

Duane Morris®

[www.duanemorris.com](http://www.duanemorris.com)

## Peer Review Protections: New Jersey and Federal

May 2, 2025

Erin M. Duffy, Esq.

©2024 Duane Morris LLP. All Rights Reserved. Duane Morris is a registered service mark of Duane Morris LLP.

Duane Morris – Firm Offices | New York | London | Singapore | Philadelphia | Chicago | Washington, D.C. | San Francisco | Silicon Valley | San Diego | Los Angeles | Boston | Houston | Dallas | Fort Worth | Austin | Hanoi  
Ho Chi Minh City | Shanghai | Atlanta | Baltimore | Wilmington | Miami | Boca Raton | Pittsburgh | North Jersey | Las Vegas | South Jersey | Lake Tahoe | Myanmar | Duane Morris LLP – A Delaware limited liability partnership

## Peer Review Protections-Roadmap

- New Jersey
  - Common law protections, with case law predating the Patient Safety Act
  - Statutory: Patient Safety Act (PSA), signed into law in 2004
- Federal: Patient Safety and Quality Improvement Act (PSQIA), signed into law in 2005
- Generally, these laws provide varying degrees of privilege to information generated by a hospital or health care practice in the process of a self-critical analysis after a near miss, preventable, or adverse event.

## Condition Self-Critical Analysis Privilege under NJ Case Law

- Prior to the Patient Safety Act, the NJ Superior Court discussed whether peer review materials were entitled to privilege in a malpractice suit brought by a patient where the patient sought to discover a copy of the hospital's peer review committee report.
- In *Christy v. Salem*, 841 A.2d 937 (N.J. Super. Ct. App. Div. 2004), the court held that peer review materials are not entitled to complete privilege. Rather, peer review materials, like other self-critical analyses are subject to a “conditional privilege.”
- The *Christy* court considered a medical malpractice plaintiff's private interest in discovering a hospital's peer review report versus the hospital's public quality of care interests in non-disclosure.
- Purely factual material in the report was discoverable, while “opinions, analysis, and findings of fact” were protected, with the exception of one sentence that could be “crucial...to the plaintiff's case.”

## Absolute Privilege under NJ Patient Safety Act (“PSA”)

- *Christy* was decided shortly before the PSA was signed into law in 2004, and is cited in the Act.
- The PSA’s goal was to improve patient safety by encouraging adverse event reporting and root cause analyses, and to create a non-punitive culture.
- The PSA created a confidential patient safety reporting system, and **absolute privilege** for information generated as a part of a self-critical analysis, *so long as the self-critical analysis is compliant with the PSA.*
- The PSA does not require a balancing test, only compliance with the PSA.

## NJ Patient Safety Act (“PSA”) – General Overview

- Applies to all health care facilities licensed pursuant to N.J.S.A. 26:2H-1 et seq., including hospitals and ambulatory care facilities
- Requires facilities to establish a patient safety committee, which must meet certain standards and perform specific patient safety activities
- Requires facilities to develop and implement patient safety plans, including creating processes for analyzing evidence-based patient safety practices, analyzing serious preventable adverse events, adverse events and near misses, and providing ongoing patient safety training
- Requires reporting serious preventable adverse events to the Department of Health and the affected patient

## NJ Patient Safety Act – Privilege

- Documents, materials, or information submitted to the Department of Health in accordance with the requirements of the PSA are confidential and not subject to discovery or admissible as evidence in any civil, criminal, or administrative action or proceeding
- Documents, materials, or information developed by facilities **exclusively** during the process of self-critical analysis in accordance with the process set forth in and requirements of the PSA are confidential and not subject to discovery or admissible as evidence in any civil, criminal, or administrative action or proceeding
- PSA does not prevent discovery of material that may have been considered in the process of self-critical analysis if it was obtained from any source or context other than those specified in the PSA (e.g., information that would otherwise be discoverable)

## Developments in NJ Case Law-Post PSA and *Christy*

- In 2014, the Supreme Court of New Jersey reviewed the absolute privilege under the PSA in an underlying medical malpractice case where a patient alleged her infant child was permanently disabled due to injuries sustained during birth in 2007 and sought discovery of a memorandum documenting a “round-table discussion” among Hospital staff conducted as part of an investigation of the patient’s delivery and neonatal care.
- The incident and round-table discussion took prior to the enactment of PSA’s implementing regulations in 2008. However, the round table discussion did comply with the PSA, including that no physicians participated in the discussion and the findings were not presented to the Patient Safety Committee.
- The NJ Supreme Court found the memorandum complied with the PSA itself, and was not required to comply with regulations not yet in effect, stating “*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.*”

## Developments in NJ Case Law-Post PSA and *Christy*

- The privilege was again addressed 2 years later by the NJ Superior Court in *Conn v. Rebustillo*, 138 A.3d 545 (N.J. Super. Ct. App. Div. May 4, 2016), which found that there are two categories of privilege with the PSA, one for documents the Department receives via mandatory reporting, and one generated during self-critical analysis.
  - A medical malpractice case, in which the hospital conducted a root cause analysis (“RCA”) “for the specific purpose of complying” with the mandatory reporting requirement
  - The hospital submitted the RCA to the Department
  - Distinguished from *Applegrad*’s consideration of procedural compliance with the PSA
  - **Holding:** For information submitted to the Department due to mandatory or voluntary reporting, the PSA does not condition privilege upon the satisfaction of any other criteria.
  - Noted that the trial court erred in relying on *Christy*’s balancing test in response to the plaintiff’s allegation that the hospital did not produce the report in compliance with the PSA
    - The court stated that the discovery issue was governed by the PSA

## Developments in NJ Case Law-Post PSA and *Christy*

- In 2018 the New Jersey Supreme Court held that that procedural compliance with the PSA is the “only precondition to application of the PSA’s privilege” in *Brugaletta v. Garcia*, 234 N.J. 225 (2018)
    - *Brugaletta* reversed a lower court finding that released a redacted version of a hospital’s incident report “produced for the sole purpose of complying” with the PSA
    - Found that the trial court exceeded its authority in finding that the defendant hospital erred in concluding that an incident was not a serious adverse event, redacting and releasing the incident report, and directing the hospital to report the adverse event to the Department
    - The finding that an event is not reportable does not abrogate the self-critical analysis privilege
    - In response to plaintiff’s argument that the court should have applied *Christy*, the Court reiterated that the plaintiff was entitled to purely factual, but not deliberative material
- This case led to a significant development in the self-critical analysis pathway to privilege

## Developments in NJ Case Law-Post PSA and *Christy*

*Brugaletta* formed the basis of the most recent PSA decision, which has significant implications for hospitals and health care facilities.

- *Keyworth v. CareOne*, 319 A.3d 464 (2024) & *Bender v. Harmony Village at CareOne Paramus*
  - *Facts:*
    - Two consolidated appeals—one where a patient at a skilled nursing facility fell and injured herself, another where a resident at an assisted living facility was attacked by another resident
    - Plaintiffs sought internal incident reports and associated documents drafted by patient safety committees at the facilities
    - Both facilities refused to provide the reports, claiming privilege under the PSA

## Recent Developments in NJ Case Law, Cont'd

- *Keyworth v. CareOne*, 319 A.3d 464 (2024)
  - Holding:
    - Court held that the incident reports drafted by the patient safety committees at each of the facilities were discoverable despite the privilege provision of the PSA
    - Court found that both facilities had failed to comply with the requirements of the Act—the “only precondition” to receiving privilege

## Recent Developments in NJ Case Law, Cont'd

- *Keyworth v. CareOne*, 319 A.3d 464 (2024)
  - Specifically, the facilities failed to comply with the PSA's requirement that patient safety committees "not constitute a subcommittee of any other committee"
    - the facilities' patient safety committees did not operate independently from other committees within the facility
    - The facilities treated their quality assurance and improvement committees as patient safety committees to comply with **both** the requirements of the PSA and their federal Quality Assurance and Performance Improvement requirements under the Federal Nursing Home Reform Act
    - These dual-purpose committees were noncompliant with the requirements of the PSA

## Recent Developments in NJ Case Law, Cont'd

- *Keyworth v. CareOne*, 319 A.3d 464 (2024)
- The exclusivity requirement for the patient safety committee is significant because other statutes may impose additional requirements regarding committees on health care facilities
- ***Takeaway from case:*** The decision highlights the necessity of procedural compliance with each of the requirements of the PSA in order to maintain privilege over adverse event reports.

## NJ Patient Safety Act– Patient Safety Committee Requirements

- Patient safety committee must meet certain requirements and standards set forth in the regulations, including:
  - Composition of committee must include the required members set forth in the PSA
    - Chairperson appointed by the CEO/administrator of the facility, medical director, chief nursing executive, risk manager, ad hoc members selected by the chairperson based on the relevance of their job responsibilities and experience to the conduct of a root cause analysis of a specific adverse event or near miss under investigation
    - Additional requirements/conditions must be met if a health care system owns multiple NJ facilities and wants to operate the patient safety committee at the system level
  - ***Patient safety committee cannot be a subcommittee of any other facility/health care system committee***
  - Chairperson of committee must report directly to the CEO or other administrative head of the system
  - Committee must meet at least quarterly, and minutes must contain certain content set forth in the PSA

## NJ Patient Safety Act– Patient Safety Committee Requirements

- Patient Safety Committee must perform certain specific activities, including:
  - Develop a written patient safety plan and review and revise as needed (and at least once every 3 years)
  - Develop training programs, share information regarding reporting, maintain internal tracking systems for reporting of adverse events and near misses
  - Develop and recommend measures to minimize the risk of preventable adverse events
  - Assure timely reporting of serious preventable adverse events
  - Review developments in patient safety practices and recommend changes to policies
  - Assemble a team to conduct a root cause analysis of all serious preventable adverse events, and at least one per year of a preventable adverse event not subject to mandatory reporting or a near miss reported to the committee
  - Analyze aggregated data quarterly in the internal tracking system to identify patterns
  - Document recommended changes to policies and whether they are adopted and monitor modified policies to determine their impact

## NJ Patient Safety Act– Written Patient Safety Plan Requirements

- The Patient Safety Plan must include the following elements:
  - A process for staff to follow in reporting preventable adverse events and near misses to the committee that is accessible at all times the facility is operating
  - A process for ongoing review & application of evidence-based patient safety practices
  - Policies to conduct RCAs of all serious preventable adverse events and annually at least one other preventable adverse event not subject to mandatory reporting, or a near-miss reported to the committee
  - A process for monitoring the impact of changes recommended by the committee and implemented by the facility
  - Policies for ongoing training for personnel (1x a year for staff and during new employee orientation) and documentation of such training

## NJ Patient Safety Act– Reporting

- The PSA includes reporting requirements, including:
  - Reporting of serious preventable adverse events that occur in the facility to the Department of Health in the required timeframes and submission of an RCA that includes certain required components.
  - Disclosure to the patient of any serious preventable adverse event that affected the patient and any adverse event resulting from an allergic reaction that was not previously documented in the patient's chart.
  - Procedures for informing employees of the option to submit voluntary reports to the Department of Health of preventable adverse events not subject to mandatory reporting and near-misses.

## Federal-Patient Safety and Quality Improvement Act (PSQIA)

- Applies to entities and individuals licensed to provide health care services, including long term care facilities, ambulatory surgical centers, physicians, and pharmacies.
- Establishes a voluntary reporting system in which providers may report to patient safety organizations information regarding improving safety, health care quality or patient outcomes.
- Protection only for patient safety work product (“PSWP”), which is information (1) prepared by a provider for reporting to a patient safety organization; (2) developed by a patient safety organization for the conduct of patient safety activities; and (3) that identifies or constitutes the deliberations or analysis of/identifies the fact of reporting pursuant to a patient safety evaluation system.
- PSWP excludes information collected or maintained *separately* from a patient safety evaluation system.

## PSQIA, Continued

- Generally, protects patient safety work product from subpoena in proceedings against providers, discovery in civil/criminal/administrative proceedings, Freedom of Information Act requests, and inclusion in professional disciplinary proceedings
- Exceptions to privilege include HHS secretary investigations; use in a criminal proceeding in certain circumstances; for equitable relief under the Public Health Service Act; in the case of provider authorizations; and certain disclosures of non-identifiable PSWP

## Takeaway from Self-Critical Analysis Case Law

- Defendants likely will not continue to rely on the common law self-critical analysis privilege under *Christy* with respect to materials not exclusively developed under the PSA
- *Christy* does not necessarily provide additional protections to materials, and the court has not clearly applied it in post-PSA cases
- In fact, the PSA stated explicitly: “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.”
- Thus, it may be more apt to structure critical analysis to fit within the guaranteed privilege of the PSA, rather than hoping for *Christy*’s subjective balancing test as a backstop

## Key Takeaways-PSA

- Strict compliance with **ALL** of the relevant procedural regulations in the PSA is a prerequisite for the PSA privilege to apply
- ***Patient safety committee must operate independently from other committees within the facility***
- Investigations that are undertaken pursuant to other laws are not shielded by the PSA privilege, nor are documents or information that may have been considered in the process of self-critical analysis if obtained from any source or context other than those specified in the PSA

## Questions?

Erin Duffy

[emduffy@duanemorris.com](mailto:emduffy@duanemorris.com)