

RISK MANAGEMENT NEWS

A RISK MANAGEMENT NEWSLETTER FOR MILLENNIUM INSURANCE CO. INSURED

Informed Consent Helps Avoid Lawsuits

Since allegations of “lack of informed consent” and “battery” are common components of many medical malpractice lawsuits, the intention of this abbreviated article is to provide legislative and risk management insight regarding issues of informed consent. The complete article with liability and risk management commentary can be found in **Trends** – Millennium’s single-article publication dedicated to reviewing current medical liability loss trends. The article may also be viewed on our website at www.millenniumins.com.

The Law

In Pennsylvania, a claim for failing to obtain informed consent is considered a battery. A claim for lack of consent for surgery can be maintained even where there is no allegation of negligence in the actual performance of the procedure. Informed consent has been codified most recently by the 2002 passage of the MCARE Act which superseded all prior attempts to codify the doctrine. The MCARE Act does not apply retroactively, however, and does not address all of the details of informed consent that have been addressed by the courts up to the time of its passage. Consequently, common law decisions continue to be authoritative on some of the important aspects of the doctrine.

Unlike common law or prior legislation which required informed consent to be obtained only prior to performing surgical procedures, the MCARE Act requires that, except in emergencies, a physician is obligated to obtain informed consent prior to –

- performing surgery, including the related administration of anesthesia;
- administering radiation or chemotherapy;
- administering a blood transfusion;
- inserting a surgical device or appliance; and

- administering an experimental medication, using an experimental device, or using an approved medication or device in an experimental manner.

The Act, unlike any prior law, will also hold a physician liable for failure to seek a patient’s informed consent if the physician knowingly misrepresents to the patient his or her professional credentials, training or experience.

In obtaining informed consent, the patient must be advised of those *material facts, risks, complications and alternatives* that a reasonable person in the patient’s situation would consider significant in deciding whether to undergo the procedure. Under the MCARE Act, the jury is permitted to take into consideration both what a reasonable patient would want to know and what the doctor is required by his profession to disclose. (Act 13 is available on the MCARE website at: www.mcare.state.pa.us)

Consent is a Process

Remember, informed consent is a process and not merely a form. In order to ensure that patient rights are adequately honored, it is essential that a written protocol be developed to outline and describe your informed consent process. Include these four key components:

- **Consent Discussion** – The consent form should **never replace** a physician-patient discussion. Physicians must reveal the nature and purpose of proposed treatment, risks and benefits of proposed treatment, probability of success, alternative to proposed treatment, and the risks of foregoing treatment.
- **Patient Education** – Provide educational pamphlets, written handouts and preoperative and post operative instructions for patients to better understand the possible complications involved in the proposed procedure and facilitate informed decisions.

INFORMED CONSENT CHECKLIST

To make sure that you are adhering to accepted informed consent principles, remember the following:

- ✓ Obtain informed consent to avoid allegations of *lack of informed consent* and *battery*
- ✓ Avoid misrepresentation of your professional credentials, training or experience.
- ✓ Disclose the material facts, risks, possible complications, and alternatives that a “reasonable person” would consider significant.
- ✓ Document the consent discussion in the medical record.
- ✓ Discuss and document potential outcomes should a patient refuse treatment.
- ✓ Enhance the physician-patient relationship and improve patient satisfaction through the informed consent process.

Inside This Issue:

Informed Consent	Page 1
Protecting Your Medical Practice	Page 2
State Board of Medicine Requirement	Page 2
Statute of Limitations	Page 3
Millennium Announcements.....	Page 4

Protecting Your Medical Practice

Performance Appraisals and Disciplinary Actions

How disciplined is your practice when it comes to employee performance appraisals? If yours is like many other busy practices, performance evaluations are often times neglected because other duties may take priority. However, it is essential that you establish guidelines as to when performance appraisals will be conducted within your practice. Ideally, they should



take place after an employee's probationary period (e.g., three months) and then again every six to twelve months. During the assessment, employees should be given specific and objective information about his/her job performance since their previous assessment or since being hired. If you give the employee vague feedback, you will be doing both your practice and the employee a disservice.

Information communicated to the employee during the appraisal process should coincide with the employee's job description. It is very important that each employee have a well-written, legally safe job description that will allow for effective communication about the employee's performance of those items. Avoid assessing your employees by items which are not in the job description. You should make a point to advise the employee when modifications or additions to the current job description are made.

In an attempt to conduct an effective appraisal, it is necessary that you maintain current and ongoing documentation in the personnel file to guide you through the process. The accumulated information will give credence to both positive and negative feedback to the employee. Be able to give legitimate reasons and state examples for all negative feedback or criticisms given to the employee. Remember that it is equally important to praise employees who exhibit

satisfactory or exceptional accomplishments.

The performance appraisal process not only allows for evaluation of employees' performance but serves other functions as well. These include:

1. Guidance for employee development,
2. Aid in decisions with regard to salary increases, promotions, demotions or discharge, and
3. Assistance in assessing present personnel strength and in planning employment needs for the future.

Another fundamental element is the establishment of progressive disciplinary policies which outline the steps your practice will take to help employees improve performance problems before they lead to termination. This would include:

1. A set of employment standards,
2. Consequences for failure to meet standards, and
3. Progressive steps for disciplinary proceedings. The steps should, at the very least, include a documented verbal warning, a written warning (e.g., "job in jeopardy"), and lastly, termination.

In order to reduce the risk of legal action, you should have adequate documentation in the personnel file. When you conduct a disciplinary conference with an employee, obtain the employee's signature documenting the conference. Consistently apply disciplinary action policies fairly and equally among all employees and have witnesses to all efforts.

Termination agreements are becoming more accepted today in the medical profession as they offer some degree of protection from wrongful termination litigation. If you are ever in doubt as to whether an employee's termination may cause subsequent ramifications for your practice even if you have a legitimate reason for your decision to terminate an employee, or you would like additional information about termination agreements, contact your attorney for legal advice.



State Board of Medicine Requirement

Self-Reporting of Medical Professional Liability Actions

In the event you are served with a lawsuit, the MCARE Act of 2002 mandates that all physicians are obligated to self-report to their respective state licensing board within **60 days** of receipt of notice of any of the following: receipt of service of a civil malpractice complaint, notice of a disciplinary action by another jurisdiction, any controlled substance conviction, and any arrests for criminal offenses such as homicide, assault, sexual offenses, and controlled substance violations.



Reports must be sent to the following address and must include the following information and documents:

Pennsylvania State Board of Medicine
Attn: MCARE Reports
P.O. Box 2649
Harrisburg, PA 17105-2649

1. The court where the case was filed
2. Docket number
3. The date the civil complaint was served on the physician
4. A description of the allegations
5. A complete copy of the civil complaint (DO NOT SUBMIT WRIT OF SUMMONS) or court documents relating to disciplinary action, conviction or arrest.

If you fail to properly report, once the Department learns of the action, the Department's Legal Office staff may send you a courtesy letter, informing you of the duty to report and asking that you do so. However, if 60 days have elapsed since you received the notice and you have not reported the action to the licensing board, you are subject to prosecution under the MCARE Act for failure to report and the Department of State Legal Office may file disciplinary charges against you, with or without having first sent you a courtesy letter.

As a service to our insured physicians, a Millennium defense attorney will help you prepare a summary of the allegations contained in the complaint for you to submit to your state licensing board.

If you should have any questions regarding your obligation to self-report professional actions, you may contact the Millennium Claim Department at **610-848-7300** or you may access MCARE's Act 13 at www.mcare.state.pa.us.



STATUTE OF LIMITATIONS

How long does a patient have to file suit?

The courts have held that an individual asserting a cause of action is required to use due diligence to inform himself or herself of the facts and circumstances upon which the claimed right of recovery is based and institute suit within the applicable **two-year** statute of limitations.



Attorneys who represented patients in these legal actions however, frequently challenged this two year statute through various legal processes. Section 513 of the MCARE Act of 2002 addresses the "Statute of Repose" which establishes an outside limit of seven years in which a malpractice action may be filed. Within this seven-year period however, the new law maintains the current two-year statute of limitations "Discovery" rule in addition to the clarifications outlined below.

The General Rule

The cause of action must be commenced within **seven years** from injury date.

- An adult surgical patient experienced severe pain well after any surgical pain should have subsided. Two surgeons suspected that her pain was caused by internal suturing. Subsequent to the additional surgery to relieve the problem, the patient sued the physician.
- The suit was filed within two years of the second surgery but well beyond the **two years** the patient came to know the cause of her severe pain. The Court dismissed the claim pursuant to the Statute of Limitations justifying that the two year statute of limitations began once the patient knew she had an injury related to her earlier surgery.

Exceptions

1. In the event a **foreign object** is unintentionally left behind, the "Discovery Rule" would still apply, *i.e.*, *two years from the date it was discovered or should have been discovered*.
 - An adult surgical patient undergoes a hysterectomy. Six years later she seeks surgery for abdominal adhesions and a lap pad is subsequently found. The patient filed suit 18 months later. The court would permit the suit to proceed based on the Statute of Limitations Discovery Rule as the suit was filed within the two years of the date the object was discovered.
2. Situations involving **minors**, *i.e.*, individuals who are under the age of 18, have seven years from date of injury to file suit, or after minor reaches the age of 20 whichever is later.
 - Given the proper circumstances, a minor could commence an action as late as 25 years of age.
 - A 10 year-old male patient sought treatment for abdominal pain in the emergency department of a local hospital. The patient was discharged only to return several days later with appendicitis and peritonitis. This child has until the age of 20 to bring a lawsuit. However, if a 17 year-old male child sought the same treatment he would have until the age of 20 to file suit if it can be established that he in fact knew that he was the victim of malpractice. If this patient's attorney can establish that his client was unaware of the malpractice within the first two years after the date of treatment he could, under certain circumstances, bring action against the physician up to seven years from the date of injury under the Statute of Repose.
3. There is a two year statute of limitations from date of **death** for wrongful death and survivor's action, unless there is proof of fraud or concealment of cause of death by the physician.
 - A 55 year-old male sought treatment for chest pain in a local emergency department. The patient was discharged with a diagnosis of intercostal myalgia, and dispensed a prescription. The patient suffered a heart attack and died several days later. Under the Statute of Limitations, the family would have two years from the date of death to file suit.



Disclosure Statement

The information in this publication is provided for educational purposes only and is not intended to set or reflect the standard of care within medical practice. Millennium Insurance Company is not engaged in rendering legal or other professional service and the information provided does not constitute legal advice. If legal or other expert assistance is desired or needed, the services of a competent professional should be sought.

(continued from page 1)



- **The Consent Form** – Develop a consent form for those procedures requiring consent and obtain a

patient's signature for consent. Do not delegate this important task.

- **Documentation** – In addition to the consent form, it is necessary to document the informed consent discussion in the patient's medical record to demonstrate the interactive nature of the consent process. Consider the following points when documenting this discussion:

- Confirm that the consent discussion took place and the patient either consented or declined to consent.
- Detail the patient-specific items that were discussed and/or emphasized.
- Has a consent form been signed?
- Specify the educational handouts or information sheets provided to the patient.
- Indicate whether the patient viewed any media-assisted programs, visual aids, or if internet resources were recommended.
- Note the patient's language, if other than English, and the name and relationship of the translator.

Obtain Informed Refusal

When discussing the nature of a suspected clinical diagnosis and the risks and alternatives to a proposed procedure or treatment, physicians should also disclose the potential outcomes if recommended treatment is not carried out. In the event a patient (or the patient's legal representative) declines the recommended procedure or treatment, their decision should be documented in the medical chart and an informed refusal form completed. Give the patient a copy of the informed refusal form. If the patient should refuse to sign it, note their refusal on the refusal form and in the patient's medical chart. Detail the following when documenting informed refusal:

- Name of the proposed treatment/procedure
- Benefits and risks of the proposed treatment/procedure
- Statement that the patient refused treatment/procedure despite the benefits and risks and the physician's recommendation
- Risks and expected or possible consequences of refusal
- Patient's (or legal representatives) signature including date and time
- Printed name and signature of the person who provided the information and obtained the patient's refusal

Conclusion

Pennsylvania law relies on the "prudent patient standard" or what a reasonable patient would want to know about the recommended treatment. The primary theme emphasized throughout this law is to ensure that patients are provided with all the material facts needed to make an informed choice with respect to the medical options proposed. Additionally, the MCARE Act requires physicians to not knowingly misrepresent professional credentials, training, or experience to a patient.

Although the law is strict, your efforts in obtaining consent will not only avoid the potential allegations of "lack of informed consent" or "battery", it affords the opportunity to enhance physician-patient relationships and improves overall patient satisfaction.

If you should require assistance in developing an informed consent or informed refusal document, please contact the Risk Management Department at Millennium Insurance Company at 610-848-7300.

Millennium Insurance Company appreciates the efforts of Dan Ryan of the law firm of O'Brien & Ryan for his contributions to this article in explaining the obligations of physicians as specified by Pennsylvania law.

Risk Management CD Released

By now, all Millennium insured physicians should have received a copy of **A Patient's Story: The Power of Apology**. In sponsorship with *To Your Health Talk Radio* hosted by Sheri Putnam, the program seeks to assist physicians with the difficult task of disclosing unanticipated medical outcomes by exploring the challenges faced by both patients and physicians as a result of a medical error.

After listening to the CD, complete and return the enclosed questionnaire to qualify for CME. While appreciating the convenience of this activity, you will gain a better understanding of how disclosure may minimize the opportunity of a malpractice lawsuit. If you have not received your complimentary copy, contact the Millennium Risk Management Department at **610-848-7300**.

Visit Our Redesigned Website

Visit the redesigned Millennium website at

www.millenniumins.com

for the latest information on claims made coverage, application procedures, risk management and claim reporting.

We welcome your feedback!