DISCOVERY OF SENTINEL EVENT AND ROOT CAUSE ANALYSIS DOCUMENTS IN ERB'S PALSY AND MALPRACTICE LITIGATION

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Almost every hospital in the state, and in the country, is accredited by the Joint Commission on Accreditation of Health Care Organizations (JCAHO). JCAHO is a national organization that sets standards, generally based on federal regulations, and then issues accreditation to a health organization that "substantially complies and continually make efforts to improve the care and services it provides[1]." A hospital must have accreditation by JCAHO, in order to be paid by Medicaid, Medicare, and most major health insurance organizations. In order to maintain accredited status, a hospital is required to comply with a host of published standards that JCAHO enforces.

In 1996, JCAHO promulgated its Sentinel Event Policy and Procedures. They state, in relevant part:

I. Sentinel Events

A 'sentinel event' is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function....

Such events are called "sentinel" because they signal the need for immediate investigation and response.

Our practice concentrates on birth trauma litigation. There, we see a lot of Erb's Palsy cases.[1] The loss of the use of an affected arm due to a shoulder dystocia, and an Erb's Palsy that

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[1] How a baby gets Erb's Palsy:

Plaintiffs typically contend that Erb's Palsy (a/k/a brachial plexus palsy) is a birth injury, that happens when the nerves in the baby's neck and upper shoulder are injured during delivery. As a result, the newborn has a partial loss of use and function of the arm.

These babies get stuck in his mother's birth canal. Typically, they are large ("macrosomic"). The bigger the baby, the greater the chance of the getting stuck in the birth canal (shoulder dystocia).

This injury happens because the shoulder gets impacted (trapped) beneath the mother's public bone. This is called "shoulder dystocia." If a delivering doctor or midwife uses excessive force ("traction") on the baby's head and neck, in an effort to dislodge the baby, stretched the nerves emanating from the neck and down the shoulder (the "brachial plexus"), resulting in nerve injury causing a partial paralysis of the arm on the affected side.

is diagnosed while the newborn is still in the nursery (the usual case), clearly falls within the definition of a "sentinel event." While this article emanates from our prosecution of birth trauma cases, the general principles herein apply to any kind of malpractice case.

In its Sentinel Event Alerts, Issue #30 (July 21, 2004), JCAHO specifically noted that "cases considered reviewable under the Sentinel Events Policy are 'any perinatal death or major permanent loss of function unrelated to a congenital condition in an infant having a birth weight greater than 2500 gram." Most babies with shoulder dystocia and Erb's Palsy are large (3500 grams or more), and the Erb's Palsy is usually diagnosed in the newborn nursery. Therefore, it is beyond question that the hospital and doctors know of the baby's injury contemporaneously with his birth. That, by definition, constitutes a "sentinel event" that triggered mandatory reporting requirements.

As part of the Sentinel Event Policy, the JCAHO requires all health care organizations to perform a "root cause analysis" whenever a "sentinel event" occurs, and to use the information from the data analysis to identify changes that will improve performance or reduce the risk of future "sentinel events." To maintain JCAHO accreditation, healthcare organizations must also ensure that the processes for investigating and making an action plan to reduce the risk of similar events are defined and implemented.

The Joint Commission for Accreditation of Healthcare Organizations (JCAHO) issued criteria for reporting an occurrence as a sentinel event. Failure to comply with the reporting requirement will place the facility on accreditation-watch status:

> "If a recipient of care is affected by one or more of the items listed below, then the incident must be reported to the JCAHO:
>
> (1) an event resulting in an unanticipated death or major permanent loss of function, not related to the natural course of the patient's illness or underlying condition .

More information is available on the authors' website, www.ErbsPalsyOnline.com.

If the hospital is not in compliance with JCAHO, which includes filing required Sentinel Event Reports with JCAHO, it could lose its JCAHO-accreditation, which would effectively put the hospital out of business.

In NY, one may expect that when the plaintiff tries to get the required Sentinel Event and Root Cause Analysis documents, defense counsel will object and interpose a verbal assertion of privilege under Education Law §652 7(3) and the Public Health Law 2805-m.

We submit that any claim of privilege is improper, and the "sentinel event" and root cause analyses documents are discoverable.

A. The Documents Are Relevant

According to CPLR 3101, plaintiff may obtain full disclosure of any matter, that is not privileged, which is material, relevant or necessary to the subject matter involved in the pending action.

The required investigation is presumed to have complied with the JCAHO and NY State mandates, that involve a review to determine what went wrong in the course of the birth that resulting in the loss of function of an arm. This is the exact same core question to be answered in the malpractice litigation. Relevance is undeniable.

B. The Burden of Establishing a Privilege is on the Defense.

The defense typically seeks to assert a privilege that would shield them from discovery. However, any privilege that is contrary to the broad mandate of CPLR 3101 must be construed narrowly. The basic premise that litigation is a search for the truth, yields only in the face of overwhelming policy considerations to the contrary. The question to be addressed by the court is whether any privilege exists that rises to this level.

As a starting-off point, the burden of establishing a claim of privilege is on the party asserting it (here, the defendants), and the asserted protection must be narrowly construed,

consistent with the purposes underlying the claimed immunity. Spectrum Systems v. Chemical Bank, 89 NY2d 371, 377, 575 NYS2d 809; University of Pennsylvania v. EEOC, 493 US 182, 189; Matter of Priest v. Hennessy, 51 NY2d 62, 68, 431 NYS2d 511. That is because a claim of privilege, by its very assertion, seeks to hide facts (truth) from exposure.

As a result, any privilege should be "strictly confined within the narrowest possible limits consistent with the logic of its principle." (8 Wigmore, Evidence [McNaughton rev, 1961], § 2291, p 554.) "[Much] ought to depend on the circumstances of each case" (Matter of Priest v Hennessy, *supra*, p 68; Matter of Jacqueline F., supra, p 222). Only if the injury resulting from disclosure is greater than benefit thereby gained, should the privilege be recognized (8 Wigmore, Evidence [McNaughton rev, 1961], § 2285; see, also, Garner v Wolfinbarger, 430 F2d 1093, 1100-1101), and even then policy reasons might require disclosure (Matter of Priest v Hennessy, *supra,* pp 69, 71; Beard v. Ames et al, 96 A.D.2d 119, 468 NYS2d 253.

The burden of proving the applicability of privilege is a heavy one, and it's on the hospital to do so. Thus, the Fourth Dept. rejected a Rochester hospital's assertion of privilege, in Little v. Highland Hospital of Rochester, 721 N.Y.S.2d 189 (2001), holding:

> Defendant did not establish that those items were "generated in connection with a quality assurance review function pursuant to Education Law §6527 (3) or a malpractice prevention program pursuant to Public Health Law §2805-j" (Maisch v Millard Fillmore Hosps., 262 AD2d 1017). **Thus, defendant failed to meet its burden of establishing that those items are confidential and protected from disclosure** by Education Law §6527 (3) and Public Health Law §2805-m (see, Maisch v Millard Fillmore Hosps., *supra*, at 1017-1018). **Defendant also failed to meet its burden of establishing that the statutory provisions for confidentiality and protection from disclosure of certain records** (see, Education Law §6527 [3]; Public Health Law §2805-m) extend to its written plan for reviewing, evaluating and maintaining the quality of patient care and identifying and preventing medical, dental and podiatric malpractice. **Thus, the court properly directed defendant to provide plaintiff with a copy of its plan**.

C. Distinguishing JCAHO-Required Reports from Peer Committee Reviews.

Education Law §6527(3) provides a limited privilege from discovery of "peer committee review" materials as to persons who are not defendants in a lawsuit. Such "peer committee reviews" are typically in the nature of Mortality and Morbidity Committees ("M&M committees") that hospitals voluntarily create to discuss specific patients' care for quality assurance purposes. Even then, the prohibition of discovery of "testimony" offered at peer committee review proceedings "shall not apply to the statements made by any person in attendance at such a meeting who is a party to an action or proceeding, the subject matter of which was reviewed at such meeting" (Education Law § 6527[3]; see also, Carroll v St. Luke's Hosp. of Newburgh, 91 A.D.2d 674, 457 N.Y.S.2d 128; De Paolo v Wisoff, 94 A.D.2d 694, 461 N.Y.S.2d 893). "Statements of a defendant in medical malpractice litigation that were made before a peer review board or for quality assurance evaluation are not privileged when they relate to the subject matter of the litigation (see, Education Law § 6527[3]; Public Health Law § 2805-m [2]; Logue v. Velez, 92 NY2d 13, 18-19)." Bryant v. Bui, 1999 NYSlipOp 07781, 1999.NY.0051407, 4th Dept., 1999.

This privilege has no application to JCAHO reporting requirements. "Sentinel Event" and "root cause analysis" documents are not prepared as part of any Mortality and Morbidity Committee meeting that would invoke the limited protections under the Education Law. The testimonies of the defendants, in most cases, will establish that there was no "M&M Committee" (peer committee review) in most cases.

A "sentinel event report" and "root cause analysis" is prepared in the regular course of business of the hospital, and does not emanate from any quality assurance review in the nature of an M&M Committee. Therefore, it is explicitly discoverable pursuant to CPLR 3101(g)'s mandate that:

> "there shall be full disclosure of any written report of an accident prepared in the regular course of business operations or practices of any person, firm, corporation, association or other public or private entity."

Since these documents were required by JCAHO, they are analogous to MV-104 accident reports that are required by the New York State Department of Motor Vehicles, and which are *routinely discoverable* in automobile accident cases. CPLR 3101(g); Smith v. Young, 455 N.Y.S.2d 956; 116 Misc. 2d 619 (Onandaga Co.).

Thus, in Schaeffer v. Brookdale Univ. Hospital, 14 Misc.3d 1226 (2007), the Brooklyn Supreme Court (Demarest, J.) ruled that documents prepared for an education accreditation agency (analogous to documents prepared for JCAHO accreditation) are discoverable:

> **The accreditation of a hospital residency program by an independent private association is unrelated to the statutory purpose**. As noted in its own guidelines, ACGME's purpose is to protect residents and "the quality of teaching, learning, research, and professional practice." Patient care is not among its stated concerns. As noted in Interfaith Medical Center v. Sabiston, (136 AD2d at 243), "[s]uch an accreditation involves a determination of the sufficiency of the program as an educational enterprise." **The fact that medical residency programs are subject to regulation by the Board of Regents and the Commissioner of Education (see Interfaith v. Sabiston), does not establish defendants' right to a protective order pursuant to the Public Health and Education Laws as defendants contend**.

Our research has not located any appellate-level cases specifically determinative of the discovery of JCAHO-required Sentinel Event Reports in New York State. However, there is a substantial body of controlling law allowing such discovery from other states, that we suggest should be followed.

In Reyes v. Meadowlands Hosp. Medical Center, 355 N.J. Super. 226, 809 A.2d 875 (2001) New Jersey's highest court held that:

> [T]he internal review which is the subject of this motion, as described in the Hospital's Sentinel Event Policy Statement, includes a wide range of potential misuse in the application and/or invocation of this alleged "privilege." Although Ms. Reyes' unexpected death fits the profile of cases which warrant a thorough and honest investigation to determine what if any systematic changes are needed to avoid its recurrence, thereby improving the quality of care for future patients, the legal declaration this court is being asked to make [by the defense] goes far beyond these individual facts. ...

> ....A review of the examples previously listed as Sentinel Events: (i) Environmental events that injure patients/staff or require patient evacuation, such as fires and toxic spills; (ii) Events causing disruption of the hospital's ability to provide medical services, such as power outages, labor unrest and riot; (iii) Media investigations or media reports involving alleged violations of regulatory agency requirements, reveals more a desire by the Hospital to control the dissemination of potentially embarrassing information rather than a genuine interest in the enhancement of patient care. In short, these “Sentinel Events,” on their face, go far beyond the professed “advancement of medical knowledge” justification argued by defendants, and wander freely in the world of public relations....
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> **This court holds that the Sentinel Event Policy invoked by defendant Meadowlands Hospital does not create a self-critical analysis privilege, insulating any and all discussions and statements made and conclusions reached by the participants therein and actions taken by the Hospital pursuant thereto not subject to the Civil Rules of Discovery**. Defendants' application for a protective order under *R.* 4-10-3 is denied.

Kentucky courts *routinely* require the disclosure of Sentinel Event reports and Root Cause Analyses. We have collected five Kentucky court orders resulting in directions discarding all claims of privilege, and allowing this discovery.

Virginia has a peer committee review and quality assurance statute similar to NY’s. In Riverside Hospital v. Johnson, 272 Va 518, 636 S.E.2d 416 (2006), Virginia’s highest court was confronted with a claim of privilege for the same materials, and held:

> The documents at issue are not documents generated by a peer review or other quality care committee referred to in the statute. Thus they are not proceedings, minutes, reports, or other communications "of" or "originating in" such committees. The question is whether they qualify for the privilege because they are "communications . . . provided to" such peer review or quality care committees.

The Court further found that hospitals could improperly attempt to immunize any documents from discovery by casually asserting that they were part of peer committee review, or quality assurance, even though they are not:

> A literal application of the phrase "all communications, both oral and written, . . . provided to such committees" would impress the privilege on every document and every statement made available to a committee or entity identified in the statute. Such an application would allow a health care facility to immunize from disclosure every statement or document maintained by the facility simply by

insuring that such statement or document was provided or available to a peer or quality review committee. Considering this phrase in the context of the entire section, however, shows that the General Assembly did not intend such a broad application of the privilege. For example, the privilege attaching to oral communications regarding a specific medical incident involving patient care is limited.

These limitations on the application of the privilege are consistent with preserving the confidentiality of the quality review process while allowing disclosure of relevant information regarding specific patient care and treatment. "The obvious legislative intent [of the statute] is to promote open and frank discussion during the peer review process among health care providers in furtherance of the overall goal of improvement of the health care system. If peer review information were not confidential, there would be little incentive to participate in the process." HCA Health Services of Virginia, Inc. v. Levin, 260 Va. 215, 221, 530 S.E.2d 417, 420 (2000). **It is [only] the deliberative process and the conclusions reached through that process that the General Assembly sought to protect.** See Code § 8.01-581.16 (providing immunity for actions taken by persons involved in the peer review process).

The deliberative process involving evaluation of patient safety conditions and the design of initiatives to improve the health care system both necessarily begin with factual information of patient care incidents occurring within the health care facility. **The use of this factual information in some way in the peer review or quality care committee process alone is insufficient to automatically cloak such information with the protection of non-disclosure. Factual patient care incident information that does not contain or reflect any committee discussion or action by the committee reviewing the information is not the type of information that must "necessarily be confidential" in order to allow participation in the peer or quality assurance review process.** Rather such information is the type, contemplated by Subsection (C) of Code § 8.01-581.17, which the General Assembly has specifically instructed should not be brought within the scope of those items entitled to the privilege under any other part of the section.

Applying these principles, we conclude that **the documents at issue here** are of the nature of those described in Code § 8.01-581.17(C) and **are not privileged.**

We believe that the same policy determinations are equally applicable to NY cases, so that the result should be the same. A hospital defending a malpractice claim ought not be allowed to hide relevant evidence by cloaking it in claims of privilege. That is especially so with respect to reports that are mandated by the Dept. of Health, and are in the nature of required accident reports prepared in the regular course of business that are specifically discoverable under CPLR 3101(g).

1.http://cms.h2e-online.org/ee/regsandstandards/jcaho/