

Foundations of Patient Safety: First, Pick Your Privilege

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In the wake of the IOM report To Err is Human: Building a Safer Health System and the patient safety standards established by the Joint Commission on the Accreditation of healthcare Organizations (JCAHO), health care entities are rushing to improve their performance by implementing patient safety programs. While all of these efforts are highly laudable and probably overdue, the problem of protecting the highly sensitive information generated in this process sometimes gets lost in the shuffle. This article will address some of the problems commonly seen in these programs and will address ways in which an attempt can be made to protect the information.

Privileges in General

If the information is to be protected, it must be rendered confidential. This is typically done by invoking a privilege against discovery in litigation. The first decision point in the process is to determine which privilege may be most useful to protect the information. Privileges are very sensitive things and will be destroyed if not cared for properly. Think of a privilege like you would think of a butterfly's wing: it obscures the view, but is extremely fragile. Courts take a very dim view of privileges and will often deny them if given the chance. The program should be carefully constructed to incorporate the requirements of the privilege, rather than trying to impose a privilege after the fact.

There are essentially three privileges that are commonly used to protect information in health care. The first is the attorney-client privilege, which, unfortunately, has limitations. It works well if the client is an individual, but less well if the client is an entity. Which of the entity's communications are protected? It may not be reasonable to assume that all are protected. Additionally, this requires that an attorney have input into the process, which is not always desirable (and may be expensive) in internal committees and programs. This may not be the best

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EMTALA: A Quick Review and Legislative Update

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If you are taking the time to read this then you certainly know about the Emergency Medical Treatment and Active Labor Act ("EMTALA") and its profound impact on the delivery of healthcare in this country. Enacted in 1986 to prevent the "dumping" of patients without health insurance, this federal legislation applies to all hospitals participating in the Medicare program. The scope of EMTALA has expanded steadily over the years since its enactment. A recent set of rules issued by the Centers for Medicare and Medicaid Services ("CMS" or HCFA with a new name) attempts to clarify some of the compliance issues raised by prior rulemaking efforts and court opinions construing the scope of the EMTALA mandates. We'll take a look at some of these proposed rules.

But first, a quick review of the EMTALA basics that we all know so well: EMTALA requires all hospitals involved in the Medicare program to... 1) provide a "medical screening exam 2) ...to any person who "comes to the emergency department 3)... to determine if an "emergency medical condition" exists and, if so, to 4)... provide that individual with "necessary stabilizing treatment" or an "appropriate transfer." Penalties for non-compliance have been recently increased to \$ 50,000 for each EMTALA violation. Penalties can be levied not only against the offending hospital and its employed physicians, but to on-call physicians as well.

A recent set of CMS rules designed to clarify a variety of EMTALA compliance issues is set to become effective October 1, 2002. Determining how these rule clarifications do, or do not, affect your hospital should be

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choice for a number of reasons.

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The second privilege is the attorney work product doctrine. This generally protects the mental impressions of the attorney as he/she is developing a litigation strategy, which clearly should not be shared with the plaintiff. This privilege, however, is only useful if it can be shown that litigation has commenced or is reasonably anticipated. Again, this will require the involvement, at some level, of an attorney, which again may not be desirable.

The third privilege that is commonly used in health care is the peer review privilege. This privilege is granted by state statute, if granted at all, and may vary from state to state. In North Carolina, this protects the proceedings of a medical review committee, including its records and minutes, as well as those things that the committee considers in reaching its conclusions. N.C. Gen. Stat. §90-21-.22A. Thus, if one is to invoke the privilege, one must bring the information within the purview of a medical review committee. As noted before, courts do not like privileges and will construe them narrowly. Accordingly, if the material appears to be used for any purpose other than consideration by a medical review committee, its protection could be jeopardized.

Patient Safety Committees

Many hospitals have implemented patient safety committees to deal with the issues surrounding compliance with JCAHO standards. Some hospitals have simply re-tooled their safety committees to perform this additional function. This may not be a good idea if one is going to seek protection for the materials generated by or considered by the committee.

The original safety committee was probably set up to deal primarily with Environment of Care issues. These committees were largely concerned with hazards in the environment and employee or visitor safety. The membership roster included multi-function representation, such as environmental services, plant operations and other non-clinical departments. These individuals are not equipped to deal with clinical patient safety issues, hence they will be of little benefit to the group. The minutes of safety committee meetings are not confidential, and probably cannot be made so by any legitimate mechanism. Additionally, it is difficult to represent that a group with non-clinical members is an integral part of the deliberations of a medical review committee.

If a patient safety committee is established, there should be guidelines for it. It should only include clinical personnel. Additionally, the facility should ensure that the medical review committee reviews the committee's minutes and reports, or a summary thereof. Do not allow these materials to be used for any purpose other than performance improvement, such as claims management.

Root Cause Analyses

Properly performed root cause analyses (RCA) are extremely useful tools for process improvement. However, as the original brouhaha over their disclosure to the JCAHO showed, the information in an RCA is *extremely* sensitive. Risk management frequently participates in or plays an integral role in facilitating the work of the RCA team. It is recognized that risk management can gain tremendous insight into the nature and cause(s) of the event through the RCA process. However, the same can be said for other peer review activities.

While it is recognized that this is not the case, courts often view the role of risk management as protecting the hospital's assets, not improving the quality of patient care. Accordingly, the presence of risk management in the RCA process could abrogate the peer review protection for this material. This information should probably be treated with the same deference as any other peer review information. Given the tremendously sensitive nature of the information, it is better to be safe than sorry.

Conclusion

The structure of any patient safety program is extremely important. The better the patient safety process, the more sensitive information will be brought to light. If the program is structured to bring it under the peer review process, and the program actually lives under this process, it may be far more effective, while still protecting the facility from liability.

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a risk management priority for the fall (of course, you'll also need to find time for a few other items such as figuring out what HIPPA actually means, staff recruitment, OIG compliance and locating affordable professional liability insurance). These new EMTALA rules include the following:

- **Hospital-Owned Ambulances-** In general, a patient in an ambulance owned by a hospital is deemed to have "come to the emergency department" of that hospital and EMTALA rules apply. This is so even if the ambulance is not on hospital property. The new rules make clear that transfers to facilities other than hospitals providing emergency treatment (e.g. an assisted living facility) are not within the scope of EMTALA;
- **Dedicated Emergency Departments-** The new proposed rules attempt to further clarify which hospital facilities are actually covered by EMTALA. The rule explains that "Dedicated Emergency Departments" are covered while other hospital-owned facilities are not. The definition of "dedicated Emergency Departments is expansive enough to include freestanding labor and delivery departments and psychiatric units, in addition to typical emergency departments. Importantly, this is so whether or not these departments are on the hospital's main campus. The new rule extends (and limits) EMTALA to any department of the hospital where a "prudent layperson" might reasonably expect to receive emergency medical care.
- **Inpatient vs. Outpatient-** Confusion persists about when, and how, EMTALA applies to inpatients and outpatients and whether the same standards apply to both. The proposed rules attempt to bring some clarity to these issues. The new rule states that EMTALA only applies to inpatients where the inpatient is admitted to the hospital for further treatment of an ongoing "emergency medical condition." Once an inpatient's emergency condition is stabilized, EMTALA no longer applies. With respect to outpatients, the new rules confirms that EMTALA is not applicable to outpatients who visit hospital facilities in connection with a scheduled appointment. The key in both cases is whether the individual seeking treatment presents with a currently existing "emergency medical condition."

The proposed new rules address a variety of topics in addition to those summarized above. As those of you responsible for compliance well know, these rules are ever-changing so careful consultation with your attorney is essential to staying abreast of the most recent EMTALA requirements.

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**Proposed Federal Law Would Limit Recoveries
in Medical Malpractice Lawsuits**

Federal Legislation now pending in the U.S. Congress would significantly rewrite the rules for medical malpractice lawsuits across the country. House Resolution 4600 and its counterpart Senate Bill 2793, known as the HEALTH Act of 2002 would reduce the number of extreme verdicts seen in recent years in the healthcare industry, allocate damages to specific individuals, reduce attorneys fees and allow evidence of insurance to be introduced at trial. The bill is designed to reduce the burden the current medical malpractice system places on health care in this country.

The proposed legislation limits non-economic damages in any medical malpractice lawsuit to \$250,000. This would limit damages for pain, emotional distress and loss of enjoyment of life. The bill would also limit punitive damages to two times the economic damages or \$250,000, whichever is greater and imposes very high standards to establish these damages. Punitive damages are typically awarded in cases of gross negligence to punish a defendant for outrageous conduct. Economic damages including costs of past or future medical expenses, lost wages and similar objective damages would not be impacted by this legislation.

The bill also abolishes joint and several liability in these cases. The bill provides that in any medical malpractice lawsuit with more than one defendant, each defendant shall only be responsible for that percentage of the damages directly attributable to that particular defendant. In short, this "Fair Share" rule would allocate damages based on a percentage of fault established by the trier of fact.

Furthermore, the legislation sets maximum limits on contingency fees for plaintiff's attorneys. Based on a multi-tiered system, a successful plaintiff's attorney can receive a contingency fee of no more 40% of the first \$50,000 recovered. The contingency fee limits decrease up until the maximum contingency fee restriction of no more than 15% of recoveries greater than \$600,000. The bill would reward plaintiff's attorneys who settle their cases for smaller sums, and reduce incentive to hold out for larger recoveries in a single case. A plaintiff attorney who settles 10 cases for \$50,000 each, or a total of \$500,000 will receive a fee of \$200,000, while a competing attorney who settles one case for \$500,000 will only receive a total fee of \$75,000. These contingency fee limits would apply to all cases whether settled or brought to trial.

In addition, the bill allows evidence of collateral source funds or insurance to be introduced at trial. This encourages juries to recognize that health insurance and/or Medicaid or Medicare may be used by injured plaintiffs to provide for medical care, while at the same time defendants typically have multi-million dollar insurance policies that will be responsible for payment of damages in a case.

The bill also provides for other types of medical malpractice reform such as modifications to statutes of limitations for minors, limitation of liability associated with FDA approved medical devices and encourages structured settlements. If this bill becomes law, it will supersede all state law to the contrary.

This legislation will likely face significant opposition by trial lawyers. However, as of this writing more than 100 members of Congress have officially endorsed this bill, and President George W. Bush at a recent speech in High Point, NC called for limits on medical malpractice awards and encouraged reform to repair the nation's medical liability system.

Ken Nanney, J.D.

Ken Nanney serves as Corporate Counsel for Union Regional Medical Center and has been a member of NC ASHRM since 1994.

Find the full text of the bill at www.aha.com and click on the "Professional Liability Reform" section.

MEMBER NEWS . . .

Congratulations:

Richard Thompson – new Director of Risk Management for Onslow Memorial Hospital.

Lisa Byrd – new Director of Risk Management for Scotland Memorial Hospital.

Cheryl Koob – new Director of Corporate Risk Management for the Moses Cone Health System, Greensboro, NC.



Certifications:

Cynthia Hall, MSN, RN, LNCC - passed her certification exam for legal nurse consultants.

Graduations:

Lindsay Mitchell, daughter of Sharon Musselman (GE Medical Protective) graduated from East Carolina University's School of Nursing and now works at Rex Hospital in the Mother/Baby Department. Lindsay is also busy planning her wedding set for October 5, 2002.

Jay Holland, former NCASHRM member and formerly with MMI/St. Paul has passed the bar exam and will work with Smith, Moore Law Firm in Raleigh. Jay and his wife, Brandi also had a baby boy this past Summer.