Katten

Katten Muchin Rosenman LLP

The Medical Studies Act Under Attack: Problems and Proposed Solutions

Session Questions and Answers

Presented by Michael R. Callahan, Partner

Q: ***What if the patient or family participates in the RCA—is work still protected?***

A: Many hospitals have been fairly proactive in meeting with the patient and the family when an adverse incident occurs. In fact, this is an accreditation standard. The level of family involvement varies from hospital to hospital. I have not seen a policy, however, in which the family is involved in the actual RCA which would suggest that they participate in committee reviews as opposed to selected information. Actually the latter, in my opinion, is more appropriate than receiving the former.

You also have to consider whether you are seeking privilege protections under the Medical Studies Act and/or the Patient Safety Act. Under both statutes, the privilege protections cannot be waived as long as the information is being used to improve quality outcomes and reduce risk as specifically set forth under your bylaws, rules, regulations and policies. Sharing facts, outcomes, results and conclusions with families is what is typically shared. This information is not privileged anyway but should suffice, along with explaining the process by which the adverse event in question is being reviewed. To share confidential and privileged RCA, peer review and quality analyses, at least in my opinion, goes beyond what is necessary in order to be transparent with the patient and the family.

Q: ***Are there ways different quality committees within a hospital can share information discussed within their separate meetings and maintain the MSA privilege over the shared information? What about across different hospitals within the same health care system?***

A: Sharing privileged information by and between different quality committees within the hospital is expected, if not required, depending on the adverse incident in question. For example, an occurrence which involves a wrong site surgery could involve the Surgical Review Committee, an RCA Committee, a Performance Improvement Committee and ultimately the MEC depending on the issue and outcome of these reviews. If relying on the lessons learned in the ***Edwards*** and *SwedishAmerican* decisions, whatever information is collected once the investigation or Medical Studies Review is triggered, as per your bylaws and policies, including the subsequent reviews and analyses become privileged and can be used and shared within the hospital with the appropriate identified committees and individuals charged with the responsibility to review the incident.

If committees have separate but parallel authority/responsibility to review an adverse event then you need to make sure that each investigation/Medical Studies Review is appropriately described and followed so as to maximize the privilege protections over what you are seeking to protect as per the recommendations that I provided during the program and as set forth in the power point materials.

With respect to sharing privileged information between hospitals in the same health care system, again, if the information in question qualifies as being privileged at the outset, it will remain privileged even if shared with other system hospitals. So, if the wrong site surgery analyses and reports in the example above for Dr. Callahan were shared with other systems hospitals via appropriate peer review and related committees because Callahan is on staff at a number of the system hospitals, the privilege is not waived or lost. BUT, keep in mind that under Illinois law, Callahan must agree in advance that such privileged information can be shared between different licensed facilities. This “agreement” is typically set forth in the appointment/reappointment forms and/or in an employment agreement. It is also a best practice to have an information sharing policy for the system.

Q: ***Can the committee that authorizes the review be any quality committee, or must it be a medical staff committee. i.e., hospital quality committee that reports to the hospital governing board?***

A: The Medical Studies Act refers both to medical staff and hospital committees. You would want to make sure, however, the process followed to convert the information to privileged materials, as per the court decisions, is followed.

Q: ***Recently our risk group has been discussing whether peer review documents are considered to contain "statements" which we are being asked to produce in the course of discovery. Your thoughts?***

A: Peer review documents which are privileged and confidential are not subject to discovery or admissibility into evidence. Referring to these documents as "statements" or some other term does not make them any less privileged from discovery. Keep in mind, however, that the conclusions reached, as opposed to any recommendations, are not privileged. Using the example above, if the hospital placed Dr. Callahan on an FPPE based on the wrong site surgery event, the plaintiff would not be entitled to the privileged information generated by the various committees if correctly protected but the hospital would have to disclose the fact that Callahan was placed on an FPPE plan.

Q: ***Does the Medical Studies Act apply to outpatient medical practices? How will these decisions and the MSA impact outpatient settings such as procedures done at an ambulatory surgicenter?***

A: The MSA privilege protections apply to the following provider entities:

a) medical organizations under contract with HMOs or with insurance or other health care delivery entities or facilities

b) committees of ambulatory surgical treatment centers or post-surgical recovery centers or their medical staffs

c) committees of licensed or accredited hospitals or their medicals staffs or their designees

To my knowledge, there are no appellate court decisions which have applied or interpreted (a) or (b) above. If the term "outpatient medical practices" refers to an individual physician or physician group practice the general view is that the MSA does not apply. The term "medical organization" is not defined. One could argue that a group practice qualifies if under contract with an HMO or other insurance or other healthcare delivery entities or facilities but this might be a stretch. Given the rather strict interpretation that courts have applied to the MSA, the fact that committees of physician group practices is not included on the list of covered entities does not bode well for such an argument. For example, the appellate court decision in *IDFPR v. Walgreens*, was the first appellate court decision in the country to apply and uphold the privilege protections under the Patient Safety Act as applied to the medication error reports that Walgreens collected and reported to its PSO. Walgreens also argued that the reports were privileged under the MSA but the appellate court rejected the argument because pharmacies are not listed as a current entity

Because the MSA does specifically include committees of ambulatory surgical treatment centers the privilege protections would apply if compliant with the court decisions and recommendations as recommended during the webinar.

Q: ***How applicable is the MSA to non-physician licensed independent practitioners who are deemed non-medical staff members yet have increased front-line roles in our hospitals?***

A: The MSA privilege protections apply to the listed covered entities. It does not attempt to limit or define the individuals involved in privileged peer review and quality of care activities. The term "or their designees" can apply to any health care professional, practitioner or other person so identified as a designee by a qualified committee as reflected in your bylaws and policies. This is one of the reasons I suggested that hospitals and covered entities should include a definition of "designee" in their governance documents and also in the qualified committee's policies which could and probably should include, among others, non-physician licensed independent practitioners.

Q: ***Does the MSA apply to the results of an RCA or other investigation after an adverse event if the hospital does not belong to a PSO?***

A: An RCA analysis can certainly be considered privileged from discovery under the MSA if you comply with the Act and the court decisions and recommendations as explained during the webinar. As mentioned above, however, the conclusions or outcomes most likely will not be protected. It depends, therefore, on what is meant by the "results". Some hospitals specifically do not treat the resulting action plans as privileged because they want to be able to otherwise demonstrate compliance with state and federal regulations while keeping privileged and confidential the underlying analyses and reports which led to the creation of the action plan. The same analysis applies to where the hospital has included RCAs in its patient safety evaluation system (PSES) as part of its participation in a PSO.

Q: ***What about the protections afforded under the Patient Safety Act and membership in a PSO as applied to incident reporting?***

A: As mentioned during the webinar presentation, the PSA generally provides privilege protections to a greater range of patient safety activities and licensed entities including incident reporting as long as this activity is included in a provider's PSES and the report is either actually reported or functionally reported to a PSO or is considered deliberations or analysis in the PSES. There is no reported Illinois appellate court decision as to whether an incident report qualifies as privileged patient safety work product under the PSA in a medical malpractice action. The *Ingalls Hospital v. Daley* appeal which was identified during the program will be the first appellate court decision to address this question. A decision is expected in late spring or early summer.

Case law around the country is split on this question and the answer depends, in part, on whether state and/or federal laws require that incident reports be reported to the state or must be collected and maintained and made available to a government regulatory body. Illinois previously adopted a statute which imposed mandated adverse event reporting regarding specific incidents, such as wrong site surgery, but the law has not yet been implemented. Even if this was the case, the statute includes privilege protections very similar to the MSA.

For additional resource information regarding the Patient Safety Act privilege protections, I have prepared numerous presentations on the subject, which are available for review and download here.