**RECORD IMPOUNDED**

NOT FOR PUBLICATION WITHOUT THE
APPROVAL OF THE APPELLATE DIVISION

SUPERIOR COURT OF NEW JERSEY
APPELLATE DIVISION
DOCKET NO. A-4342-15T1

JANELLE BRUGALETTA,

Plaintiff-Respondent,

v.

CALIXTO GARCIA, D.O.,
STEVEN D. RICHMAN, M.D. and
PATRICK J. HINES, M.D.,

Defendants,

and

CHILTON MEMORIAL HOSPITAL,

Defendant-Appellant.

**APPROVED FOR PUBLICATION**

**February 6, 2017**

**APPELLATE DIVISION**

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Argued December 6, 2016 – Decided February 6, 2017

Before Judges Fisher, Ostrer and Vernoia.

On appeal from an interlocutory order of the Superior Court of New Jersey, Law Division, Passaic County, Docket No. L-112-15.

Anthony Cocca argued the cause for appellant (Bubb, Grogan & Cocca, LLP, attorneys; Mr. Cocca, of counsel and on the briefs; Katelyn E. Cutinello, on the briefs).

Ernest P. Fronzuto argued the cause for respondent (Fronzuto Law Group, attorneys; Mr. Fronzuto and Casey Anne Cordes, on the brief).

The opinion of the court was delivered by

OSTRER, J.A.D.

This medical malpractice case involves the Patient Safety Act (the Act), N.J.S.A. 26:2H-12.23 to -12.25, which creates an absolute privilege over certain documents that a hospital develops as part of a self-critical analysis. See N.J.S.A. 26:2H-12.25(g). The trial court compelled defendant Chilton Medical Center (Chilton)[1] to disclose to plaintiff, Janelle Brugaletta, a redacted report containing Chilton's self-critical analysis of Brugaletta's care. The court ordered disclosure because it found: (1) Brugaletta had suffered a "serious preventable adverse event" (SPAE), see N.J.S.A. 26:2H-12.25(a); and (2) Chilton failed to report the SPAE to the New Jersey Department of Health (the Department) or to Brugaletta, as the Act required. See N.J.S.A. 26:2H-12.25(c), -12.25(d).

By leave granted, Chilton appeals from the court's order. Chilton disputes the court's finding that Brugaletta suffered a SPAE and contends the court erred in compelling it to report the SPAE to the Department and Brugaletta. More importantly, Chilton argues the Act's absolute privilege over a self-critical analysis may not be pierced based on a failure to report a SPAE.

[1] Plaintiff denominated defendant as "Chilton Memorial Hospital" in her complaint. Chilton answered the complaint in the name of "AHS Hospital Corp./Children Medical Center."

Rather, Chilton contends the privilege is conditioned solely on compliance with statutory and regulatory mandates governing the formation of a patient safety plan and related procedural requirements. See N.J.S.A. 26:2H-12.25(b).

We agree the privilege does not depend on compliance with the requirement to report a SPAE to the Department or the patient. We therefore reverse the trial court's order compelling partial release of a document revealing Chilton's privileged self-critical analysis. We also reverse the finding that there was a reportable SPAE because the finding lacked sufficient credible evidence in the record.

I.

In the underlying malpractice action, Brugaletta alleges she arrived at Chilton's emergency room on January 20, 2013, complaining of abdominal pain and a fever that had persisted for seven days. A twenty-three-year-old college student, she also complained of bodyaches, weakness, and a cough "productive of . . . thick phlegm." Her initial diagnosis was pneumonia. After she was admitted, she continued to complain of abdominal pain. A CT scan of her abdomen and pelvis was performed the day after she arrived at the hospital. It revealed a pelvic abscess that "most probably" resulted from a perforated appendix, according to one physician's report.

A large amount of purulent fluid[2] was drained through the right ischial fossa.[3] Although her abdominal symptoms soon improved, she developed fasciitis[4] in the right thigh and right buttock muscle. One physician stated the fasciitis resulted from "the leakage of the drainage around the [ischial] nerve." Beginning January 23, 2013, Brugaletta underwent multiple debridements[5] of the thigh and buttock muscles. She also had an appendectomy. In the midst of those repeated procedures, Brugaletta missed doses of a post-operation antibiotic despite a physician's orders, which were recorded in his January 30, 2013 progress note.[6] When Brugaletta was finally discharged on

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[2] "Purulent fluid" is fluid that contains pus. Stedman's Medical Dictionary 1607 (28th ed. 2006).

[3] The "ischial fossa" refers to a space between muscle and skin in the pelvic region. See Stedman's, supra, 765.

[4] "Fasciitis" refers to an inflammation of a particular kind of tissue that covers the body below the skin. Stedman's, supra, 700, 706.

[5] A "debridement" is a procedure whereby "devitalized tissue and foreign matter" are removed from a wound. Stedman's, supra, 496. The post-operative notes of January 23, 2013 reported "abundant dead fascia."

[6] We note that plaintiff does not address this oversight in her complaint, nor is it clear from the limited record before us that plaintiff is aware of it. The oversight is documented in the non-privileged chart. Although Chilton disclosed the document to the trial court as part of its ex parte submission, Chilton recognized that the document is not privileged and was included among its voluminous document production to Brugaletta.

February 13, 2013, she was still suffering from severe pain; she was instructed to use a walker or a person to assist her; and she was prescribed pain medication and intravenous antibiotics for administration at home.

In her initial complaint, Brugaletta alleged that Chilton and various providers negligently diagnosed and treated her condition. In particular, she highlighted the delay in diagnosing her "ruptured appendix and pelvic abscess." In her first amended complaint, she added that physicians negligently failed to detect a second abscess on her CT imaging.

In response to Brugaletta's discovery demands, Chilton identified but withheld as privileged the document at issue in this case. Described as an "Event Detail History with all Tasks," Chilton asserted it was privileged pursuant to the Act and implementing regulations, as well as other grounds.[7] Brugaletta sought to compel production, initially seeking the court's in camera review. Chilton opposed and sought a protective order. In support, Chilton submitted the certification of Ebube Bakosi, M.D. the then-current chair of

[7] Chilton asserted privilege over another document pursuant to the Act and the common law "conditional privilege" as set forth in Christy v. Salem, 366 N.J. Super. 535, 540-42 (App. Div. 2004). The court's order allowing Chilton to withhold that document is not at issue in this appeal.

Chilton's Preventable Events Review Committee (PERC), formerly known as the Patient Safety Committee.

The trial court ordered the document's production for in camera review. The court also permitted Chilton to file an ex parte brief to present document-specific arguments against disclosure. Upon review, the court found that Chilton prepared the document, which the court marked as DCP-2, in accordance with the procedural requirements of the Act and implementing regulations. However, the court concluded that the document revealed that Brugaletta had suffered a separate SPAE and Chilton failed to report that SPAE to the Department or disclose to Brugaletta.[8]

The court determined that when a hospital fails to report a SPAE to the Department or a patient, the court is empowered to compel it to do so. The court also concluded if the hospital's reporting failure was arbitrary or capricious, then the hospital shall lose its privilege under the Act. The court held that when the hospital has erred in failing to report without acting arbitrarily or capriciously, then a lesser remedy is appropriate. Applying those standards, the court found that

[8] Because we find DCP-2 is privileged and there is insufficient evidence supporting the court's finding of a SPAE, we do not detail the nature of the SPAE found by the court in order to protect Chilton's privilege against disclosure of its self-critical analysis.

Chilton made a "clear error in judgment," but did not act arbitrarily or capriciously. The court concluded under those circumstances it was appropriate to release only the portion of DCP-2 that described the SPAE, while redacting the balance. Nonetheless, the portion to be disclosed still revealed aspects of Chilton's self-critical analysis.

This appeal followed. Chilton contends the court erred in compelling it to disclose DCP-2, albeit redacted. Chilton argues that the court lacked authority to review its determination that no SPAE occurred and to compel reporting; and, in any event, neither the Act nor the implementing regulations authorize the partial or total loss of the privilege when a hospital fails to report a SPAE when required. Brugaletta argues the trial court did not err, and its order promotes compliance with the Act's reporting mandate.[9]

[9] Brugaletta also contends the trial court erred in finding that Chilton complied with the privilege's procedural prerequisites. As a result, she contends not even a limited privilege existed under the Act, and the discoverability of DCP-2 should have been analyzed under Christy, supra, 366 N.J. Super. at 540-42. However, in order to challenge the trial court's order, Brugaletta was required to file a cross-appeal. See Franklin Discount Co. v. Ford, 27 N.J. 473, 491 (1958) ("[A respondent], in order to attack the actions below which were adverse to him, must pursue a cross-appeal."); Pressler & Verniero, Current N.J. Court Rules, comment 2 on R. 2:3-4 (2016) ("Ordinarily, a respondent . . . must cross-appeal in order to obtain relief from the judgment."). We therefore shall not reach the issue. For the same reason, we shall not address her argument that she (continued)

II.

We review the trial court's discovery decision for an abuse of discretion, but we shall not defer to the trial court's decision if "based on a mistaken understanding of the applicable law." C.A. ex rel Applegrad v. Bentolila, 219 N.J. 449, 459 (2014) (internal quotation marks and citation omitted). We review legal issues de novo, including the trial court's interpretation of the Act. Ibid.

In interpreting the Act and effectuating the Legislature's intent, we look first to the plain language, reading it as an integrated whole. Id. at 459-60. "If the plain language is clear, the court's task is complete." In re Kollman, 210 N.J. 557, 568 (2012). If it is unclear or ambiguous, we may resort to extrinsic aids. Ibid. "It is not the function of [a] [c]ourt to 'rewrite a plainly-written enactment of the

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(continued)
was entitled to access Chilton's ex parte brief, the hearing transcripts "placed on a sealed record," and the judge's sealed statement of reasons for its order.

We also decline both parties' request that we endorse the trial court's procedural measures for protecting the document's confidentiality during its proceedings pending our review. The court's thoughtfulness is evident. We also appreciate the parties' desire for guidance. However, this aspect of the matter is not disputed. It also is conceivable that in another case and setting, a trial judge's exercise of discretion might call for different measures. We therefore believe it is inappropriate for us to reach the issue.

Legislature []or presume that the Legislature intended something other than that expressed by way of the plain language.'" DiProspero v. Penn, 183 N.J. 477, 492 (2005) (quoting O'Connell v. State, 171 N.J. 484, 488 (2002)). We respect, although we are not bound by, an agency's statutory interpretation embodied in its regulations. See Hargrove v. Sleepy's, L.L.C., 220 N.J. 289, 301-02 (2015); see also Mayflower Sec. Co. v. Bureau of Sec., 64 N.J. 85, 93 (1972) (stating an appellate court is "in no way bound by the agency's interpretation of a statute").

In this case, we do not write on a clean slate. The Supreme Court in C.A. reviewed in detail the purpose, structure, and meaning of the Act and its implementing regulations. C.A., supra, 219 N.J. at 460-68; see also Conn v. Rebustillo, 445 N.J. Super. 349, 354-57 (App. Div. 2016). We shall not repeat that analysis here.

We focus on distinct obligations the Act imposes on a hospital: self-critical analysis and reporting. With respect to self-critical analysis, a hospital must create a safety plan establishing a dedicated patient safety committee. N.J.S.A. 26:2H-12.25(b). The purpose of such committees is, among other things, to provide processes by which hospitals can conduct analyses of harmful events and carry out root cause analyses for all SPAEs. Ibid.; N.J.A.C. 8:43E-10.4(d)(7). The reporting

obligation involves two recipients: regulators and patients. See N.J.S.A. 26:2H-12.25(c) and N.J.A.C. 8:43E-10.6 (requiring reporting to the Department);[10] N.J.S.A. 26:2H-12.25(d) and N.J.A.C. 8:43E-10.7 (requiring disclosure to patient).

The definition of a "serious preventable adverse event" is gleaned from the definitions of its constituent terms. An "adverse event" is "a negative consequence of care that results in unintended injury or illness." N.J.S.A. 26:2H-12.25(a). "Serious" means "result[ing] 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." Ibid. "Preventable" means "could have been anticipated and prepared against, but occurs because of an error or other system failure." Ibid.

To encourage compliance with the two obligations – self-critical analysis and reporting – the Act creates a privilege. "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 patients], and the investigative process that may or may not lead to such

[10] The statute requires reporting to the Department of Human Services in the case of State psychiatric hospitals. N.J.S.A. 26:2H-12.25(b). For simplicity's sake, we will refer only to the Department.

reporting." C.A., supra, 219 N.J. at 467. This evidentiary privilege is broad: The covered items "shall not be . . . 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(f)(1), -12.25(g)(1).

The Act separately defines the privilege over reports depending on their potential recipient. With respect to reporting to regulators, N.J.S.A. 26:2H-12.25(f) creates a privilege over "documents, materials, or information received by [the Department] . . . pursuant to the provisions of subsections c[, which relates to mandatory reporting of SPAEs], and e[]," which relates to the voluntary reporting of non-SPAEs, that is, "near-misses, preventable events, and adverse events that are otherwise not subject to mandatory reporting pursuant to subsection c[] . . . ." Regarding reporting to patients, N.J.S.A. 26:2H-12.25(g) creates a privilege over "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" pertaining to mandatory reporting of SPAEs to patients.

At issue in this case is the privilege over self-critical analysis. In addition to creating a privilege over SPAE reports to patients, subsection (g) extends a privilege to "[a]ny

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 [SPAEs] . . . ." (Emphasis added). Subsection (b) compels hospitals to "develop and implement a patient safety plan," and to do so "[i]n accordance with the requirements established by the commissioner by regulation." N.J.S.A. 26:2H-12.25(b). The subsection does not refer to the obligation to report SPAEs. That reporting obligation is imposed by N.J.S.A. 26:24-12.25(c).

Thus, the only statutory precondition of this self-critical analysis privilege is compliance with subsection (b), pertaining to safety plans. The plain language of subsection (g) does not condition the privilege over self-critical analysis on compliance with the reporting obligation. In other words, so long as the self-critical analysis is conducted according to the proper procedures as set forth in the hospital's safety plan, it is protected.

Although the regulations clarify preconditions of the privilege, they do not vary our conclusion that the privilege over a self-critical analysis exists independent of compliance with the reporting obligation. Specifically, N.J.A.C. 8:43E-10.9(b) defines the privilege as covering "[d]ocuments,

materials, and information (including RCAs [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 . . . ." N.J.A.C. 8:43E-10.9(b) (emphasis added); see also C.A., supra, 219 N.J. at 468. Accordingly, the sole requirement for the privilege to apply under subsection 10.9(b) is that the self-critical analysis be undertaken according to the appropriate procedure.

The fact that the privilege is conditioned upon procedural (and not substantive) concerns is further established by an examination of the regulations cited by subsection 10.9(b). The first of the three cited regulations, N.J.A.C. 8:43E-10.4, prescribes in greater detail than the Act the structure and duties of a patient or resident safety committee. The second, N.J.A.C. 8:43E-10.5, specifies in detail the safety planning obligation.

We recognize that the third, N.J.A.C. 8:43E-10.6, addresses in detail the obligation to report SPAEs to the Department, N.J.A.C. 8:43E-10.6(a)-(d), and specifies several categories of SPAEs. N.J.A.C. 8:43E-10.6(e)-(j). However, we do not construe section 10.9 to mean that the self-critical analysis privilege

depends on reporting SPAEs to the Department. Notably, subsection 10.6(l) addresses the required contents of a root cause analysis. We presume the reference in subsection 10.9(b) to a self-critical analysis performed in accordance with section 10.6 was intended to require compliance with subsection 10.6(l).

In short, the relevance of the three regulations, including section 10.6, is their impact on the manner in which self-critical analyses are performed. They elaborate the "process of self-critical analysis" cited in subsection 10.9(b).

Furthermore, were reporting SPAEs a condition of the self-critical analysis privilege, N.J.A.C. 8:43E-10.9(b) logically would also have referred to a fourth regulation, N.J.A.C. 8:43E-10.7, which details the obligation to report SPAEs to patients. Omission of section 10.7 reflects the Department's view that reporting SPAEs is not a precondition of the self-critical analysis privilege. We have found nothing in the Department's rulemaking record that would support a contrary conclusion. See 39 N.J.R. 314(a) (Feb. 5, 2007) (proposed rulemaking); 40 N.J.R. 1094(a) (March 3, 2008) (final adoption).

In C.A., the Court upheld a hospital's assertion of the self-critical analysis privilege over a document pertaining to a child born with anoxic brain injury. C.A., supra, 219 N.J. at 452-54. The Court held that the hospital complied with the

Act's broad prerequisites set forth in N.J.S.A. 26:2H-12.25(b). Id. at 468-72. Since the hospital prepared the document before the Department adopted its regulations, compliance with them was not required. Id. at 468-69.

The Court expressly rejected a connection between complying with the reporting obligation and the self-critical analysis privilege. The hospital had decided that the treatment did not result in a SPAE. Id. at 471. Significantly, our court found that decision "debatable," and concluded the newborn suffered a "potential" SPAE, and the hospital should have referred the matter to its patient safety committee to determine whether it was reportable. C.A. ex rel Applegrad v. Bentolila, 428 N.J. Super. 115, 153-54 (App. Div. 2012), rev'd, 219 N.J. 449 (2014). But the Supreme Court responded:

> 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).
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> [C.A., supra, 219 N.J. at 471 n.14.]

In Conn, we emphasized the dichotomy between the two obligations — reporting and self-critical analysis — and the accompanying privileges. At issue was the privilege under N.J.S.A. 26:2H-12.25(f) governing reports to regulators. Conn, supra, 445 N.J. Super. at 350-51. We rejected the suggestion that the privilege depends on compliance with the safety planning mandates of subsection (b). Id. at 357. Rather, the privilege depended solely on whether the Department received the documents pursuant to N.J.S.A. 26:2H-12.25(c) and (e), governing mandatory and voluntary reporting to regulators. Ibid. Applying this same dichotomy, Conn supports our conclusion that the privilege over self-critical analysis as defined at N.J.S.A. 26:2H-12.25(g) does not depend on compliance with the mandatory reporting requirement of N.J.S.A. 26:2H-12.25(c).

Finally, we note that predicating the self-critical analysis privilege on complying with the SPAE reporting obligation could lead to a result that we doubt the Legislature intended. We have in mind cases where a hospital denied that a serious adverse event was preventable. In general, the proponent of an evidentiary privilege must establish the prerequisites of the privilege. See Horon Holding Corp. v. McKenzie, 341 N.J. Super. 117, 125 (App. Div. 2001) (applying attorney-client privilege). Thus, to assert the self-critical

analysis privilege, the hospital would have to prove a serious adverse result was not preventable if it did not report it. The proofs would likely overlap with those relevant to the alleged negligence in the underlying case. We doubt the Legislature contemplated that a court would need to conduct such a mini-trial in which the burdens are reversed in order to recognize the self-critical analysis privilege.

In sum, the trial court erred in predicating the privilege over a self-critical analysis on the hospital's compliance with its obligation to report a SPAE to regulators or the patient.

III.

We must still consider whether the trial court erred in (1) determining that Chilton violated its reporting obligation, and (2) compelling it to report to the Department and Brugaletta. The court predicated its order on its finding that Brugaletta suffered a SPAE. We conclude that the finding lacked support of sufficient evidence in the record. See Rova Farms Resort, Inc. v. Investors Ins. Co. of Am., 65 N.J. 474, 484 (1974). We therefore reverse the trial court's order compelling Chilton to report.[11]

[11] Given our disposition, we need not address three additional questions that may be implicated by the court's order. First, we need not decide the standard of review of a hospital's determinations as to whether a SPAE has occurred and whether to (continued)

We may presume for purposes of our analysis that Brugaletta suffered an "adverse event" consisting of the fasciitis of her right lower extremity, which was a "negative consequence of care that result[ed] in unintended injury or illness . . . ." See N.J.S.A. 26:2H-12.25(a); N.J.A.C. 8:43E-10.3. We may also presume it was serious if she suffered a "loss of a body part . . . or loss of bodily function" for at least one week or at the time of her discharge. See N.J.S.A. 26:2H-12.25(a); N.J.A.C. 8:43E-10.3.

But the trial court did not identify record evidence for the conclusion that this was a "preventable event" — that is, it "could have been anticipated and prepared against, but occur[red] because of an error or other system failure." See

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report it. Second, we do not address whether a plaintiff has a private right of action to compel a hospital to fulfill its reporting obligation, particularly as it relates to reporting to regulators. See R.J. Gaydos Ins. Agency, Inc. v. Nat'l Consumer Ins. Co., 168 N.J. 255, 271, 272 (2001) (noting that we have "been reluctant to infer a statutory private right of action where the Legislature has not expressly provided for such action" and setting forth a test for ascertaining whether a private right of action is implied). In this regard, we note the Department is empowered to enforce the reporting requirement by imposing penalties up to $100,000 on non-compliant general hospitals. N.J.A.C. 8:43E-3.4(a)(14)(i). Third, we do not reach the issue whether, based on principles of primary jurisdiction, the agency, as opposed to the court, should decide in the first instance whether a reportable SPAE has occurred. See Smerling v. Harrah's Entm't, Inc., 389 N.J. Super. 181, 187 (App. Div. 2006); Muise v. GPU, Inc., 332 N.J. Super. 140, 158-59 (App. Div. 2000).

N.J.S.A. 26:2H-12.25(a); N.J.A.C. 8:43E-10.3. We emphasize one of the three elements of a "preventable event" is the element of causation. Not only must the event be one that a hospital could have "anticipated and prepared against", and not only must there be "an error or other system failure", but the event must occur "because of" the error or system failure. N.J.S.A. 26:2H-12.25(a); N.J.A.C. 8:43E-10.3.

The evidence does not support a finding that the causation element was satisfied. The record clearly supports the trial judge's finding there was an error in Brugaletta's care. We may assume for argument's sake that the error could be "anticipated and prepared against." However, the trial court does not rely on an expert opinion to conclude that Brugaletta's serious adverse event occurred "because of" that error. Under the facts of this case, an expert opinion was essential. See Kelly v. Berlin, 300 N.J. Super. 256, 268 (App. Div. 1997) ("[I]n general, a jury should not be allowed to speculate without aid of expert testimony in an area where laypersons could not be expected to have sufficient knowledge or experience." (internal quotation marks and citation omitted)). In its absence, the court's conclusion that Brugaletta suffered a SPAE was not supported by sufficient record evidence.

In sum, the trial court erred in compelling Chilton to: (1) disclose the redacted memorandum revealing its self-critical analysis, and (2) report an alleged SPAE to the Department and Brugaletta.

Reversed.