

Katten

ECRI Institute

Wednesday, June 17, 2020

**Recent Contrasting and Conflicting
Patient Safety Act Opinions and
Lessons Learned**

Michael R. Callahan, Of Counsel
Katten
312-902-5634
michael.callahan@katten.com

Program Goals

- Summarize, contrast and compare the decisions in *Rumsey v. Guthrie Medical Group* and *Ungurian v. Beyzman*
- Identify the courts' errors in the *Ungurian* decision and how they affected the outcome
- Identify what should be considered peer review and patient safety activities
- Instruct how to maximize the Patient Safety Act protections based on lessons learned from these and other court rulings

Rumsey v. Guthrie Medical Group (U.S. Dist. Ct. N. Dist. Penn. (September 26, 2019))

- **Background**

- This is a medical malpractice case arising from a claim that the defendants failed to test or treat him for a MRSA infection which became worse subsequent to an elective procedure.
- The case was in federal court based on diversity jurisdiction.
- Plaintiff sought to discover information regarding Guthrie's infection-prevention procedures.
- Defendant Clinic asserted privilege protections under the:
 - PSQIA
 - Pennsylvania Medical Care Availability and Reduction of Error Act ("MCARE")
 - Pennsylvania Peer Review Protection Act

Rumsey v. Guthrie Medical Group (U.S. Dist. Ct. N. Dist. Penn. (September 26, 2019))

- **Disputed Documents and Decision**

- “A copy of all infection prevention and infection control materials which Defendants’ received prior to May 1, 2017 from Vizient PSO and/or any other company”
 - MCARE does not apply to Vizient materials because it only protects documents “solely prepared or created for the purpose of complying with [state law] or of reporting...”
 - MCARE only applies to providers. Vizient is not and therefore MCARE did not provide any protection to prevent discovery.
 - The court, however, found that the PSQIA applies to documents produced by a PSO for the purpose of conducting patient safety activities and therefore the Vizient materials were privileged under the Act.

Rumsey v. Guthrie Medical Group (U.S. Dist. Ct. N. Dist. Penn. (September 26, 2019))

- “A copy of any and all correspondence and communications between defendant and any federal, state, county or local governmental agency within the past 5 years on the subject of infection prevention, infection reporting, infection management and infection rates”
 - Government correspondence is not part of Guthrie’s PSES and was not reported to Vizient PSO.
 - Consequently, these communications are not privileged under the PSQIA or any other statute.
- “A copy of Defendant’s agenda, notes and any and all written records of Defendant’s monthly (or other than monthly) quality committee meetings...insofar as they discuss infection prevention or infection control”
 - “The is the quintessential example of patient safety work product”
 - “Quality committee meetings are a core aspect of Guthrie’s [PSES]”

Rumsey v. Guthrie Medical Group (U.S. Dist. Ct. N. Dist. Penn. (September 26, 2019))

- ““Agendas, notes and other written records from these meetings are squarely work product and are ‘deliberations or analyses’ of a [PSES]”
- All of these materials are privileged under the PSQIA, MCARE and the Pennsylvania Peer Review Protection Act
- Deposition of Clinic witness about quality committee meetings, knowledge gained through the PSES, how the committee meetings determine infection preparedness, the data used to reach preparedness conclusions and why they collected certain data and not others.
- This information was privileged because the questions sought information generated within the PSES
- Policies are not privileged

Impact and Takeaways

- Stresses the importance of a provider's PSES policy and detailed identification of patient safety activities and what is considered and treated as PSWP
- Multiple privilege statutes can apply – they are not mutually exclusive
 - First reported case to rely on “deliberations and analyses” standard for creating PSWP
 - Policies are not protected
 - Communications with government officials are not protected
 - Does not rely on the “sole purpose” standard which is a requirement under MCARE although the court did reference that documents were prepared “for reporting to a PSO”

Ungurian v. Beyzman, Sup. Ct. of Pennsylvania (2020 PA Super. 105 (April 28, 2020))

- **Background**

- Plaintiff is a mother who sued the hospital and multiple physicians and other corporate entities alleging negligence during a cystoscopy procedure to remove kidney stones which led to the total and permanent incapacity of her son
- During discovery, the Plaintiff served requests for documents and interrogatories on all the Defendants
- Hospital asserted that five of the documents requested were privileged from discovery under the Patient Safety Act and/or the Pennsylvania Peer Review Protection Act (“PRPA”)

Ungurian v. Beyzman, Sup. Ct. of Pennsylvania (2020 PA Super. 105 (April 28, 2020))

- The disputed documents were:
 - an event report relating to “surgery, treatment, test, invasive procedure” prepared by a clinical leader (the “Burry Report”)
 - a Serious Safety Event Rating Meeting Summary
 - meeting minutes from the Patient Safety Committee
 - a Root Cause Analysis Report
 - the Hospital’s Quality Improvement Staff Peer Review Report, prepared by an outside physician
- In response to the Plaintiff’s Motion to Strike Objections and Compel Responses, the hospital’s Response included a single affidavit prepared by the Director of Patient Safety Services
- The affidavit stated that the Burry Report was “completed in compliance with Hospital’s Event Reporting Policy” and the RCA was maintained “within its [Event Reporting Policy] for reporting to CHS PSO, LLC and that it electronically submitted the Root Cause Analysis Report to CHS PSO, LLC”

Ungurian v. Beyzman, Sup. Ct. of Pennsylvania (2020 PA Super. 105 (April 28, 2020))

- The hospital did not assert the Patient Safety Act privilege protections regarding the other three documents
- There were multiple hearings and trial court orders regarding the ongoing discovery dispute, but ultimately the trial court ruled that neither the Patient Safety Act nor the PRPA protected any of the documents and, therefore, ordered the hospital to produce them
- The hospital filed an appeal from the various orders, including that they produce the credentialing files of all practitioners who provided care to the Plaintiff's son as well as any National Practitioner Data Bank Query Responses
- The Appellate Court granted the appeal because it has jurisdiction when such disputes involve assertion of a privilege

Ungurian v. Beyzman, Sup. Ct. of Pennsylvania (2020 PA Super. 105 (April 28, 2020))

- **The Burry Report**

- The hospital submitted a single affidavit, which was fairly comprehensive in terms of its relationship with the PSO and its development of a PSES policy which was facilitated by its use of the Event Reporting System (“ERS”) for the purpose of improving patient safety
- It was this procedure that resulted in preparation of documents such as the Burry Report
- The trial court, however, determined that it did not qualify as PSWP because the affidavit did not state that the Report was prepared for the purpose of reporting to the PSO
- The court cited language in the affidavit that the ERS system “is used to manage information that MAY be reported to the PSO”
- Therefore, the trial court stated that “it could have been developed for a purpose other than reporting to a PSO and still be managed within the ERS”

Ungurian v. Beyzman, Sup. Ct. of Pennsylvania (2020 PA Super. 105 (April 28, 2020))

- The Appellate Court agreed with the trial court's analysis because the hospital had failed to assert in the affidavit that it prepared the Burry Report for the purpose of reporting to a PSO and in fact reported it to the PSO
- It is very important to note that in the hospital's appellate brief, it stated the Burry Report was indeed submitted to the PSO but because no assertion was included in the affidavit and because the record on appeal did not include any evidence that the hospital had indeed made a report, the Appellate Court declined to accept this belated claim

Ungurian v. Beyzman, Sup. Ct. of Pennsylvania (2020 PA Super. 105 (April 28, 2020))

- **RCA**

- In ruling that the RCA did not qualify as PSWP, the trial court found that the affidavit did not state that it was “also developed for the purpose of reporting to the PSO”
- In addition, it noted the hospital had admitted that the “information contained in the RCA ‘is not solely in the PSES’”
- Therefore, because the RCA existed outside of the PSES, it was not privileged under the Patient Safety Act
- The Appellate Court agreed with this analysis

Legal Analysis

- **“Information contained in the RCA is not solely in the PSES”**
 - This statement by the Appellate Court, taken to its extreme, would mean that no information which is collected and maintained within a provider’s PSES would ever qualify as PSWP if the information appears elsewhere or is used outside the PSES
 - Under the Patient Safety Act, providers are specifically expected to use PSWP for all internal purposes which are not limited to patient safety activities identified in the PSES
 - Using an RCA as an example, these reports include facts from the medical record and other sources which are not necessarily privileged
 - Any discussion and analyses that take place in the PSES will include facts and the work product from these PSES identified patient safety activities are shared with committees, work force members and others in their collective effort to improve patient safety and reduce risk

Legal Analysis

- In a number of reported cases, Plaintiff's have argued that because a claimed PSWP document, such as an incident report, contained facts which are not privileged, the report itself cannot be privileged
- Courts have rejected this argument consistently recognizing that any privileged analysis will always include a discussion of the underlying facts on which the incident report, RCA, etc., is based. (See *Daley v. Ingalls Memorial Hospital*)

Legal Analysis

- **“Burry Report collected in the ERS did not qualify as PSWP because the affidavit said that such reports ‘may be reported to the PSO’ and there was nothing in the record establishing that it was reported”**
 - What is not clear in the decision is whether the hospital submits only some ERS reports to the PSO and those which it does not are considered privileged discussions or analyses (“D or A”)
 - There is no discussion about the D or A pathway for creating PSWP
 - The court does not cite to the *Rumsey v. The Guthrie Clinic* decision or the *Daley* decision as part of its analysis even though both cases involved a medical malpractice action in which the hospitals were asserting privilege protections under the Patient Safety Act

What is “Peer Review”?

- The process of improving quality and safety in healthcare organizations
- Privileging and credentialing
- Performance of a medical or quality assurance review function
- Utilization review
- Concurrent and retrospective review of medical cases and adverse events
- Root cause analysis
- FPPE and OPPE
- Collegial intervention
- Monitoring, proctoring, consultation requirements and similar remedial measures
- Medical research

Lessons Learned and Recommendations

- The heavy burden of establishing that documents and other information are privileged under state laws or the Patient Safety Act is on the provider
- Courts do not like privilege statutes and will look for various ways to rule against the assertion of a privilege
- Most courts have no knowledge or experience in working with or interpreting the Patient Safety Act which makes it imperative that providers seek to effectively educate the court about the Act with citations to favorable cases, including but not limited to *Daley v. Ingalls Memorial Hospital* and *Rumsey v. The Guthrie Clinic*
- The use of detailed affidavits also is essential to establish compliance with all of the required elements of the Act including the so-called missing assertions as determined by the trial and Appellate Court in this case
- You make your record at the trial level and cannot supplement on appeal
- In addition to a fully detailed affidavit you should consider including the PSES policy which hopefully includes provisions which support the privilege claim as well as the documents or information in dispute

Lessons Learned and Recommendations

- Consider adding screenshots of either blank forms, reports, etc., of what you treat as PSWP and/or provide the documents in dispute, but with the privileged information redacted.
- Consider submitting the documents for an in camera inspection to the court if this might work in your favor. This obviously is a judgment call that you make with legal counsel. If you choose this route, make sure you obtain a protective order and that you use the written authorization permissible disclosure exception under Final Rule Section 3.206(b)(3)
- Use defense attorneys who are well acquainted with your PSES and related policies, the Patient Safety Act and how to assert the privilege and/or with outside legal experts who can assist and collaborate with the provider's defense attorney
- Your PSES policy should be reviewed and updated to capture all of the patient safety activities, reports, analyses, etc., for which you want to assert the privilege protections under the Patient Safety Act

Lessons Learned and Recommendations

- The PSES policy should specifically delineate what information is being reported to the PSO and what information is being treated as deliberations or analysis
- If the provider is collecting all of certain reports within its PSES but only reporting some of them, the unreported ones should be identified as D or A if you intend to keep them privileged as well.
- Although there is no time limit as to when a document must be reported, if that is your intent, not reporting them within a reasonable time period will be used against you.
- If holding on to a report for a particular purpose for a longer period of time than usual, you should document the reasons for doing so.
- Keep in mind that once collected and maintained in the PSES and not dropped out, the information remains privileged PSWP. It is not clear whether the hospital made this argument or not.

What is “Peer Review”?

- Efforts to improve patient care and reduce morbidity or mortality
- Tracking, investigating and managing unacceptable behavior identified in Code of Conduct - Disruptive Behavior Policies
- Physician wellness evaluations and activities
- Evaluating healthcare providers regarding performance, skill, technique, competence, utilization and compliance with hospital and medical staff bylaws, rules, regulations and policies
- Review and establishment of standards of care
- Analyses undertaken for the purpose of reducing the risk of harm
- Peer review investigations and hearings
- All of the discussions, analyses and work product produced by these activates

How to Maximize Peer Review Privilege Protections

- Know your state laws and the Patient Safety Act
 - What is the scope of covered activities?
 - What provider and other entities can assert the privilege?
 - Can the privilege be waived and, if so, how?
 - Can privileged documents be shared by and between affiliated entities whether licensed providers or not?
 - Can identifiable physician Peer Review information be shared among affiliated providers?
 - Is the privileged information protected from discovery and admissibility into evidence?
 - Do the protections apply in both states and federal proceedings?

How to Maximize Peer Review Privilege Protections

- Can the privileged information be shared with third parties and, if so, how?
- How can or how should the privileged information be shared internally?
- Is the information only privileged if it is initiated by or through designated committees?

How to Maximize Peer Review Privilege Protections

- Know how the state and federal courts have interpreted the laws
- Define what you consider to be “Peer Review” activities and what you are treating as privileged information with an eye towards the answers to the questions above as well as the language and interpretation of state laws and the Patient Safety Act
- Create policies and procedures which reflect these standards and decisions and interpretations such as in your Patient Safety Evaluation System (“PSES”) Policy
- Continue to track statutory and case law developments and update your policies and procedures accordingly
- Disclose your policies and procedures as evidence to support your assertion of privileged protections
- Use detailed affidavits to help educate the court as to your compliance with the state and federal privileges including the use of screenshots, redacted PSWP and other related information

How to Maximize Peer Review Privilege Protections

- Remember, the state and the Patient Safety Act privileges are not mutually exclusive – both can be asserted depending on the documents and information in question
- Remember too that the Patient Safety Act provides more protection than the laws in the New York, Pennsylvania and West Virginia and therefore you should lead with the Patient Safety Act privilege
- BUT consult with your legal counsel

Katten Locations

CHARLOTTE

550 South Tryon Street
Suite 2900
Charlotte, NC 28202-4213
+1.704.444.2000 tel
+1.704.444.2050 fax

CHICAGO

525 West Monroe Street
Chicago, IL 60661-3693
+1.312.902.5200 tel
+1.312.902.1061 fax

DALLAS

2121 North Pearl Street
Suite 1100
Dallas, TX 75201-2494
+1.214.765.3600 tel
+1.214.765.3602 fax

HOUSTON

700 Milam Street
Suite 1300
Houston, TX 77002-2736
+1.713.270.3400 tel
+1.713.270.3401 fax

LONDON

Paternoster House
65 St Paul's Churchyard
London EC4M 8AB
United Kingdom
+44 (0) 20 7776 7620 tel
+44 (0) 20 7776 7621 fax

LOS ANGELES – CENTURY CITY

2029 Century Park East
Suite 2600
Los Angeles, CA 90067-3012
+1.310.788.4400 tel
+1.310.788.4471 fax

LOS ANGELES – DOWNTOWN

515 South Flower Street
Suite 4150
Los Angeles, CA 90071-2212
+1.213.443.9000 tel
+1.213.443.9001 fax

NEW YORK

575 Madison Avenue
New York, NY 10022-2585
+1.212.940.8800 tel
+1.212.940.8776 fax

ORANGE COUNTY

100 Spectrum Center Drive
Suite 1050
Irvine, CA 92618-4960
+1.714.966.6819 tel
+1.714.966.6821 fax

SHANGHAI

Suite 4906 Wheelock Square
1717 Nanjing Road West
Shanghai 200040
P.R. China
+86.21.6039.3222 tel
+86.21.6039.3223 fax

WASHINGTON, DC

2900 K Street NW
North Tower - Suite 200
Washington, DC 20007-5118
+1.202.625.3500 tel
+1.202.298.7570 fax

Katten refers to Katten Muchin Rosenman LLP and the affiliated partnership as explained at katten.com/disclaimer.

Attorney advertising. Published as a source of information only. The material contained herein is not to be construed as legal advice or opinion.