

Preventive Action

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DISCLOSING MEDICAL ERRORS

By the Risk Management Experts at
First Professionals Insurance Company



The manner in which an adverse event or medical error is disclosed is tantamount to claim avoidance. Although most states require that a physician inform their patient in the event an adverse incident results in injury or serious harm, virtually all physicians consider it a moral and ethical duty. The legal requirements to disclose a medical error are often set forth by statutes and administrative codes governing professional licensing. Generally, such disclosure is a non-delegable duty and should be done, in person, by the physician. In many instances, the same statutes that require disclosure of medical error or outcomes of care that result in harm to a patient also serve to protect the disclosing physician to the extent that the disclosure itself may not later be used against the physician as an

acknowledgment of an admission of negligence, or introduced as evidence.

Defining Medical Error

There are situations when it is difficult, if not imprudent, to differentiate an adverse event from a medical error and thus determine if the legal threshold to disclose has been met. In such instances it is best to seek legal or risk management guidance before notification is made to the patient. In most cases, defining a medical error becomes a legal, rather than medical issue. While some states do not define a medical error, they may have statutes which define a “medical injury”. The following statutory language is an example of one state’s rather expansive definition of what constitutes a medical injury:

“...any adverse consequences arising out of or sustained in the course of the professional services being rendered by a medical care provider, whether resulting from negligence, error, or omission in the performance of such services; or in breach of warranty or in violation of contract; or from failure to diagnose; or from premature abandonment of a patient or of a course of treatment; or from failure to properly maintain equipment or appliances necessary to the rendition of such services; or otherwise arising out of or sustained in the course of such services.”

An unanticipated outcome may be an omission as well as a commission. The

most common cause of an unanticipated outcome is the known, but low probability, adverse event.

Failure to Disclose Medical Error

There may, however, be barriers to disclosure. Financial, psychological and cultural barriers are examples of why disclosure of medical error has been withheld. The premature assignment or assumption of blame and risk of a failed response are prevalent root causes for failing to inform or timely disclose an untoward event to patients. Ethical and legal requirements notwithstanding, patients are far more likely to seek legal action following an adverse event or unanticipated outcome when disclosure is not made or made incorrectly.

How to Disclose Medical Error

Disclosure of a medical error or unanticipated outcome is an uncomfortable situation to be sure. To avoid compounding the situation, adhere to the essential components of disclosure:

1. Timely
2. Proper Setting
3. Accurate
4. Factual
5. Responsive
6. Document

An admission of liability is never required as means of disclosure. Before disclosure is made to the patient or patient’s family members, try to obtain as much factual information pertaining to the error or outcome as possible.

Continued on page 2

TABLE OF CONTENTS

Page 3	Red Flags Rule Will Not Apply To Most Physicians
	News Alert
Page 4	Legal FAQs



Anesthesiologists Professional Assurance Company



Anesthesiologists Professional Assurance Company publishes Preventive Action on a quarterly basis as a service to policyholders. Information in this publication does not establish a standard of care, nor is it a substitute for legal advice. The information and suggestions contained in this newsletter are generalized and may not apply to all practice situations. Anesthesiologists Professional Assurance Company recommends you obtain legal advice from a qualified attorney for a specific application to your practice. The information should be used as a reference guide only.

For comments, questions or to obtain additional copies contact the Anesthesiologists Professional Assurance Company Risk Management department at 866-294-6014, ext. 3016.

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Continued from page 1

Seek legal or risk management guidance. Communicate in a manner that is open, forthright and expresses empathy. Do not seek to lay blame nor make excuses. Make it known should information or details be unknown at the time of disclosure. Indicate what steps will be taken to obtain such information. Invite questions and seek answers. Remain responsive to the emotional needs of the patient or family member.

Documenting Disclosure

Carefully document the disclosure. Chart the time, date and place as well as the individuals present. Note the information conveyed, including the known facts, condition and treatment of the patient. Document your discussion of the immediate and long term effects or prognosis, if known. Delineate the current and future clinical interventions. The records should clearly reflect what questions were posed and what the responses were, offers of assistance, if any, as well as the treatment plan agreed upon. Document the agreement (or refusal) for subsequent meetings, the reason for any incomplete disclosure and what follow-up is intended.

Any subsequent discussions should also be carefully documented. The medical record should reflect the efforts that were made to accommodate the patient and family members as well as the information which was known, or unknown, predating the extent of disclosure made. The motivation behind pursuing a claim or suit following an unanticipated outcome or medical error may ultimately come from someone other than the patient. Depending on the circumstances, the best risk management measure may be to increase your communication with the patient and the patient's family members.

Risk Management Guidelines:

- Comply with applicable legal requirements regarding disclosure.
- Do not delegate the duty of disclosure.
- Disclose adverse events and medical error in person to the patient or family member.
- Do not assume or assign blame.
- Adhere to the essential components of disclosure: Timely, Proper Setting, Accurate, Factual, Responsive, and Document.
- Ascertain as much factual information as possible before disclosure is made.
- Communicate in a manner that is open, forthright and expresses empathy.
- Invite questions and seek answers.
- Remain responsive to the emotional needs of the patient or family member.
- Carefully document the disclosure.
- Document the measures undertaken to accommodate the patient.
- Seek legal or risk management guidance, when necessary. ●

Red Flags Rule Will Not Apply To Most Physicians

Federal Trade Commission regulations issued in 2007, known as the “Red Flags Rule” (“Rule”), required that certain entities develop and implement written identity theft prevention and detection programs to protect consumers from identity theft. However, the Rule did not specifically state whether physician practices were subject to the Rule requirements. It remained uncertain if physicians, lawyers, dentists and other professionals should be classified as “creditors” for the purposes of compliance with the Rule just because they do not receive payment in full at the time that they provide their services.

Clarification came in December 2010 with passage of “Red Flag Program Clarification Act of 2010”, which limits the type of “creditor” that must comply with the Rule.

Not billing or receiving payment in full at the time a physician provides services will not result in the physician being considered a creditor under the Rule.*

In light of the new law, the Rule will not apply to most physician practices.

For physicians who are otherwise not exempted, First Professionals has developed a packet of materials to help clarify the Rule pertaining to patient identity theft protection standards. The packet contains an overview of the new Rule, risk management guidelines, and website references. It also contains several forms and templates to assist with compliance measures.

For additional information regarding the Rule or the Red Flag Program Clarification Act of 2010 go to:

- <http://www.ftc.gov/bcp/edu/microsites/redflagsrule/index.shtml>
- <http://www.ftc.gov/bcp/edu/pubs/articles/art11.shtm>
- <http://www.gpo.gov/fdsys/pkg/BILLS-111s3987enr/pdf/BILLS-111s3987enr.pdf>
- www.ama-assn.org,

*The law indicates that creditors that fall under the Rule are only those who regularly and in the ordinary course of business: (1) obtain or use consumer reports, directly or indirectly, in connection with a credit transaction; (2) furnish information to certain consumer reporting agencies in connection with a credit transaction; or (3) advance funds to or on behalf of a person, based on the person’s obligation to repay the funds or on repayment from specific property pledged by them or on their behalf (this does not include creditors who advance funds on behalf of a person for expenses incidental to a service provided by the creditor to that person). Creditors that fall under one of the above-mentioned categories must comply with the Rule. —

News Alert

Burnout Among Doctors Could Hurt Patients Too

In a recent issue, the journal *Anesthesiology* published two studies on medical-staff burnout. In the first study, a Vanderbilt University School of Medicine team administered an online survey to all members of one perioperative unit. Researchers found that physicians, particularly residents, were at higher risk of burnout than nurses and other personnel. Another group of researchers at Northwestern University’s Feinberg School of medicine focused on burnout among senior physicians. They found that about half of the anesthesiologists they surveyed—55 doctors in all—met their criteria for “high burnout” or “moderately-high burnout.” While it is unclear if physician burnout has a direct adverse effect on patient care, it’s almost certain that it makes doctors more unhappy thus hurting patients in turn. Dr. Tait Shanfelt, a Mayo Clinic hematologist, wrote an editorial to accompany the studies. The doctor wrote, “Studies have found that burnout and dissatisfaction influence patient compliance, patient satisfaction with the medical care, and quality of care...Burnout is also associated with medical liability suits and turnover which can create substantial costs to hospital and practice groups.” (*LA Times*, 1/4/11) —



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What is an 'error of commission'?

An error which occurs as a result of an action taken. Examples include when a drug is administered at the wrong time, in the wrong dosage, or using the wrong route; surgeries performed on the wrong side of the body; and transfusion errors involving blood cross-matched for another patient. Errors of omission may or may not lead to adverse outcomes.

What action should be taken when a summons and complaint is received?

Immediately notify First Professionals by calling the Claims Department at (800) 741-3742, ext 3047. If you

are served, First Professionals only has a limited number of days to assign a defense attorney and prepare a response to be filed on your behalf. It is important to not discuss the case with the patient, the patient's attorney or other parties involved in the care and treatment of the patient. You should gather and secure the patient's records immediately.

What is an 'adverse drug reaction'?

An undesirable response associated with use of a drug that either compromises therapeutic efficacy, enhances toxicity, or both.

What is 'direct liability'?

Direct liability is defined simply as being responsible for your own acts. If you deviate from the acceptable standard of care in the manner in which you practice medicine, then you are negligent and directly responsible.

If the patient is present and has the capacity to make healthcare decisions, when does HIPAA allow a healthcare provider to discuss the patient's health information with the patient's

family, friends, or others involved in the patient's care or payment for care?

If the patient is present and has the capacity to make healthcare decisions, a healthcare provider may discuss the patient's health information with a family member, friend, or other person if the patient agrees or, when given the opportunity, does not object. A healthcare provider also may share information with these persons if, using professional judgment, he or she decides that the patient does not object. In either case, the healthcare provider may share or discuss only the information that the person involved needs to know about the patient's care or payment for care.

What is meant by "active communication" as part of the "time out" process?

"Active communication" doesn't necessarily mean everyone has to repeat the same information. The members of the team may signal their agreement by a brief oral acknowledgement, a nod or some other gesture. The point is, absence of a response should not be interpreted as agreement. •