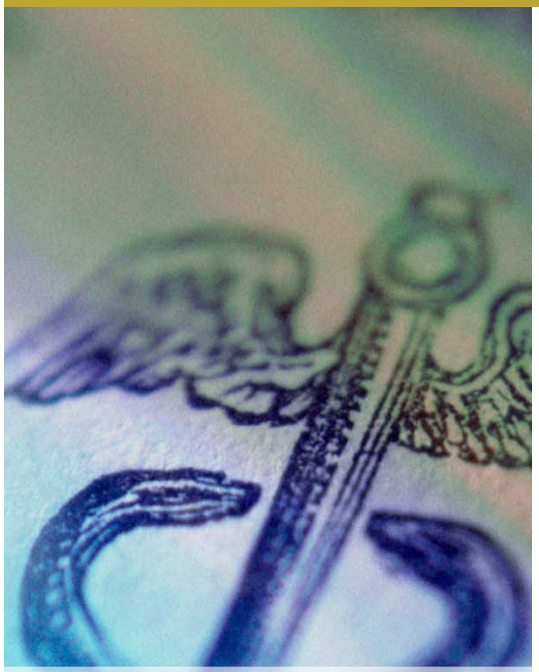

Illinois Medical Studies Act Under Attack: Problems and Proposed Solutions

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Speaker Bios

Michael R. Callahan, Partner - michael.callahan@kattenlaw.com

Michael R. Callahan assists hospital, health system and medical staff clients on a variety of health care legal issues related to accountable care organizations (ACOs), patient safety organizations (PSOs), health care antitrust issues, Health Insurance Portability and Accountability Act (HIPAA) and regulatory compliance, accreditation matters, general corporate transactions, medical staff credentialing and hospital/medical staff relations.

Michael's peers regard him as "one of the top guys […] for credentialing—he's got a wealth of experience" (Chambers USA). Additionally, his clients describe him as "always responsive and timely with assistance," and say he is "informed, professional and extremely helpful" and "would recommend him without reservation" (Chambers USA). Michael's clients also commend his versatility, and say "He is willing to put on the hat of an executive or entrepreneur while still giving legal advice," according to Chambers USA.

He is a frequent speaker on topics including ACOs, health care reform, PSOs, health care liability and peer review matters. He has presented around the country before organizations such as the American Health Lawyers Association, the American Medical Association, the American Hospital Association, the American Bar Association, the American College of Healthcare Executives, the National Association Medical Staff Services, the National Association for Healthcare Quality and the American Society for Healthcare Risk Management.

Michael was recently appointed as chair of the Medical Staff Credentialing and Peer Review Practice Group of the American Health Lawyers Association. He also was appointed as the public member representative on the board of directors of the National Association Medical Staff Services.

He was an adjunct professor in DePaul University's Master of Laws in Health Law Program, where he taught a course on managed care. After law school, he served as a law clerk to Justice Daniel P. Ward of the Illinois Supreme Court.

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Program Goals

- Provide an overview of the Medical Studies Act as well as the evolving case law interpretation of the privilege protections
- Provide a summary of the recent Grossheusch and Nielson decisions and the impact on hospital and medical staff peer review and quality assurance procedures
- Identify proposed bylaw and policy modifications to limit the adverse impact of these Court decisions in order to maximize the privilege protections
- Recommend litigation steps to take in defending against discovery requests

Key Provisions of the Medical Studies Act

- "All information, interviews, reports, statements, memoranda, recommendations, letters of reference or other third party confidential assessments of a health care practitioner's professional competence"
- "Or other data of… health care entities or facilities,… committees of ambulatory surgical centers or post-surgical recovery centers or their medical staffs, or committees, or committees of licensed or accredited hospitals or their medical staffs… or their designees"
- "Used in the course of internal quality control or a medical study for the purpose of reducing morbidity or mortality"
- "Or for improving patient care"
- "Shall be privileged [and] strictly confidential"

Key Provisions of the Medical Studies Act

- "Shall be used only for medical research…"
- "The evaluation and improvement of quality care"
- "Or granting, or limiting or revoking staff privileges or agreements for services"
- The privilege cannot be waived

Jenkins v. Wu (Il. Sup. 1984)

- **Factual Background**
  - In this medical malpractice action the defendants refused to produce the following categories of requested documents in response to plaintiff's motion to compel
    - Personnel file of the defendant treating physician and all reports of medical review panels regarding patient care provided by the physician during 1978
    - All reports or other evidence of complaints or accommodations relative to the quality of health care provided by the physician

Jenkins v. Wu (Il. Sup. 1984)

- All reports of medical review panels, lectures given in which the plaintiffs case was discussed as related to the patients treatment found in review committees or investigative files
- The hospital's entire files relating to its 1978 accreditation

Jenkins v. Wu (Il. Sup. 1984)

- **Trial Court Decision**
  - Court held that the MSA violated the equal protection clause of the U.S. and Illinois constitutions because it denied access of peer review information to a patient but made it available to physicians when defending against disciplinary actions
  - The MSA constituted special legislation in violation of the Illinois constitution
  - The defendant's attorney was held in "friendly contempt". The Supreme Court allowed a direct appeal based on the trial court's ruling controlling that the MSA was unconstitutional

Jenkins v. Wu (Il. Sup. 1984)

- **Illinois Supreme Court Decision**
  - The Court rejected both constitutional arguments
  - In doing so the Court made the following comments
    - The MSA provides for the discovery of a patients records which are the source of a malpractice claim
    - Not only do malpractice plaintiffs have full and complete access to their own records, they can also depose all persons involved in their treatment and engage experts to give opinions as to the quality of care received

Jenkins v. Wu (Il. Sup. 1984)

- Therefore, the denial of this information to such plaintiffs should have little impact on their ability to maintain their course of action
- Purpose of the MSA was not to facilitate the prosecution of malpractice cases but to ensure the effectiveness of professional self-evaluation in the interest of improving the quality of health care

Nielson v. Swedish American Hospital

- **Factual Background**
  - This is a medical malpractice action in which the plaintiff sued the hospital after her bladder was injured after the removal of a cyst at it's outpatient facility which then required an emergency surgical repair at the hospital
  - Based on this adverse event, three quality control reports ("QCRs") were prepared by nurses involved in the patient's initial and subsequent surgery and forwarded to the hospital's Director of Risk Management
  - The risk manager is a member of the Committee for Quality Improvement and Safety ("CQI") the Board of Directors Quality and Safety Leadership Committee and the Medical Staff Quality Safety Committee ("QA/I")

Nielson v. Swedish American Hospital

- According to the medical staff bylaws, committees and their sub-committees as well as their designees, were established to conduct peer review and quality improvement activities for the purpose of reducing morbidity and mortality and improving patient care
- QA/I requested that information involving "medical occurrences" be collected on it's behalf using the QCRs which was a template formed and developed in 1999 and which identified specific occurrences for which it proactively sought such information
- The risk manager received and reviewed the QCRs as part of the Quality and Resource Department as a designee of the QA/I that collects data for analysis by its subcommittees.

Nielson v. Swedish American Hospital

- The Women's Health Quality and Safety subcommittee of the QA/I reviewed the reports and provided its findings to the QA/I and CQI. No actions were taken regarding the physicians and their privileges. The nurses in their affidavits stated that they completed the QCRs at the request of the QA/I and forwarded them to the Risk Management Department

Nielson v. Swedish American Hospital

- **The QCR Form**
  - The QA/I determined that a 'medical occurrence' could affect a patient's morbidity and mortality. Hence, the QA/I requested this their information be gathered for it and on its behalf of these subcommittees
  - "Such information is a quality-improvement tool and is confidential under the Illinois Medical studies act"
  - The form contains checklists under the headings of medical and non-medical occurrences. Medical occurrences include blood transfusion, infection, a code during treatment, quality of services, patient found on floor
  - Non-medical occurrences included property loss/damage, slip and fall/non patient, legal action, vehicular accident

Nielson v. Swedish American Hospital

- The form contains a section requesting the circumstances of the issue be described and instructs the individual completing the form to "send to Risk Manager or Administrator of SIR (non-medical). The Risk Manager is described as being a member of the CQI and the QA/I

Nielson v. Swedish American Hospital

- **Policy and Procedure Manual**
  - QCRs "will be used to communicate occurrences or variances affecting patients, physicians, visitors, volunteers, students, employee property, the hospital's property"
  - "Information will be used to monitor, evaluate and approve the quality and safety of services"
  - "Any employee, student, volunteer, visitor, or physician involved in, observing or discovering an occurrence" must complete the QCRs and submit to a supervisor
  - "Reportable occurrence or variance in any event which is not consistent with quality health care or normal operations, reflects recurring concerns or problems, or indicates the potential for a claim or lawsuit"

Nielson v. Swedish American Hospital

- "QCRs should be sent to Risk Management as soon as possible to facilitate follow up, investigation, resolution and data collection"
- If identified as a medical occurrence the chief medical quality officer "or his designee will determine if a team should be convened to conduct an investigation"
- QCRs forms are "a significant component of the hospital's quality improvement program but also the Risk Management Department "reviews all QCRs and conducts an investigation of occurrences or variances which require a more complete documentation, follow up from risk management perspective, or reporting under the Safe Medical Devices Act"
- "A QCR may serve as a report to legal counsel to assist in the defense of a lawsuit or a claim"

Nielson v. Swedish American Hospital

- **Trial Court Order**
  - Hospital refused to turn over the three QCRs arguing that they were protected from discovery under the Medical Studies Act. The reports were submitted to the court for in camera review
  - Trial court granted plaintiff's motion to compel even though it noted that the QCRs were quality information of the committees
  - Upon the hospital's refusal to produce the reports it was held in "friendly contempt" and an interlocutory appeal to the Court of Appeals was filed

Nielson v. Swedish American Hospital

- **The Appellate Court's Analysis and Decision**
  - The Court determined that the trial court's conclusion that the QCRs were generated solely at the direction of the QA/I and CQI committees and used solely for quality assurance purposes was against the manifest weight of the evidence because the form and the policies in question clearly indicated that the forms served multiple purposes including risk management and billing, all of which are reviewed from a risk management perspective
  - In response to the hospital's argument that clear use of specific forms intended for peer review and quality assurance purposes should be privileged so as not to delay necessary reviews and until a qualified committee meets, the Court expressed concern that the hospital was essentially arguing that all medical occurrence QCRs should be considered privileged and not just the three reports at issue

Nielson v. Swedish American Hospital

- The hospital also argued that the QA/I as a whole directed hospital personnel to complete QCRs as its "designees" then submit to the committee for it's review. Thus the QCRs were initiated by the committee and existed solely for the committee
- The hospital also argued that the committee proactively determines to undertake a quality review of patient complications where, in this case, the adverse event in an outpatient facility resulted in a hospital admission. Thus it's "designees" were obligated to commence the review process by completing and submitting the QCRs
- In holding that the QCRs were not privileged under the MSA the Court made the following determinations:
  - The QCRs were not privileged because the designees completed them before an occurrence took place

Nielson v. Swedish American Hospital

- Contrary to the First District Appeal Court's decision in Eid v. Loyola, the reports in dispute in that case were privileged because they were generated only after the risk manager received a request to conduct a review by the chair of a qualified peer review committee and because the manager was deemed to be a designee of the committee. The fact that the information could be generated before the peer review committee met or was even aware of the incident did not defeat the privilege
- Furthermore, Eid did not involve a standard request to collect all medical occurrence information or that it be shared with the risk management department to be reviewed from a risk management perspective

Nielson v. Swedish American Hospital

- "As to plaintiff's suggestion that the Department has effectively not designated any person, where any person on the premises can complete a QCR, we agree. But, even if the QA/I can designate a broad universe of designees, we conclude that the 1995 amendment does not undermine the case law that holds that the privilege applies only to information of such a committee, or, in this case designee, where the committee (or designee) is already investigating the incident at issue"
- "To hold otherwise would allow an entity such as defendant to invoke the statutory privilege whenever any medical occurrences memorialized in a QCR. by any person (employee or non employee) who observed, heard or otherwise had information concerning the event.

Nielson v. Swedish American Hospital

- "Such a practice 'swallows the rule' and makes everything confidential, except for the patient's on medical records." (Citing to Chicago Trust, 298 Ill. App. 3d at 406)
- The Court stated the QCRs are not used for commencing an investigation but, as stated in the hospitals policy, they are used "to communicate occurrences or variances affecting patients, physicians, visitors, volunteers, students, employee property, and hospitals property"
- The decision of whether to investigate is not made until after the medical-occurrence QCRs were forwarded to other personnel and only if the chief medical officer or other person determines that "a team should be convened to conduct an investigation"

Nielson v. Swedish American Hospital

- Although the QCRs commence the process they do not commence an investigation, plus they serve a dual purpose and are not used exclusively for quality assurance or improvement purposes
- The trial court's decision to require the hospital to turn over the three QCRs was affirmed
- The hospital's petition for leave to file an appeal was denied by the Illinois Supreme Court

Grosshuesch v. Edward Hospital

- **Factual Background**
  - This is a medical malpractice action involving the death of a newborn child who suffered numerous medical issues including necrotizing entercolitis
  - Based on the mother's complaint to the hospital's patient advocate regarding the care and treatment of her and her newborn child the complaint and the infant's death constituted "review indicators" under this hospital's Peer Review Policy and its Medical Staff Quality Committee ("MSQC") charter
  - The MSQC liaison reached out to two physician peer reviewers on the medical staff one whom reviewed and commented on the obstetrical care given to the plaintiff and the other reviewer commented on the neonatal care provided to the child

Grosshuesch v. Edward Hospital

- The notes and each peer reviewer's comments including conclusions and/or requests for additional information were entered onto an electronic data base which notes were considered when the MSQC subsequently met on two occasions
- After a lawsuit was filed the plaintiff sought all of the documentation regarding the care of the child. The hospital refused to produce the notes prepared by the MSQC liaison arguing that they were privileged under the Medical Studies Act

Grosshuesch v. Edward Hospital

- **Trial Court Decision**
  - In support of the hospital's arguments and their response to the plaintiff's motion to compel, the hospital submitted an initial and a subsequent affidavit which contained the following:
    - The peer review policy of the MSQC and the Medical Executive Committee of the Medical Staff was adopted in order to "improve the overall quality and care rendered and to reduce morbidity and mortality"
    - Based on the complaint the matter was referred to the MSQC for peer review pursuant to the policy

Grosshuesch v. Edward Hospital

- The information and conclusions relating to this investigation which were later provided to the MSQC for consideration and evaluation, were part of the internal quality control process and therefore privileged. The MSQC also had instructed the liaison to assist the committee by coordinating the investigation into the complaint.
- As part of the investigation the liaison worked with the peer reviewers and that the notes made by the liaison as part of the investigation "served as an integral function in the peer review gathering and decision making process and served as documentation vital to the process of improving the quality and care rendered at Edward Hospital".

Grosshuesch v. Edward Hospital

- The trial court ruled that the documents at issue had to be produced and upon denial of the hospital's motion for reconsideration and its refusal to produce the documents, the hospital was held in contempt thereby triggering the automatic interlocutory appeal to the Court of Appeals.

Grosshuesch v. Edward Hospital

- **Court of Appeals Analysis and Decision**
  - The Court rejected the hospital's argument that based on the peer review policy, an investigation begins if certain quality indicators are triggered such as the death of a patient or newborn. Thus the policy authorized the initiation of the investigation before the adverse event actually occurred.
  - In doing so, the Court made the following determinations:
    - "We find that Edward Hospital's argument is contrary to over 20 years of precedent establishing that the Medical Studies Act cannot be used to conceal relevant evidence that was created before a quality assurance committee or its designees authorize an investigation into a specific incident"

Grosshuesch v. Edward Hospital

- Citing to and distinguishing this case from previous Appellate Court decisions, the Court concluded that the MSA "does not insulate from discovery documents that were generated before a peer review committee or its designee authorize an investigation of a specific incident." The hospital's "MSQC enacted in 2008 was [not] sufficient to shield from discovery [the liaison's] notes on the peer reviewers' input regarding the care that the plaintiff...received in 2013".
- Because the liaison had not been authorized or engaged by the MSQC directly when she prepared her notes and because the MSQC was not itself engaged in an investigation regarding the incidents the notes were not privileged under the Medical Studies Act.

General Comments, Lessons Learned and Recommendations

- **General Comments**
  - Despite the Courts' narrow interpretation of the scope of privilege protections under the MSA, it is important to educate judges as to the broad scope of patient safety and quality improvement activities conducted by committees which are protected under the Act.
  - All efforts to improve patient care and reduce mobility and mortality are not always tied to an adverse event or adverse occurrence.
  - The MSA is much broader than the concept of "peer review" which is a somewhat limiting term because it suggests that the MSA only applies when physicians are reviewing their peers when there is a patient injury.

General Comments, Lessons Learned and Recommendations

- It is important to realize that most trial judges are predisposed to erring on the side of protecting patients, therefore are more inclined to narrowly construe all statutory or other forms of privilege, including attorney-client work product and opinion work product.
- There is no language in the MSA which requires that information cannot be privileged until an "investigation" has been authorized by a qualified committee or its designee.

General Comments, Lessons Learned and Recommendations

- **Lessons Learned and Recommendations**
  - Include a definition of "Peer Review" and "Peer Review Committee" which reflects the broad language of the MSA and which specifically identifies all peer review, quality and related committees.
  - Include a definition for "Designees" as being those individuals and categories of professionals who have been specifically identified by qualified peer review committees as acting on behalf of these committees when reviewing specific adverse events at or shortly after their occurrence.

General Comments, Lessons Learned and Recommendations

- Consider including a definition called "Medical Studies Review" which reflects the initiation of an investigation as authorized by a qualified committee.
- Keep in mind that the term " investigation" has Data Bank implications and therefore hospitals and medical staffs typically do not use that term except when disciplinary or corrective action is requested.
- In coming up with a definition of this term or under the definition of "Peer Review" conduct an inventory of all quality insurance, peer review and related activities as well as forms, reports and other forms which are utilized for the purpose of improving patient care or reducing morbidity or mortality.

General Comments, Lessons Learned and Recommendations

- Medical studies reviews should commence immediately when and an adverse event has occurred or is identified.
- Consider using incident or occurrence reports which essentially contain only factual or non-sensitive information which would be produced pursuant to a discovery request but does not contain initial impressions, analysis or others sensitive information which could undermine a hospital's defense.
- This more limited report should then be provided to a qualified committee or designee to request that the medical studies review/investigation be initiated consisted with the Appellate Court decision Eid.
- This communication, request and response needs to be documented.

General Comments, Lessons Learned and Recommendations

- Information gathered through the medical studies review process should be utilized only by identified peer review committees and sub-committees.
- You cannot assert both the MSA privilege and any of the attorney-client work product or opinion privileges for the same document because they are mutually exclusive.
- Collecting and using information for the purpose of improving patient care and reducing mobility and mortality is not the same as collecting information and anticipation of litigation.
- Privileged information should not be used for the "original course of business such as evaluating liability exposure, rendering a legal opinion, assessing actual or potential losses or corrective action taken against hospital employees.

General Comments, Lessons Learned and Recommendations

- Information which is developed specifically for a risk management or activity unrelated to a medical studies or peer review will not be privileged simply because it was transmitted and reviewed by a qualified committee.
- In addition to providing copies of relevant bylaws, peer review and quality policies and procedures which support the hospital's assertion of the MSA privilege, it is extremely important to include detail affidavits which, at a minimum, include the following information:
  - Identify the qualified committees involved in particular peer or medical studies review.
  - Identify which parties were treated as "designees" under these documents.

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General Comments, Lessons Learned and Recommendations

- Identify which specific designee, if utilized, was involved in the particular review.
- Identify the forms used for purposes of the review which were created by or authorized to be used by the qualified committee.
- Identify why the specific occurrence in question triggered a medical studies or peer review as identified and authorized by qualified committee.
- If using a limited factual occurrence or incident form, identify when the form was created.
- Identify when the designee informed the qualified committee of the nature of the occurrence and request that a medical studies or peer review be initiated.

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General Comments, Lessons Learned and Recommendations

- Identify when the committee or committee designee specifically authorized the initiation of the review.
- Identify when the review was conducted, the forms and information obtained and when this information was transmitted to the qualified committee.
- Identify when the committee met to review the privileged information and how the information was utilized consistent with the bylaws and peer review policies.

- Remember that qualified committee's recommendations are privileged but final actions are not.

General Comments, Lessons Learned and Recommendations

- If participating in a Patient Safety Organization ("PSO") consider including all information relating to patient safety activities including peer review quality and performance improvements information reports, within your patient safety evaluation system.
- The privilege protection under the Patient Safety and Quality Improvement Act 2005 covers all licensed entities is not limited to "committees or their designees," applies to a broader range of activities, applies in all states and federal proceedings and is not subject to discovery or permissibility into evidence. The privileges can never be waived.

General Comments, Lessons Learned and Recommendations

- Depending upon the information involved, a hospital can assert protections under both the MSA and the PSA.
- There is a pending appeal before the First District Court of Appeals involving Ingalls Hospital which asserted privilege protections under the Patient Safety Act regarding incident reports which were collected and reported to its PSO. The trial court, without any real analysis, required the Hospital to turn over the reports.

QUESTIONS

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