 *et seq.;* the common law self-critical analysis privilege, and Hospital policy. Ultimately, only the privilege under the New Jersey Act was pursued.
[15] In order to be privileged under the PSA, an incident report must have been completed for the purpose of providing it to a statutorily-created Patient Safety Committee in accordance with a patient safety plan. *N.J.S.A.* 26:2H-12.25.b.; *N.J.A.C.* 8:43E-10.4 (a)-(b) and 10.9(b)1.
[16] *Brugaletta,* 234 N.J. at 234.
[17] *Id.* at 235.
[18] *Id.*
[19] *Id.*
[20] *Brugaletta v. Garcia,* 448 *N.J.Super.* 404, 408, 419 (App. Div. 2017).
[21] *Id.* at 414-415.
[22] *Id.* at 418-419.
[23] *Brugaletta,* 234 N.J. at 241.
[24] *Id.* at 242.
[25] *Id.*, citing N.J.A.C. 8:43E-3.4(a)(14).
[26] *Id.*
[27] *Id.* at 247.
[28] *N.J.S.A.* 26:2H-12.25g.(1).
[29] *Brugaletta,* 234 *N.J.* at 243 (internal citations omitted).
[30] *N.J.S.A.* 26:2H-12.25h.
[31] *Brugaletta,* 234 *N.J.* at 247.
[32] *Id.* at 245.
[33] *Id.* at 245-246.
[34] *Id.* at 249.
[35] *Id.* at 246, *citing N.J.S.A.* 26:2H-12.25j.
[36] *Id.* at 246-247.
[37] *Id.*
[38] *Id.* at 246.
[39] *Id.* at 249.
[40] *Id.* at 250.
[41] *Id.* at 256-257.
[42] *Id.* at 256.