

**Florida Association Medical Staff Services
(FAMSS)
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***Current Issues in Negligent Credentialing
Part 1***

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Goals of Program

- What must a plaintiff establish in order to succeed in a negligent credentialing case
- Review of recent cases and their impact on a hospital's duty to protect patients
- How to successfully defend against these actions
- The importance of establishing and uniformly applying credentialing criteria as well as documenting grounds for exceptions to minimize negligent credentialing claims
- What impact does your state's peer review confidentiality statute have on the hospital's ability to defend against these lawsuits
- How to maximize your peer review protections as applied to physician profiling and P4P information

Environmental Overview

- Plaintiffs are looking for as many deep pockets as possible in a malpractice action
 - Hospital has the deepest pockets
- Tort reform efforts to place limitations or “caps” on compensatory and punitive damages has increased efforts to add hospitals as a defendant
- Different Theories of Liability are utilized
 - Respondent Superior
 - Ø Find an employee who was negligent
 - Apparent Agency
 - Ø Hospital-based physician, i.e., anesthesiologist, was thought to be a hospital employee and therefore hospital is responsible for physician’s negligence

Environmental Overview (cont'd)

- Doctrine of Corporate Negligence
 - Ø Hospital issued clinical privileges to an unqualified practitioner who provided negligent care
- Emphasis on Pay for Performance (“P4P”) and expected or required quality outcomes as determined by public and private payors
- Greater transparency to general public via hospital rankings, published costs and outcomes, accreditation status, state profiling of physicians, etc.

Environmental Overview (cont'd)

- Required focus on evidenced-based guidelines and standards and the six Joint Commission competencies (patient care, medical knowledge, practice based learning and improvement, interpersonal and communication skills, professionalism and systems based practice) and ongoing and focused professional practice evaluation (“OPPE” and “FPPE”) as a basis of determining who is currently competent to exercise requested clinical privileges
- The result of all of these evolving developments is an unprecedented focus on how we credential and privilege physicians as well as the volume of information we are requesting and generating as part of this ongoing analysis

The Tort of Negligence

- Plaintiff must be able to establish:
 - Existence of duty owed to the patient
 - That the duty was breached
 - That the breach caused the patient's injury
 - The injury resulted in compensable damages

Duty - Doctrine of Corporate Negligence

- Hospital, along with its medical staff, is required to exercise reasonable care to make sure that physicians applying to the medical staff or seeking reappointment are competent and qualified to exercise the requested clinical privileges. If the hospital knew or should have known that a physician is not qualified and the physician injures a patient through an act of negligence, the hospital can be found separately liable for the negligent credentialing of this physician
- Doctrine also applies to managed care organizations such as PHOs and IPAs

Duty - Doctrine of Corporate Negligence (cont'd)

- Restatement of this Doctrine and duty is found in:
 - Case law, i.e., Darling v. Charleston Community Hospital
 - State hospital licensing standards
 - Accreditation standards, i.e., Joint Commission and Healthcare Facilities Accreditation Program, NAMSS
 - Medical staff bylaws, rules and regulations, department and hospital policies, corporate bylaws and policies

Duty - Doctrine of Corporate Negligence (cont'd)

- Some questions associated with this duty:
 - How are core privileges determined?
 - Based on what criteria does hospital grant more specialized privileges?
 - Are hospital practices and standards consistent with those of peer hospitals?
 - Were any exceptions to criteria made and, if so, on what basis?

Duty - Doctrine of Corporate Negligence (cont'd)

- Were physicians to whom the exemption applied “grandfathered” and, if so, why?
- Did you really scrutinize the privilege card of Dr. Callahan who is up for reappointment but has not actively practiced at the Hospital for the last six years?
- Has each of your department’s adopted criteria which they are measuring as part of FPPE or OPPE obligations such as length of stay patterns or morbidity and mortality data?

Breach of Duty

- The hospital breached its duty because:
 - It failed to adopt or follow state licensing requirements
 - It failed to adopt or follow accreditation standards, i.e., FPPE and OPPE
 - It failed to adopt or follow its medical staff bylaws, rules and regulations, policies, core privileging criteria, etc.
 - It reappointed physicians without taking into account their accumulated quality or performance improvement files

Breach of Duty (cont'd)

- It reappointed physicians even though they have not performed any procedures at hospital over the past two years and/or never produced adequate documentation that the procedures were performed successfully elsewhere
- It failed to require physicians to establish that they obtained additional or continuing medical education consistent with requirement to exercise specialized procedures
- It appointed/reappointed physician without any restrictions even though they had a history of malpractice settlements/judgments, disciplinary actions, insurance gaps, licensure problems, pattern of substandard care which has not improved despite medical staff intervention, current history or evidence of impairment, etc.

Breach of Duty (cont'd)

- It failed to grandfather or provide written explanation as to why physician, who did not meet or satisfy credentialing criteria, was otherwise given certain clinical privileges
- It required physician to take ED call even though he clearly was not qualified to exercise certain privileges
- Violated critical pathways, ACOG, ACR standards

Causation

- The hospital's breach of its duty caused the patient's injury because:
 - If the hospital had uniformly applied its credentialing criteria, physician would not have received the privileges which he negligently exercised and which directly caused the patient's injury
 - History of malpractice suits since last reappointment should have forced hospital to further investigate and to consider or impose some form of remedial or corrective action, including reduction or termination of privileges, and such failure led to patient's injury
- Causation is probably the most difficult element for a plaintiff to prove because plaintiff eventually has to establish that if hospital had met its duty, physician would not have been given the privileges that led to the patient's injury
- Plaintiff also must prove that the physician was negligent. If physician was not negligent, then hospital cannot be found negligent

Examples of Negligent Credentialing Cases

- Darling v. Charleston Community Memorial Hospital (1965)
 - First case in the country to apply the Doctrine of Corporate Negligence
 - Case involved a teenage athlete who had a broken leg with complications and was treated by a family practitioner
 - Leg was not set properly and patient suffered permanent injury
 - Hospital claimed no responsibility over the patient care provided by its staff physician

Examples of Negligent Credentialing Cases (cont'd)

- Court rejected this position as well as the charitable immunity protections previously provided to hospitals
- Part of the basis for the decision was the fact that hospital was accredited by the Joint Commission and had incorporated the Commission's credentialing standards into its corporate and medical staff bylaws

Examples of Negligent Credentialing Cases (cont'd)

- These standards reflected an obligation by the medical staff and hospital to make sure physicians were qualified to exercise the privileges granted to them
- Physician was found to be negligent
- The medical staff and hospital's decision to give privileges to treat patients with complicated injuries to an unqualified practitioner directly caused the patient's permanent injuries. Therefore, the hospital was held liable for the damages

Examples of Negligent Credentialing Cases (cont'd)

- Frigo v. Silver Cross Hospital (2007)
 - Frigo involved a lawsuit against a podiatrist and Silver Cross
 - Patient alleged that podiatrist's negligence in performing a bunionectomy on an ulcerated foot resulted in osteomyelitis and the subsequent amputation of the foot in 1998

Examples of Negligent Credentialing Cases (cont'd)

- The podiatrist was granted Level II surgical privileges to perform these procedures even though he did not have the required additional post-graduate surgical training required in the Bylaws as evidenced by completion of an approved surgical residency program or board eligibility or certification by the American Board of Podiatric Surgery at the time of his initial appointment in 1992

Examples of Negligent Credentialing Cases (cont'd)

- At the time of his reappointment, the standard was changed to require a completed 12 month podiatric surgical residency training program, successful completion of the written eligibility exam and documentation of having completed 30 Level II operative procedures
- Podiatrist never met these standards and was never grandfathered. In 1998, when the alleged negligence occurred, he had only performed six Level II procedures and none of them at Silver Cross

Examples of Negligent Credentialing Cases (cont'd)

- Frigo argued that because the podiatrist did not meet the required standard, he should have never been given the privileges to perform the surgery
- She further maintained that the granting of privileges to an unqualified practitioner who was never grandfathered was a violation of the hospital's duty to make sure that only qualified physicians are to be given surgical privileges. The hospital's breach of this duty caused her amputation because of podiatrist's negligence

Examples of Negligent Credentialing Cases (cont'd)

- Jury reached a verdict of \$7,775,668.02 against Silver Cross
- Podiatrist had previously settled for \$900,000.00
- Hospital had argued that its criteria did not establish nor was there an industry-wide standard governing the issuance of surgical privileges to podiatrists
- Hospital also maintained that there were no adverse outcomes or complaints that otherwise would have justified non-reappointment in 1998

Examples of Negligent Credentialing Cases (cont'd)

- Court disagreed and held that the jury acted properly because the hospital's bylaws and the 1992 and 1993 credentialing requirements created an internal standard of care against which the hospital's decision to grant privileges could be measured
- Court noted that Dr. Kirchner had not been grandfathered and that there was sufficient evidence to support a finding that the hospital had breached its own standard, and hence, its duty to the patient
- This finding, coupled with the jury's determination that Dr. Kirchner's negligence in treatment and follow up care of Frigo caused the amputation, supported jury's finding that her injury would not have been caused had the hospital not issued privileges to Dr. Kirchner in violation of its standards

Examples of Negligent Credentialing Cases (cont'd)

- Jury verdict was affirmed. Petition for leave to appeal to Illinois Supreme Court was denied
- See also Larson v. Wasemiller (Minn. Sup. Ct. 2007)
 - For the first time, the Supreme Court of Minnesota recognized that the tort of negligent credentialing “is inherent in and the natural extension of well established common law rights”

Examples of Negligent Credentialing Cases (cont'd)

- Court noted that at least 30 states recognize this tort theory and only two states, Pennsylvania and Maine, have rejected the claim. Other related theories are direct or corporate negligence, duty of care for patient safety, negligent hiring and negligent selection of independent contractors
- Court further held that the tort of negligent credentialing was not pre-empted by the peer review statute

Examples of Negligent Credentialing Cases (cont'd)

Smithey v. Brauweiler (2008)

- Dr. Brauweiler was a family practitioner who applied for and received medical staff privileges at Sandwhich Community Hospital (now Valley West Community Hospital), including obstetrical privileges, in 1991.
- In 1995, he delivered a child by operative vacuum delivery. Delivery was successful but child needed resuscitation. Through no fault of physician, resuscitation was delayed leading to permanent brain damage. Lawsuit was filed in 1997 for alleged negligence against hospital and Dr. Brauweiler.

Examples of Negligent Credentialing Cases (cont'd)

- During deposition, physician testifies that a vacuum extraction would be a deviation of the standard of care if done at +1 station or higher.
- Dr. Brauweiler was reappointed each time with OB privileges, including the specific grant of operative vacuum and operative forceps delivery which were separate privileges in 2000. No adverse results in other vacuum delivery cases.
- In 2001, he delivered a child by vacuum delivery but this time, vacuum extractor was performed 22 times in 33 minutes because it kept popping off. Infant was presenting at +1 the whole time. OB was called and did a C section.

Examples of Negligent Credentialing Cases (cont'd)

Apgars were 2, 3 and 6. Infant diagnosed with hypoxic ischemic encephalopathy. Lawsuit was filed in 2003 against Dr. Brauweiler and amended in 2005 to include the hospital on a negligent credentialing claim.

- In 2002, he withdrew his OB privileges.
- Plaintiff's attorney argued that hospital was negligent in granting OB privileges to Dr. Brauweiler in the first place and especially after the 1995 case even though he was not at fault.
 - Plaintiff contended that the case should at least have called into question the physician's qualifications.

Examples of Negligent Credentialing Cases (cont'd)

- Hospital decided that it did not want to run the risk of losing at trial and settled case for almost \$8 million.
- Defense not able to introduce the peer review record of hospital to establish that it met its duty because they were inadmissible under the Medical Studies Act.
- IHA has set up a round table discussion of expert defense and corporate attorneys to discuss how to best defend against these corporate negligence cases in light of more aggressive tactics by plaintiff's attorneys and problems caused by the MSA.

Joint Commission Standards on Focused and Ongoing Performance Monitoring

- Standard 03.01.01
 - Medical Staff oversees quality of patient care treatment and services
 - Is responsible for ongoing evaluation of competency and delineation of privileges

Joint Commission Standards on Focused and Ongoing Performance Monitoring (cont'd)

- Standards MS 05.01.01
 - Medical Staff actively involved in measurement, assessment, and improvement of specified areas such as adverse privileging decisions, mediations, operative procedures and clinical practice functions
 - The purpose of these Standards is to establish additional evidence-based processes to determine a practitioner's competency
 - With regard to privileging, the new Standard imposes a higher burden in determining whether the applicant or current medical staff physician has the degree of training, education and experience required to perform each of the requested privileges and procedures

Joint Commission Standards on Focused and Ongoing Performance Monitoring (cont'd)

- Information about a practitioner's scope of privileges must be updated as changes in clinical privileges are made
- Medical staff and governing board must develop criteria that will be considered when deciding to grant, limit or deny requested privileges – ties in with CMS Conditions of Participation and concerns about use of core privileging not related to actual evidence-based privileging
- If privileging is unrelated to quality of care, treatment and services or professional competence, evidence must exist that impact of resulting decisions on the quality of care, treatment, and services is evaluated

Joint Commission Standards on Focused and Ongoing Performance Monitoring (cont'd)

- MS.06.01.03 - Credentialing
 - Emphasis is on three new concepts
 - General Competencies
 - Ø Patient care (compassionate, appropriate, effective)
 - Ø Medical/clinical knowledge (demonstrated knowledge and application of biomedical, clinical and social services)
 - Ø Practice-based learning and improvement (is physician obtaining CMEs) (use of scientific evidence and methods to investigate, evaluate and improve practices)

Joint Commission Standards on Focused and Ongoing Performance Monitoring (cont'd)

- Ø Interpersonal and communications skills (demonstration of interpersonal and communication skills to establish and maintain professional relationships)
- Ø Professionalism (commitment to continuous professional development, ethical practice, reactivity to diversity and a reasonable attitude)
- Ø Systems-based practice (is physician abiding by all policies, participating in EHR initiatives, modifying behaviors based on profiling data)

Joint Commission Standards on Focused and Ongoing Performance Monitoring (cont'd)

- ∅ Looks for a balance between clinical and professional behavior
- Focused Professional Practice Evaluation
- Ongoing Professional Practice Evaluation

Joint Commission Standards on Focused and Ongoing Performance Monitoring (cont'd)

- MS.08.01.01 – Focused Professional Practice Evaluation
 - Standard expects the medical staff to identify and implement a method of evaluating practitioners without current performance documentation at the hospital, whether the physician is new or is an existing physician seeking new privileges, including processes where quality of care concerns arise, criteria for extending the evaluation period, and for communicating and acting on the results of the evaluation
 - Need adequate information to confirm competence
 - Core privileging

Joint Commission Standards on Focused and Ongoing Performance Monitoring (cont'd)

- A period of focused professional practice evaluation is implemented for all initially requested privileges (EP1)
 - Must develop criteria to evaluate performance of physicians when issues affecting patient safety and quality of care are identified (EP2)
 - Performance monitoring includes:
 - Ø Criteria
 - Ø Method for setting up a monitoring plan
 - Ø Method for identifying duration of the plan
 - Ø Identifying circumstances when an outside review will be sought (EP3)

Joint Commission Standards on Focused and Ongoing Performance Monitoring (cont'd)

- Evaluation consistently applied (EP4)
- Focused review triggers are defined (EP5)
- Need to focus on the particular issue or privileges in question to make sure physician is currently competent to exercise same. Cannot avoid review simply because physician has no problems with other privileges (EP6)
- Must develop standard and criteria for determining what form of monitoring is to take place (EP7)
- How is resolution of performance defined – results or timing (EP8)
- Resolution standard uniformly applied (EP9)

Joint Commission Standards on Focused and Ongoing Performance Monitoring (cont'd)

- Would require “performance monitoring” particularly for those new physicians who have yet to establish a track record with the hospital or when questions about competency or ability are raised
- Methods of focused professional practice evaluation can include, but are not limited to chart review, monitoring, clinical practice patterns, simulation, proctoring, external peer review, and discussion with other individuals involved in patient’s care
- All accumulated information from focus evaluation process must be integrated into performance improvement activities

Joint Commission Standards on Focused and Ongoing Performance Monitoring (cont'd)

- MS.08.01.03 – Ongoing Professional Practice Evaluation
 - Under the ongoing professional practice evaluation, there is a heightened emphasis on evaluating a physician's practice so as to identify trends that impact on quality of care and patient safety. Such criteria can include but are not limited to, the following:
 - Ø Review of operative and other clinical procedures performed and their outcomes

Joint Commission Standards on Focused and Ongoing Performance Monitoring (cont'd)

- Ø Pattern of blood and pharmaceutical usage
 - Ø Request for test and procedures
 - Ø Length of stay patterns
 - Ø Morbidity and mortality data
 - Ø Practitioners usage of consultants
 - Ø Other relevant criteria
- Ongoing evaluation must be factored into any decisions to maintain, revise or revoke privileges

Joint Commission Standards on Focused and Ongoing Performance Monitoring (cont'd)

- Problems identified during ongoing review should trigger a focused review or other intervention. Generally looking for patterns or trends
- “Ongoing” does not mean once a year
- Medical Staff Bylaws must evidence how the staff will evaluate and act upon a report of concerns relating to a practitioner’s clinical practice and/or competence and further, that the concerns are uniformly investigated and addressed

Joint Commission Standards on Focused and Ongoing Performance Monitoring (cont'd)

- Evaluation can be based on different sources of information such as chart reviews, direct observation, monitoring, consultations with other care givers, etc.
- Must have a clearly identified process to facilitate evaluation of each physician (EP1)
- Data to be collected is determined by each department and approved by the organized medical staff (EP2)
- Information from ongoing performance monitoring is used to continue, revoke or limit any or all existing privileges (EP3)

Defending Against a Corporate Negligence Claim

- Existence of duty and breach of duty and causation is usually established through expert testimony
- Expert must establish that duty was not met, i.e., that hospital adopted and followed all standards as reflected in its bylaws and procedures, and/or no breach occurred and/or if there was a breach, it did not cause patient's injuries

Defending Against a Corporate Negligence Claim (cont'd)

- Courts and juries may be less likely to hold in favor of the plaintiff even if, for example, a physician's lack of qualifications or history of malpractice actions raises the issue of whether privileges should have been granted, as long as some action was taken, i.e., physician was being monitored or proctored or was under a mandatory consultation
- A judge and jury will be more likely to find in favor of the plaintiff if the hospital did absolutely nothing with respect to the physician's privileges

Defending Against a Corporate Negligence Claim (cont'd)

- It will be important for hospital to establish that there is not necessarily a black and white standard on what qualifications are absolutely required before issuing clinical privileges although such a position, at least for certain privileges, may have been established, i.e., PTCAs
- Also, the hospital should argue that even if a physician was identified as having issues or problems, a reduction or termination of privileges is not always the appropriate response. Instead, the preferred path is for the hospital to work with the physician to get them back on track by implementing other remedial measures such as monitoring, proctoring, additional training, etc. (See Golden Rules of Peer Review at p. 69)
- Attempt to introduce physician's peer review record to establish that Hospital met it's duty

Defending Against a Corporate Negligence Claim (cont'd)

- You must evaluate whether your peer review statute does or does not allow introduction of peer review record into evidence for this purpose
- Denying a plaintiff access to this information usually makes it more difficult to prove up a negligent credentialing claim
- Most statutes do not permit the discovery or admissibility of this information because to do so would have a chilling effect on necessary open and frank peer review discussion. There is no statutory exception that allows a hospital to pick and choose when I can or cannot introduce information into evidence

Defending Against a Corporate Negligence Claim (cont'd)

- In Frigo, hospital's attempt to establish that duty was met by showing, through the peer review record, that podiatrist had no patient complaints or bad outcomes was denied because prohibition on admissibility into evidence was absolute
- Court stated, however, that this information was somewhat irrelevant because the Hospital clearly did not follow its own standards

Other Preventative Steps to Consider

- Conduct audit to determine whether hospital and medical staff bylaws, rules and regulations and policies comply with all legal accreditation standards and requirements
- If there are compliance gaps, fix them
- Determine whether you are actually following your own bylaws, policies and procedures

Remember: Bylaws, policies and procedures and guidelines are all discoverable. They also create the hospital's internal standard. If you do not follow your bylaws and standards, you arguably are in breach of your patient care duties

- If you are not following your bylaws and policies, either come into compliance or change the policies
- Update bylaws and policies to stay compliant

Other Preventative Steps to Consider

(cont'd)

- Confer with your peers. Standard of care can be viewed as national, i.e., Joint Commission, internal or area-wide so as to include the peer hospitals in your market. If your practices deviate from your peers, this will be held against you as a breach of the standard of care
- It is very important to understand from your insurance defense counsel how plaintiff's attempt to prove a corporate negligence violation as well as how these actions are defended
 - These standards have a direct impact on hospital prophylactic efforts to minimize liability exposure

Other Preventative Steps to Consider

(cont'd)

- What testimony must plaintiff's expert assert to establish a claim and what must defense expert establish to rebut?
- Every state has its own nuances and you must understand them in order to defend accordingly
- Does your state peer review statute allow for the introduction of confidential peer review information under any circumstances either to support a plaintiff's claim or to defend against it?
- If the file information would help the hospital, can the privilege be waived in order to defend the case? Realize that plaintiff also would have access. Will this help or hurt you?

Other Preventative Steps to Consider

(cont'd)

- The answers to these questions are important because the hospital may want to create a record of compliance with its duty that is not part of an inadmissible peer review file. This effort must be coordinated with internal and/or external legal counsel
- Otherwise, take steps for maximizing protections under peer review confidentiality statute.