THE TRANSFORMATION OF HEALTHCARE: FACING THE FUTURE TOGETHER

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THE TRANSFORMATION OF HEALTHCARE: FACING THE FUTURE TOGETHER

YEAR IN REVIEW: LEGAL DEVELOPMENTS AFFECTING MSPs

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

COVID-19

EEOC Attack On Late Career Physician Policies

Peer Review Privilege

Peer Review Privilege

- **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 because 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

Peer Review Privilege

- **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 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.

Peer Review Privilege

- "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 was not part of Guthrie's PSES.
  - Consequently, these communications are not privileged under 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]"

Peer Review Privilege

- “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

Peer Review Privilege

- **Ungurian v . Beyzman, 2020 PA Super. 105 (No. 298 MDA 2019) (April 28, 2020)**
  - **Background**
    - This is another medical malpractice case in which the mother of the plaintiff sued the hospital and multiple physicians alleging negligence during the cystoscopy procedure to remove kidney stones which led to the total and permanent incapacity of her child.
    - The documents in dispute during discovery included an event report, a serious safety event rating meeting summary, meeting minutes from the patient's safety committee, a root cause analysis report and the hospital's Quality Improvement Staff Peer Review Report.
    - The hospital asserted privilege protections under the Patient Safety Act and the Pennsylvania Peer Review Protection Act

Peer Review Privilege

- **Courts Opinions**
  - The trial court and appellate court rejected the hospital's assertion of both privileges, although applied differently to the different documents in dispute, claiming that the plaintiff did not meet the required standards for obtaining privileged protection under both statutes in addition to relying on a previous Pennsylvania Supreme Court case that very narrowly construed the scope of privilege protections under the Pennsylvania law
  - The case currently has been appealed to the Pennsylvania Supreme Court
  - See attached summary and recommendations concerning this decision

Peer Review Privilege

- **Hyams v . CVS Health Corporation, Northern Dist. Cal., Case No. L.18-cv-06271-BJH (LVN) (December 11, 2019)**
  - **Background**
    - This is yet another medical malpractice action and first reported decision in the state of California to interpret the scope of privilege protections under the Patient Safety Act.
  - **Court's Decision**
    - This district court decision provides the most detailed analysis of the "deliberations or analysis" method of creating privileged patient safety work product ("PSWP") as distinguished from information which is actually reported to a patient safety organization as the other basic method of obtaining privilege protections

Peer Review Privilege

- **Lessons Learned**
  - Although some courts have held that the document which contains non-privileged factual information commingled with privileged patient safety work product is not subject to discovery, this court held that the non-privileged information portion of the document is not protected and therefore must be disclosed while redacting the privileged portion of the information
  - Privilege protections under the Patient Safety Act and state laws are not mutually exclusive. both can be asserted if the provider complies with the requirements under both statutes and if the hospital/provider participates in a patient safety organization.
  - Know and understand the language and requirements in all applicable statutes as well as to be aware of how the statutes are being interpreted by the courts.

Peer Review Privilege

- Key to asserting the privilege protections is the development of appropriate policies and procedures which demonstrate the scope of information the provider is seeking to keep privileged and confidential and not subject to discovery or admissibility into evidence
- Use detailed affidavits which demonstrate compliance with applicable laws and case law
- Be careful not to commingle privileged and non-privileged information in a physician's credentials file
- Because most state courts have not addressed the scope of privilege protections under the Patient Safety Act it is extremely important to educate the court regarding this law through use of policies, affidavits, screen shots of forms being collected or reported to a pso and other similar supporting materials

Doctrine of Corporate Negligence

Doctrine of Corporate Negligence

- **Tharp v. St. Luke's Surgerycenter-Lee's Summit LLC (587 S.W. 3d 647) (December 10, 2019)**
  - **Background**
    - This is a medical malpractice action in which the Plaintiff underwent a laparoscopic cholecystectomy to remove his gallbladder. Plaintiff alleges that the surgeon damaged his hepatic duct and common bile duct during the procedure causing bile leakage, inflammation and liver damage
    - Plaintiff brought a negligent credentialing claim against the hospital arguing that it failed to follow its bylaws because the hospital did not automatically remove the defendant physician from consideration during the application process because the physician had failed to provide a complete listing of the number of lawsuits in which he was a named defendant. Had they done so, the physician would not have had the opportunity to operate on the Plaintiff

Doctrine of Corporate Negligence

- The jury ruled in favor of the Plaintiff despite the hospital's argument that there was insufficient evidence to establish that it breached any duty owed to the Plaintiff and that the act of granting privileges was not the proximate cause of the Plaintiff's injuries
- The case was appealed and eventually the Supreme Court of Missouri accepted the appeal and addressed for the first time whether the State of Missouri acknowledges the Doctrine of Corporate Negligence

Doctrine of Corporate Negligence

- **Court's Decision**
  - The Court determined that the hospital owes a duty to its patients to credential only competent and careful physicians because it is foreseeable that incompetent or generally careless physicians could injure the hospital's patients
  - A Defendant breaches this duty when it fails to exercise reasonable care to perform its undertaking. In this case, a hospital fulfills its duty by using reasonable care to credential competent and careful physicians
  - Although the Court acknowledged that had the surgeon not been granted privileges because of his failure to list all prior malpractice cases, the hospital's failure to follow its bylaws alone is insufficient to show a breach of duty to credential a competent and careful surgeon. There was no evidence showing he was unqualified due to the number of lawsuits the surgeon had defended

Doctrine of Corporate Negligence

- Without evidence showing a reasonable investigation into the surgeon's background and qualifications would have revealed he was unqualified to perform laparoscopic cholecystectomies. There is no evidence that the hospital breached its duty to the Plaintiff to credential competent and careful physicians
- Even if the hospital had breached its duty, the Plaintiff must present evidence that credentialing the surgeon caused the Plaintiff's injuries
- To prove causation under the negligent credentialing theory, a Plaintiff must show:
  - But for the hospital's breach of its duty to credential a competent careful physician, the Plaintiff would not have been injured
  - The Plaintiff's injuries were a natural and probable consequence of the breach of this duty. Otherwise there is nothing to link a hospital's act of credentialing a physician to the patient's injuries

Doctrine of Corporate Negligence

- The fact that a physician may be negligent does not automatically mean that the hospital is negligent under the theory of negligent credentialing unless the patient's injuries were the result of the hospital's breach of its duty to the patient
- Although the court determined there was insufficient evidence to support the Plaintiff's negligent credentialing claim, the case was remanded for a new trial because up until the point of this decision the standard for proving a negligent credentialing claim had never been established. The Plaintiff was given a new opportunity to refile and resubmit evidence to establish a claim based on the Supreme Court's Decision

Doctrine of Corporate Negligence

- **Johnson v. Lutton, No. 1:19-CV-1877 (M.D. Penn. June 10, 2020)**
  - **Background**
    - Plaintiff brought a medical malpractice against the hospital and an orthopedic group when he developed a MRSA infection that resulted in a series of life-threatening medical issues
    - These claims included a corporate negligence claim against the group and the hospital for their collective failure to enforce appropriate policies and procedures to ensure patient safety by:
      - failing to provide sterile environments for surgeries,
      - maintain a facility free of MRSA,
      - require physicians to perform pre-surgery MRSA screenings,

Doctrine of Corporate Negligence

- properly credential physicians,
- require physicians to personally examine patients post-operation and have proper informed consent procedures in place.
- The orthopedic group filed a motion to dismiss claiming that corporate negligence charges against a physician group are “inconsistent with” Pennsylvania law

Doctrine of Corporate Negligence

- **Court's Decision**
  - The court denied the group's motion to dismiss, noting that whether a duty is owed by a medical corporation to a patient is a function of the specific relationship between the entity and the patient at issue and that such a duty is not a function of the breadth of the role the hospital assumes in the patient's care more generally
  - Thus, the doctrine in corporate negligence is a viable claim to bring against a physician group depending on the evidence

Doctrine of Corporate Negligence

- **Lessons Learned**
  - The best way to defend against a corporate negligence claim is to make sure that the hospital and the medical staff take reasonable steps consistent with standards in the industry to determine whether a physician is currently competent to exercise all of the clinical privileges which they are granted at time of appointment and reappointment
  - Because of Joint Commission standards under FPPE and OPPE requirements, this determination of current competency is an ongoing obligation and appropriate actions must be taken if competency is questioned and not wait until the time of reappointment
  - Comply with medical staff bylaws, appointment and reappointment procedures, credentialing manuals, and make sure to obtain any and all information needed in order to determine competency is critical

Doctrine of Corporate Negligence

- The Doctrine can be applied to any entity or organization which engages in appointment, reappointment and other assessments of competency which includes hospitals, surgery centers, physician groups and managed care organizations
- It is important to determine whether your state has adopted the Doctrine of Corporate Negligence as an acceptable legal theory as well as what the Plaintiff must establish in order to prove their case so that the hospital and the medical staff can take appropriate actions in order to defend against such claims
- Make sure you are taking steps to maximize your state and/or federal privilege protections so as to prevent discovery of information that the plaintiff can use to support its liability claims, including negligent credentialing, against the provider entity.

Data Bank

Data Bank

- **Long v. U.S. Department of Health and Human Services (422 F. Supp. 3d 143 (2019)**
  - **Background**
    - This case involves a lawsuit brought by an orthopedic surgeon who challenged a hospital's decision to report him to the Data Bank after he resigned while "under investigation" relating to concerns regarding his disruptive behavior as well as a series of post-operative infections which had been identified under their peer review process and which have been sent out for professional review
    - The physician had alleged that the hospital's decision in reporting him to the Data Bank was not based on professional competence or behavioral issues but because he had set up a competing MRI facility near the hospital and therefore the procedures which triggered the investigation were based on a "sham"

Data Bank

- The physician had petitioned HHS on two occasions challenging the ability of the hospital to submit a report based on his claimed retaliation for competitive reasons, both of which were rejected by HHS
- The physician subsequently filed suit in federal court seeking to challenge HHS's decision to accept the hospital's report

Data Bank

- **Court's Decision**
  - This is a very good opinion to read in identifying the process by which the Data bank reviews a disputed report submitted by a physician
  - The basic rule of the Data Bank is simply to determine whether the report is correct from a factual standpoint as well as to determine whether the action taken was indeed reportable pursuant to Data Bank guidelines
  - In this particular dispute, the Data Bank had reviewed an extensive record regarding the hospital's communications and decisions relating to the physician's disruptive behavior, post-op infection rate and adverse impact it had on hospital operations

Data Bank

- The Data Bank also addressed the physician's claim that the triggered "investigation" had, in fact, terminated and was not continuing. It pointed out that despite the fact that he had resigned, a review of the identified quality of care and related problems were ongoing and that no "final action" had been taken by the Board of Directors.
- The Data Bank also considered along with HHS whether the investigation was a pretext for anti-competitive behavior by the hospital which led to the imposition of the investigation included a requirement that he seek a psychiatric evaluation in the form of a fitness for duty evaluation
- After extensively reviewing the requirements under the Data Bank Guide Book at the time, as opposed to the most recent revisions, the Federal Court determined that the hospital's report was indeed based on professional competency rather than an anti-competitive response to the physician's MRI facility

Data Bank

- As a result, because the physician resigned while under investigation and prior to any final action, his decision to resign was reportable under Data Bank requirements
- There are a couple of disturbing rulings, however, which were reached by the Federal Court which include:
  - The court viewed a fitness for evaluation examination as a type of investigation
  - It viewed the recommendations made by the MEC and others as a “professional review action” rather than routine peer review even though no hearing rights had yet been triggered

Data Bank

- **Naini v. King County Public Hospital District Number 2 No. C19-0886-JCC (W.D. Wash. December 20, 2019)**
  - **Background**
    - Case involves a physician who's termination based on quality of care concerns was reversed by a trial court because the physician had not received his hearing rights but later was summarily suspended based on a subsequent case in which a patient had died
    - This suspension was lifted because the physician agreed to voluntarily relinquish his privileges while under investigation
    - Based on this relinquishment, the hospital advised the physician that they were going to report him, as required to the National Practitioner Data Bank
    - The physician sought a temporary restraining order to prevent the hospital from reporting him.

Data Bank

- Plaintiff argued that he would be subjected to irreparable harm if reported to the Data Bank and further, the hospital had engaged in a bad faith sham proceeding leading up to his initial termination and subsequent suspension

Data Bank

- **Court's Decision**
  - In citing to other court cases, the court acknowledged that a report to the Data Bank could result in irreparable harm to a physician's reputation and livelihood
  - The court also noted that if the hospital's actions to date represented a sham peer review a report to the Data Bank also would be troubling and could serve as grounds to enjoin the hospitals decision to file a report
  - That said, the court pointed out that the requirement to report in light of the physician's decision to relinquish privileges while under investigation is specifically required under federal law and could place the hospital in the position of being sanctioned by the government

Data Bank

- Furthermore, there is an administrative process by which a physician can challenge a hospital's decision to report in terms of whether the action was required to be reported and whether the report is factually accurate
- The court, however, expressed concern that the public's interest might be adversely effected if physicians were able to obtain injunctive relief every time a hospital was seeking to submit a report as required under federal law.
- After considering the balance of the equities as well as the congressional mandate to report in determining that there was no basis and the record to suggest that the hospital was in any way engaged in sham peer review proceedings, the court denied the physician's request for injunctive relief.

Data Bank

- **Lessons Learned**
  - A hospital's medical staff should define within its bylaws when an “investigation” is triggered which should be when a request for corrective action is submitted to the : Medical Executive Committee and only when the MEC decides to initiate an investigation either on its own or through an ad hoc committee
  - All other peer review actions, including imposition of an FPPE program, should be considered routine peer review rather than an investigation
  - Efforts should be made to pursue “collegial intervention” and other remedial measures which do not trigger hearing rights in lieu of requesting formal disciplinary/corrective action to the MEC

Data Bank

- The Data bank's interpretation of when an investigation is triggered should largely be avoided if not ignored in order to permit the hospital and the medical staff to engage in remedial actions that are designed to improve patient care and to assist the physician in adhering to quality of care and other standards
- The hospital and medical staff should utilize Physician Wellness and Code of Conduct provisions rather than pursue the corrective action/remedial action pathway if appropriate so as to avoid the determination that these trigger "investigations" for Data Bank reporting purposes
- The court's decision that a fitness for duty evaluation is an investigation is clearly wrong and should be clarified within the hospital's and medical staff's bylaws and procedures accordingly

Data Bank

- Involuntarily relinquishment while under investigation which lasts for more than 30 days is reportable to the Data Bank and the physician should be so apprised in advance of the report out of fairness.
- Familiarize yourself with what actions are and are not reported to the Data Bank. Furthermore, you should generally limit hearing rights to actions that are reportable to the Data Bank or to another governmental agency

Employment Files

Employment Files

- **Spurgeon v. Mercy Health – Anderson Hospital, (No. C-190271) Ohio Ct. App. May 27, 2020**
  - **Background**
    - Case involves a medial malpractice action against the hospital and several other defendants alleging it's nurses, physicians, and other healthcare providers failed to properly diagnose and treat their newborn son's severe meningitis, causing him to suffer permanent brain damage
    - During discovery, the Plaintiffs attempted to obtain the completed employee files of several nurses which were employed by the hospital
    - The hospital had argued that the documents were created by nursing peers for the sole purpose of quality control and were privileged and confidential under the state's peer review privilege statute.
    - The hospital appealed

Employment Files

- **Spurgeon v. Mercy Health – Anderson Hospital, (No. C-190271) Ohio Ct. App. May 27, 2020 (cont'd)**
  - **Court's Decision**
    - Appellate Court rejected the hospital's arguments because it failed to establish that it had a peer review committee for nurses and that simply asserting that there was a "quality assessment process applicable to the nursing staff" did not prove that a committee existed
    - Even if the hospital had such a peer review committee nothing in the record established that a committee ever investigated the case at issue or that the disputed documents were generated exclusively for a peer review committee

Employment Files

- **Lessons Learned**
  - Documentation regarding the structure and purpose of peer review committees in order to assert the privilege is critical
  - Here, there was no evidence that a committee even existed. Even if some of the quality records were created as a result of the adverse incident these were unrelated to nurse employment records
  - It is important to keep confidential peer review information separate and apart from an employee's human resources or employment files because employment files are generally discoverable and must always be made available if requested by the employee.
  - Privileged information which is inadvertently included in an employee's HR files also are not subject to discovery in state and/or federal courts and therefor cannot be used to defend against an employment discrimination, breach of contract or other similar lawsuit

Employment Files

- HR is not prohibited from reviewing internal privileged peer review information regarding an independent contractor or an employee but HR should be creating separate documents which can be included in the employee's HR files and therefor can be used if disciplinary action is taken so as to be introduced into evidence in a subsequent employment lawsuit.
- Similarly, it is important to keep separate a practitioner's "credentials file" which typically includes appointment and reappointment application information and other documentation which is not privileged from the practitioner's "quality file" which does include and should be limited to privileged information under state and or federal law

Hearing Rights

Hearing Rights

- **Jurenovich v. Trumbull Memorial Hospital (Case No. 2018-T-0037, OH. Ct. App., May 8, 2020**
  - **Background**
    - This case involves a physician who was immediately terminated from the medical staff because he did not advise the hospital that he had been sued for Medicare fraud which eventually was settled and dismissed
    - The medical staff bylaws imposed an obligation and responsibility on medical staff members to notify the CEO and president of the medical staff within 14 days if: "he/she is subject to a final judgment or settlement, in any court proceeding alleging that he/she committed professional negligence or fraud"
    - They further stated that: "failure to provide any such notice as required above, shall result in immediate loss of medical staff membership and clinical privileges"

Hearing Rights

- The physician argued that he should have been provided with his fair hearing rights which also were included in the bylaws and these rights superseded the Bylaw provision which was relied on by the hospital to automatically terminate him.
- He also claimed that this breach of the bylaws was a violation of his due process rights.
- The trial court ruled on behalf of the hospital and granted summary judgement.

Hearing Rights

- **Court's Decision**
  - On appeal, the court noted that medical staff bylaws are considered a contract under Ohio law
  - Under contract law, courts are required to look at the plain language of the contract where it is clear and unambiguous in order to determine the rights and obligations of the parties.
  - The court further noted that when two provisions in a contract have conflicting language, the provision that specifically relates to the underlying subject matter controls over the general
  - In this matter, the courts observed that the hearing provisions did not specifically apply to those circumstances of when a physician is terminated for failing to provide proper notice whereas the notice provision in the bylaws gave the physician the opportunity to seek a waiver from the board of directors which he failed to do.

Hearing Rights

- **Lessons Learned**
  - Your Bylaws should specifically identify what actions, if recommended or taken, trigger hearing rights and which do not so as to avoid confusion.
  - You generally should limit hearings to decisions which are reportable to the Data Bank or to some governmental agency
  - Do not grant hearing rights to denied initial appointment applications or decisions not to provide an application except in the rare instance where such a denial is reportable.
  - If giving hearing rights when a physician is automatically suspended, such as the failure to pay dues, loss or reduction of required malpractice insurance or the failure to complete medical records, limit the scope of the hearing to whether the factual basis on which the automatic suspension was imposed is or is not accurate.

Hearing Rights

- Although the court acknowledged decisions by the Supreme Court of Ohio which provide that a hospital generally is required to provide reasonable and non-discriminatory due process procedures when privileges are terminated, it pointed out that hearings are not required in every instance and none of these cases prevent the parties from agreeing to written bylaws that permit immediate revocation under specified circumstances
- Consequently, the appellate court upheld the trial court's decision to grant summary judgement on behalf of the hospital

Michael R. Callahan

A nationally recognized advisor to health care providers across the country, Michael Callahan provides deeply informed advice in all areas of Hospital-physician relations and health care regulatory compliance including EMTALA, HIPAA the Medicare CoPs and licensure accreditation standards. He is widely respected for his leading work on the Patient Safety Act from a regulatory Policy and litigation standpoint including the development of patient safety organizations (PSOs).

Practice focus

- Federal and state licensure and accreditation for Hospitals and health systems
- Hospital-physician relations including contracts, bylaws and peer review investigation and hearings
- PSOs and participating provider policies, compliance and litigation support
- CMS and state departments of health investigations
- Assisting health systems with medical staff integration

The knowledge to identify efficient and practical solutions

- Health systems, Hospitals and physician groups large and small, across the country come to Michael for practical, real-world guidance and answers to challenging legal and operational issues which Michael can provide quickly because of his many years of experience. He understands the reality of Hospital quality, peer review, risk management and related operational legal and regulatory complexities and can rely on a large client base in order to also provide better and comparative solutions.
- He also is sought out by many of the largest health systems around the country for his understanding and interpretation of the Patient Safety Act. In a case of first impression he advised a national pharmacy that became the first provider to successfully assert an evidentiary privilege under the Patient Safety Act. Since that case, he has represented or advised many Hospitals, physician groups and other licensed providers in creating or contracting with federally certified PSOs and has been directly involved in most of the major state appellate and federal court decisions interpreting the Patient Safety Act.

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