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What Must The Patient Be Told After An Adverse Event?

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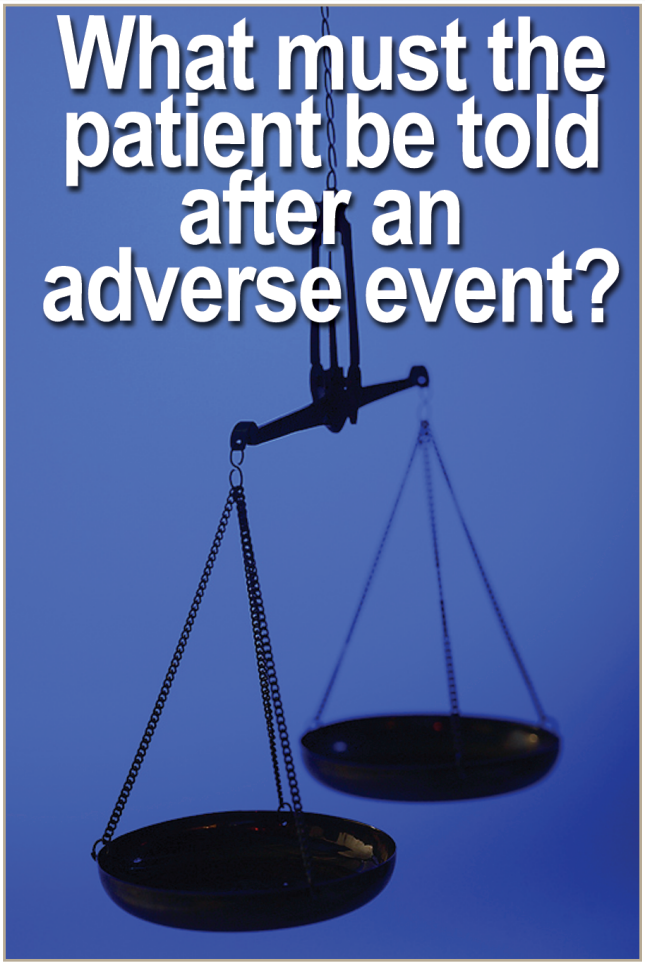

Overview

Every physician dreads the prospect of a patient suffering unintended consequences of their care. Many physicians also struggle with the appropriate type and amount of information to give their patient after an adverse event. Obviously, it is unacceptable to lie to a patient or their family regarding any event. However, a recent survey of over 2,600 doctors indicated wide variation in the disclosure of important information after an adverse event.[1] This may be due in part to a lack of understanding of disclosure requirements. The following article is intended as a summary of a physician's obligations under current New Jersey law to disclose information after an adverse event and the potentially serious consequences of misleading a patient or failing to disclose material information. Ethical and administrative codes are not covered in this summary.

In a recent case a physician accused by a patient of fraud following an adverse event was successfully defended. The Supreme Court of New Jersey ruled that at this time doctors may be sued for lack of informed consent, but not fraud, relating to post-surgical discussions. In the future, however, fraud claims may be permitted where there is harm "separate and distinct" from any alleged negligence. For example, if a surgeon cut a nerve but told the patient subsequent numbness was due to nonexistent diabetes, and prescribed unnecessary medication which caused an adverse reaction, the harm of the reaction would be due to fraud, not alleged negligence, and the doctor might have to pay "punitive" damages from personal assets, not an insurance policy.

The *Patient Safety Act of 2004* requires physicians to inform health care facilities licensed by New Jersey of all *"serious preventable adverse events"* and *"adverse events related to an allergic reaction"* during the episode of care, or if discovered afterward, in a *"timely fashion"*. The facility must assure the patient and Dept. of Health and Senior Services are notified. As an example, where a patient suffers a chemotherapy overdose and serious bodily injury due to staff error, the facility, patient and State must be notified according to the Patient Safety Act (PSA).

However, events not meeting statutory or common law criteria may not have to be reported. For instance, a medication error recognized before harm occurred may be reported to the facility, patient and State on a voluntary basis. Other cases may cause the physician to be uncertain as to whether reporting is required. Physicians may wish to contact their insurance company and seek the advice of counsel regarding how to proceed following an adverse event so as to best protect themselves, their patients and facilities from further medical/legal consequences. Doctors should also be familiar with their facility's policies and procedures for disclosure of adverse events.

Fraud and Informed Consent/Refusal

The two sources of law discussed in this article are common law and

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statutory law. Common law evolves from decisions made and followed by courts over time. Two common law doctrines which patients' attorneys may seek to apply to disclosure following an adverse event are fraud and informed consent/refusal. Fraud generally involves a statement of material fact, known to be untrue at the time it is made, with the intent that it be relied upon by another, with the other party relying upon that statement and suffering harm as a result.[2] Informed consent generally requires a physician to disclose information which a reasonable patient would find "material" to their choice among providers and reasonable medical alternatives, including non-treatment, for their condition.[3] Its corollary, "informed refusal," typically involves the failure to warn a patient of potential risks of refusing a recommended course of treatment or monitoring of their condition.[4] Statutory law is set forth by legislative bodies. It may impose duties to disclose information which are greater, less than or equivalent to common law requirements.

What are the potential penalties for fraud?

The Medical Practices Act empowers the Board of Medical Examiners to investigate "fraud, deception, false pretense" or other "dishonesty" and punish such acts by fines, temporary suspension or permanent revocation of license as well as other penalties.[5] Roughly 60 to 80 doctors lose their license each year for misconduct including fraud. Heavy fines and costs are also imposed by the Board of Medical Examiners.[6]

Can a patient sue a doctor for fraud based on a post-surgical discussion?

On June 25, 2007 the Supreme Court of New Jersey decided *Liguori v. Elmann, et al*. Therein a cardiac surgeon performed a successful quadruple bypass on a 71year old woman. She later suffered a collapsed lung. The attending surgeon, in the midst of another bypass, sent an assistant surgeon to insert a chest tube. The assistant inserted the tube but unknowingly lacerated the heart. The attending's partner later explored the patient in the operating room, repairing a small hole in the left ventricle. The partner told the attending that the chest tube was the cause of the hole he repaired. The patient was unconscious but stable. The attending testified he told the patient's family these facts. He noted the event and its cause, but not the notification, in the chart. The family claimed they were not told of the collapsed lung or chest tube insertion but only that a "small bleeder" had occurred and was repaired. The family claimed that if they had been told "the truth" they would have transferred their mother from this "unsafe environment" and would have had a better chance of preventing her death two months later from complications including a deep, infected bedsore and sepsis which occurred after the chest tube injury.

The patient's family sued the assistant surgeon for negligence in his insertion of the chest tube, claiming it ultimately caused the patient's death. They also sued the attending cardiac surgeon for fraud based on his alleged misrepresentation to the family regarding the cause and extent of injury to their mother, alleging this contributed to her death. The trial judge dismissed the fraud claim but permitted plaintiffs to sue the attending for lack of informed consent to the continuation of care by the defendants based on plaintiffs' contention that information material to their choice of health care provider was not given them by the attending. The jury found unanimously in favor of the attending cardiac surgeon on the informed consent claim and also in favor of the assistant surgeon on the negligence claim. Plaintiffs appealed but the jury's verdict was sustained by the Appellate Division and by the Supreme Court of New Jersey.[7]

The Court declined to create a common law "fraud or deceit based cause of action" against physicians for an alleged post-surgical misrepresentation. However, the basis for this decision was the absence of any harm to the patient from the alleged fraud of the attending which was "separate and distinct" from the harm resulting from the allegedly negligent chest tube insertion by the assistant. Other states, including New York, permit claims against physicians for post-surgical fraud where injuries resulting from the fraud are "separate and distinct" from the harm resulting from negligence.[8] The New Jersey Supreme Court did not say how it would decide a case in which there were injuries from the alleged fraud which were "separate and distinct" from the injuries attributed to the alleged negligence. Therefore patients' attorneys will be actively seeking such a case to bring before the Court in the hope of expanding physician liability.

What would be the consequences of a lawsuit claiming fraud?

Fraud is an "intentional" act, unlike negligence. Insurance companies do not cover physicians for "intentional acts" as public policy prohibits insuring anyone for intentional misconduct. This means the entire cost of defending a fraud case, which can be tens of thousands of dollars, would have to be paid by the individual doctor out of his or her personal assets, *even if the doctor wins*. Any judgment or settlement in favor of the patient would also have to be paid by the doctor out of personal assets. In fact the jury would review the doctor's personal assets to assist them in determining appropriate financial "punitive damages" if the jury found the doctor knowingly lied about a material fact with the intent that the patient rely upon it, and that the patient suffered harm as a result of that reliance.

Currently, patients *can* seek punitive damages for "fraudulent concealment of evidence" where a doctor alters or destroys a patient's medical record and the patient is hampered in their efforts to prove a malpractice claim as a result.[9] If a doctor performs "ghost surgery" in place of the authorized physician, the patient may obtain both compensatory damages for any injury and punitive damages for "battery", which is the intentional, unauthorized touching of another person.[10] Judgments and settlements in favor of patients in civil suits must be reported to the Board as a matter of public policy.[11] A fraud claim by a patient in a civil suit could also trigger investigations by both the health care facility and the Board of Medical Examiners, with loss of privileges and license a distinct possibility. Hence, consequences of fraud claims can be severe.

Can a doctor be sued for lack of informed consent for post–surgical discussions?

Yes. The *Liguori* case described above involved a patient family's claim that following a surgical mishap the attending surgeon failed to provide them with information which would have been "material" to a reasonable person in deciding whether to permit the defendant doctors and hospital to continue to care for their mother. They claimed the right of "self determination" enjoyed by every patient was violated by the attending surgeon, and that if they had been told the true cause and extent of their mother's injury they would have transferred her from an "unsafe environment" in time to prevent complications including a deep, infected bedsore which caused her death due to sepsis. The jury accepted the doctor's account of his post-operative conversation with the patient's

family. However, had the jury found for the plaintiffs they would have been permitted to enter an award against the doctor for part of the injuries suffered and the alleged wrongful death of the patient. This would likely have been paid by the doctor's malpractice insurance company, along with the cost of the doctor's defense, but would also have resulted in a substantial increase in the doctor's malpractice premium, or perhaps even cancellation.

What is the *Patient Safety Act* and how does it apply to adverse events?

Purpose- In April 2004 the New Jersey Legislature enacted the *Patient Safety Act*, in response to their finding that "health care literature demonstrates that the great majority of medical errors result from system problems, not individual incompetence" and that preventable errors were "inherent in all systems". The Legislature's goal was to create a system that would allow for the detection and analysis of medical errors while creating a "non-punitive culture that focuses on improving health care, not assigning blame." While finding that health care facilities and professionals must be held accountable for "serious preventable adverse events" the Legislature also recognized that "punitive environments … may be a deterrent to the exchange of information required to reduce the opportunity for errors to occur in the complex systems of health care delivery."[12]

Therefore by mandating the "confidential disclosure of the most serious, preventable adverse events" and also encouraging the "voluntary, anonymous and confidential disclosure of less serious adverse events, as well as preventable events and near misses the State seeks to increase the amount of information on system failures, analyze the sources of these failures and disseminate information on effective practices for reducing system failures and improving the safety of patients."[13] Annual summaries are issued by the Dept. of Health and Senior Services.

Patient Safety Plan-The Act requires health care facilities to create a "patient safety plan" which includes the formation of a committee and teams of facility staff, "comprised of personnel who are representative of the facility's various disciplines" and who are competent "to conduct analysis and application of evidence based patient safety practices in order to reduce the probability of adverse events resulting from exposure to the health care system across a range of diseases and procedures, and … to conduct analyses of near-misses, with particular attention to serious preventable adverse events and adverse events."[14] The law requires health care facilities to report "every serious preventable adverse event that occurs in that facility" to the N.J. Dept. of Health and Senior Services and to assure that the patient is informed.[15] The law also requires the health care facility to create a process for ongoing patient safety training for facility personnel.

Definitions- An *event* means a "discrete, auditable and clearly defined occurrence". A *near miss* is an "occurrence that could have resulted in an adverse event but the adverse event was prevented." An *adverse event* is "an event that is a negative consequence of care that results in unintended injury or illness, which may or may not have been preventable". A *preventable event* is "an event that could have been anticipated and prepared against but occurs because of an error or other system failure." A *serious preventable adverse event* is defined as "an adverse event that is a preventable event and results in death or loss of a body part, or disability or loss of bodily function lasting more than seven days or still present at the time of discharge from the health care facility." *Health care facility* is one licensed by the State of New Jersey.[16]

Duty to tell the patient- Of even greater concern to health care providers is the PSA requirement that every licensed health care facility inform every patient affected by a "serious preventable adverse event or adverse event specifically related to an allergic reaction, no later than the end of the episode of care, or, if discovery occurs after the end of the episode of care, in a timely fashion." [17] The notification can be given to a family member if the notice would "seriously and adversely affect the patient's health." If an adult patient is not informed of a serious preventable adverse event or adverse event specifically related to an allergic reaction, the facility shall assure that the medical record states the reason for not informing the patient. Pursuant to the Act, "The time, date, participants and content of the notification shall be documented in the patient's medical record." The content of the notification shall be in accordance with the rules and regulations to be set forth by the Commissioner of the Department of Health and Senior Services.[17] Most facilities have policies in place regarding notification.

Use in other settings- The PSA provides that any documents "concerning serious preventable adverse events, near misses, preventable events and adverse events that are otherwise not subject to mandatory reporting pursuant to subsection c. of this section shall not be (1) subject to discovery or admissible as evidence or otherwise disclosed in any civil, criminal or administrative action or proceeding; (2) considered a public record." Neither can this information be used in any "adverse employment action or in the evaluation of decisions made in relation to accreditation, certification, credentialing or licensing of an individual."

However, this restriction does not apply where the health care provider has shown "recklessness, gross negligence or willful misconduct, or in which there is evidence, based on other similar cases known to the facility, of a pattern of significant substandard performance that resulted in serious preventable adverse events."[18] In such cases the facility, professional boards or Attorney General may take disciplinary action. Moreover, no court has yet ruled on the conflicts between the provisions of the PSA and other law, for example, the general rule of evidence that one's own statements may be used against them.[19] Therefore caution is advised when making oral or written statements regarding adverse events.

Frequently Asked Questions- Having received an overview of the Act's provisions it may be helpful to address some of the questions frequently asked by healthcare providers who are uncertain of how this law may impact them:

What events must be reported under the PSA?

Any "*serious preventable adverse event*" or "*adverse event related to an allergic reaction*" as defined above. These must be reported by the doctor/provider to the facility and by the facility to the patient and N.J. Dept. of Health and Senior Services.[16]

Who must be told?

Generally, a competent adult patient must be informed. However, in the case of a minor or incapacitated patient their parent, guardian or family may be told. Moreover, if there is a "good faith" basis to believe that providing the information to the patient would seriously and adversely affect the patient's health, then the patient's family may be given the information instead.[17]

When must the patient be told?

During the episode of care, or if the event is discovered after the episode, in a "timely fashion."[17]

Do I have to tell them myself?

Consult the procedure at your health care facility as to whether you are personally obligated to inform the patient. The facility is required by statute to "assure" that the patient is informed of all serious preventable adverse events or adverse events related to an allergic reaction.[20] Therefore, if a healthcare provider(s) does not inform the patient or their family, regardless of whether they were involved in the event, then a facility administrator will have to notify the patient or family.

However, as a practical matter, if you contributed to the adverse event it may be better for you to explain it than to entrust the explanation to a third party who may not even be a health care provider and/or may not fully understand what happened and why the event occurred. Asking a "risk manager" to speak for you may send the wrong message to the patient as it may suggest you are more concerned about protecting yourself and the facility than about helping your patient cope with the adverse event. Some facilities require the attending physician to notify the patient.

Moreover, the patient and/or their family may expect their doctor to inform them. Your absence or silence may increase their anger, frustration and desire to seek counsel. Even if you were not involved in the event itself it may be helpful to all concerned to have a trusted doctor or other health care professional present to help explain what happened, the likely impact on the patient's health, the treatment options available and their prognosis. It is important to patients and families to answer questions directly, to the extent possible, and to explain any steps taken to prevent a reoccurrence of the event.[21]

What must the patient/ family and State be told?

The Dept. of Health and Senior Services creates and updates PSA guidelines for reports to the State. See the DHSS website www.state.nj.us/health and search "Patient Safety Initiative" for more information. Future regulations are anticipated under N.J. Admin. Code 8:43E-10. In *Liguori*[7], informed consent to continued care of the comatose patient required disclosure to the family about the cause, extent and care of her injury. Other information, such as the availability of treatment and monitoring to minimize risks of harm, may also be important to the patient,[22] and even necessary to meet informed consent/refusal requirements. Consult facility procedures and counsel for guidance on what patients or their families must be told in specific situations.There are also helpful guidelines on what to say, and how to say it, when informing patients.[22]

What must I document in the chart?

Generally, the same information provided to the patient verbally. The date, time, persons present for the notification and the content of the notification should be documented.[17] If a competent adult patient is not notified then the reason(s) that the health care provider chose to inform the family instead of the patient must also be documented.[20]

Will telling the patient or family about such an event increase the chances of a lawsuit?

It may. However, failing to tell them may also increase the chances of a lawsuit. In most *"serious preventable adverse events"* or other mishaps the patient and their family members are already aware something has gone wrong and will understandably have questions about it. Studies have shown that patients who feel their healthcare providers are hiding information from them, or worse yet misleading them, are highly motivated to seek counsel and use the court system to try to find the answers they feel their health care provider failed to give them.[21]

In contrast, some patients who get an honest explanation of the occurrence from their healthcare provider do not sue, even though they may have a legitimate claim, because they recognize errors can occur and they continue to trust health care providers who are honest with them. There is evidence to suggest an honest explanation and apology may decrease the likelihood of a lawsuit. However, pre-suit settlements may also be an important part of the statistical decrease in the number of lawsuits filed. See www.SorryWorks.net for further information.

Should I say "I'm sorry"?

In the past four years 27 states have passed laws which allow physicians to apologize when things go wrong without fear that their words will be used against them. Nine other states are considering such measures.[24] The PSA attempts to protect statements made to the patient when disclosing an adverse event.[25] However, no court has yet decided that the PSA overrides the general rule that one's statements may be used against them.[26] Patients and jurors may well interpret "I'm sorry" as an admission of fault. Again, caution is advised when communicating any mishap. In any event, efforts to prevent future adverse events are important to patients.[21] Evidence of remedial measures taken after an event to prevent recurrences is generally not admissible in court to prove negligence, though it may be used for other purposes.[23]

Can any of my statements or documentation be used against me?

The PSA indicates that the written and verbal information given by the provider/facility to the patient and/or State are not subject to disclosure, nor admissible in a civil, criminal or administrative action.[27] Generally, patients' attorneys are not allowed to obtain a facility's internal documents unless a judge finds the patient cannot obtain the facts through the ordinary pre-trial discovery process and that the need for this information outweighs the public interest in the confidential evaluations necessary to improve health care systems.[28]

However, the statements or documents may be used if a facility, professional board or the Attorney General seeks to discipline, terminate or suspend a provider who displayed "recklessness, gross negligence or willful misconduct" or a "pattern of significant substandard performance resulting in serious preventable adverse events."[29] The PSA also provides that the date, time, participants and content of the notification of the patient regarding a serious preventable adverse event or allergic reaction is to be documented in the patient's chart.[30] Patients have a right to obtain a copy of their chart.[31] Final regulations to be issued under N.J. Admin. Code 8:43E-10 may protect notification documents from disclosure; if not, patients will certainly share them with their attorney. The documents may also be available through "any source… other than those specified in this

Act".[32] No court has yet ruled on these potential "loopholes" in the law. Therefore caution is advised when communicating any mishap.

Moreover, if a doctor gives the patient an explanation at the time of the event, but later gives a different explanation in court, the patient's attorney may argue the original explanation should be put before the jury to discredit the explanation the doctor is now giving the jury. No court has yet ruled on such arguments. Therefore, doctors should be careful when explaining the perceived cause of the event in the hours or days after it occurs. Experience has shown that subsequent detailed analysis, such as that in peer review, root cause analysis or litigation, may reveal a different cause than was perceived when the event occurred. It would be wise to explain and document that the cause stated to the patient is based on a preliminary investigation.

Can the facility or Board punish me for not disclosing required information?

Yes. The health care facility is subject to fines and other sanctions for violations of the PSA.[33] Even if the patient somehow does not know about the event, the JCAHO reviews charts and may discover the incident. If there is no documentation that the patient or their family has been informed of a "serious preventable adverse event" or "adverse event related to an allergic reaction" the health care facility is subject to State fines. This could cause the health care facility or a professional board to initiate some form of disciplinary action against the "silent" provider.

Must I also report less serious incidents to the facility, patient or State?

The PSA encourages voluntary reporting of "preventable events", "adverse events" and "near misses" to the facility for the purpose of discovering and repairing defects in the health care system. Voluntary reports by the provider to the facility, patient or State are subject to the same provisions on discovery and adverse use as the more serious events for which the PSA requires notice to the facility, patient and State.[34] However, informed consent/refusal requires disclosure of information which a reasonable patient would deem "material" in making health care choices, including choice of provider, even though the PSA may not require disclosure. Patient attorneys may claim silence suggests a doctor was hiding negligence, not an explainable "complication".

What should I document to help defend myself and my colleagues?

The American Society for Healthcare Risk Management suggests documenting:

1) Clinical details. A complete, accurate factual description of the clinical information related to the event should always be entered in the medical record by the appropriate health care provider.
    - Objective details of the event, including date, time and place;
    - Patient's condition immediately prior to the event;
    - Medical intervention and response;
    - Notification of physician and/or consultants.
2) All communication between the health care provider and the patient/family. Consult your facility's requirements but this generally should include:
    - Time, date and place of discussion;
    - Names and relationships of those present for the discussion;
    - Contents of the discussion;
    - Questions asked and responses given;
    - Patient reaction and level of understanding exhibited by the patient/family;
    - Treatment alternatives, the risks and benefits of each as discussed with patient;
    - Plan for further care or monitoring, reasons for it, and any follow up discussions;
    - Any offer of assistance and the patient's response to it;
    - Note that additional information will be provided as it becomes available;
    - Avoid derisive comments about other providers and self serving statements.[35]

One may consider asking a competent patient or family member to read and sign the notification documentation. This may increase the chances of the patient seeking counsel and a copy of the document, but may also help prevent or defend later claims that appropriate disclosure was not made to the patient or family and that additional harm was suffered as a result.

Summary

At present there is no common law "fraud or deceit based cause of action" arising from a post-surgical discussion which would permit a patient to seek "punitive" damages from a doctor's personal assets. However, the law is subject to change at any time. Failure to disclose material information regarding mishaps may violate patient rights to informed consent/refusal of future care. Fraud claims are permitted for record alteration. Statutes empower the Board of Medical Examiners and health care facilities to punish fraud, dishonesty and other "willful misconduct" in any situation. Doctors and other health care providers lose their privileges and licenses each year due to misconduct including fraud. It is unacceptable to lie to a patient or their family.

The Patient Safety Act is statutory law in New Jersey. Health care providers must report to their facilities, and facilities must report to their patients and the State all *"serious preventable adverse events"* and *"adverse events related to an allergic reaction"* during the episode of care, or if discovered after the episode of care, in a timely fashion. Notification of the patient or family must be documented in the patient's chart. Voluntary reporting of "preventable events","adverse events", and "near misses" to the State is encouraged to help detect and repair flaws in the health care system. Doctors should familiarize themselves with their facility's policies and procedures regarding disclosure. Penalties may be assessed for failure to comply with this law.

The PSA attempts to offer some protection from the use of this information against health care providers except in cases of "recklessness, gross negligence, willful misconduct" or a "pattern of substandard performance resulting in serious preventable events" which may result in disciplinary

actions by the facility, professional board or Attorney General. The Dept. of Health and Senior Services has already issued some guidelines and will issue regulations governing disclosure under N.J. Admin. Code 8:43E-10 in the future. However, potential "loopholes" on access to and use of this information by patients and others against health care providers have not yet been ruled on by courts. Therefore caution is advised when communicating any mishap.

Although the PSA may not obligate a doctor to disclose a "preventable event", "adverse event" or "near miss", a patient may still claim disclosure would have altered their choice among reasonable medical alternatives, including their choice of provider. Therefore the common law duty to obtain informed consent or an informed refusal may exist even where no statute requires disclosure to a patient. Civil liability may result if the patient can prove it is more likely than not that disclosure of the omitted information would have caused a reasonable person to alter their health care choices and would likely have prevented harm. It may be wise for a doctor to contact their insurance company and seek counsel where there is uncertainty regarding disclosure duties.

Instead of viewing the law as a burden, try to recognize what may be your only opportunity to discuss the event with your patient and "set the record straight." Patients will seek answers from other health care providers who may not understand what happened and may be critical of your care. Rely upon facts, not speculation in the disclosure to the patient or State. Indicate that only a "preliminary" investigation has occurred. Avoid derogatory or self serving statements.

Never assume your spoken or written words cannot be used against you or a colleague in the event of a lawsuit, Board or facility investigation. Obtaining a competent patient or family member's signature acknowledging the date, time, participants and content of the notification may encourage patients to seek counsel and a copy of the document. However, the patient's signature may also help prevent or defend claims that timely and appropriate disclosure was not made and that lack of disclosure resulted in further harm. Silence can be worse than disclosure.

After a serious preventable adverse event or other mishap, the patient may feel wounded both physically and psychologically by their health care provider. A candid discussion may start the patient on the road to recovery and may also begin to repair the relationship between the patient and their health care provider. The report to the facility and State may ultimately spare other patients and providers from similar events and improve health care in the future.

The foregoing is not to be construed as legal advice. Health care providers should familiarize themselves with the policies, procedures and requirements of their health care facilities for reporting and disclosing such events to their facility and patients. Health care providers are advised to consult a qualified attorne on the issues discussed herein and any reated matters.❖

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Questions and/or suggestions are welcome. Call the Healthcare Risk Services Department at 1-866-RX4-RISK