Informed Consent: A Review

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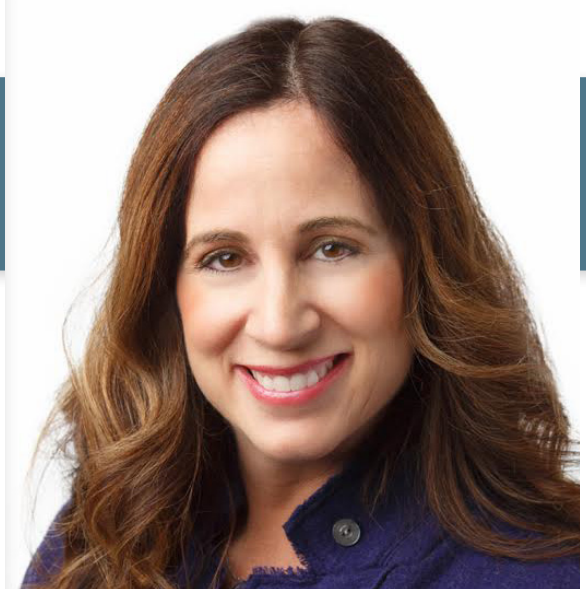

Physicians may become the subject of investigation by state licensing agencies when patients suffer side effects from a procedure, such as a cosmetic injection.

Physicians often assume this cannot happen if they obtain informed consent, but many physicians use poorly drafted informed consent forms that do not offer much protection. However, in recent years, issues with informed consent have become more prevalent and physicians are at a higher risk of liability, even for minor, seemingly obscure, omissions in the forms they use.

Physicians often use informed consent forms that they receive from colleagues or directly from a manufacturer or a drug company that provided the item or product that is the subject of the consent. Typically, these consent forms will state the major potential side effects and concerns arising from the procedure, medication, etc. However, standards for informed consent vary from state to state. This makes it difficult to find a uniform consent that works for everyone. Many physicians fail to even review the forms they use to determine if they meet state laws, standards of practice or specific regulations (such as “black box” warnings issued by the FDA). Many more physicians fail to update the forms over time as laws change or new side effects are discovered.

The legal doctrine of informed consent has evolved over the years, but generally includes two distinct components: (1) a patient’s right to determine what happens to his or her body; and (2) a physician’s duty to provide a patient with enough information to make an educated decision regarding his or her condition and proposed treatment. Individuals have the right to consent to any medical treatment or procedure. The physician’s job in the informed consent scenario is to provide the patient with enough information about the treatment or procedure in order for that individual to make an informed decision on whether to proceed. Included in the necessary information to be shared by a physician are reasonably foreseeable risks, outcomes and alternatives to the treatment or procedure, and what will happen if the patient declines the treatment or procedure. A physician does not have to explain every possible risk, but does have to explain the ones that are reasonably foreseeable. From a legal perspective generally requires the following:

a. The patient’s diagnosis;

b. The nature and purpose of a proposed treatment or procedure;

c. The risks and benefits of a proposed treatment or procedure;

d. The alternatives and associated risks and benefits; and

e. The risks and benefits of not receiving or undergoing a treatment or procedure.

A physician can only make decisions without patient consent in very limited circumstances, including:

1. Emergency Situations. A patient enters the emergency room following a severe car accident, which has left her unconscious and with internal bleeding. The patient’s next of kin is not present and will not be available in time for the physician to save the patient’s life. As a result, the physician may presume consent. This is because there is a presumption that if the patient was conscious, the patient would consent to lifesaving treatment.

2. Compulsory tests. An individual may be legally required to comply with a test or treatment. In this case, informed consent is not required.

3. Incompetence. Children and patients with mental disabilities are legally unable to provide informed consent in relation to a medical treatment or procedure. In this instance, if there is a parent or guardian present, they may be able to provide consent on behalf of the incompetent individual. However, in the event of an emergency or life-threatening medical situation, a physician may be able to provide treatment without a parent or guardian’s consent.

Generally, a patient can sue a physician for failure to obtain informed consent if the physician had a duty to inform the patient about certain material risks of the procedure or treatment. If the physician falls short in disclosing and/or explaining the risks, and the patient then consents to a procedure that he or she would otherwise not have agreed to if the physician had fully described the risks (and patient injury results) then there is a possible professional negligence claim. The patient must, however, demonstrate a connection between the alleged informed consent failure and the purported injury. The only way to avoid this potential malpractice risk is for physicians to be aware of all possible risks of the proposed procedure or treatment and to clearly communicate this information to the patient; however, it is still difficult to know when enough is enough in terms of sharing risks and information with a patient.

Another issue that physicians face is limited patient health literacy. Establishing an effective informed consent process requires an open dialogue between physician and patient regarding all aspects of the prospective procedure or treatment. This includes the benefits, alternatives, and potential complications of any treatment. It is the physician's job to ensure not only that this information is communicated to the patient, but that the patient understands what he or she is being told. Physicians often make the flawed assumption that a patient understands and can actively participate in the conversation, but this is often not the case. Patients may lack proper understanding due to barriers in language, literacy or education. It may even be that the trauma of their diagnosis and fear of the potential procedure is blocking their ability to fully comprehend what the physician is saying.

In order to assure patient comprehension, physicians should create consent forms, that lay out in detail all the information that they will be communicating verbally. Providing the patient with accurate and thorough documentation of the treatment discussion, and having a written confirmation of the patient's decision serves a number of important functions. Not only does it demonstrate that the patient understands, but it is also serves as a legal record that the conversation occurred. If the patient was to bring a malpractice claim alleging improper or lack of informed consent, the document would serve as some protection for the physician. In addition, in order to confirm patient understanding, it is helpful to require that the patient state in their own words what they understand and what they can expect from the procedure after their discussion with the physician.

Consent documents must also be written at an appropriate reading level, with medical terms defined in non-technical language, and in a language that the patient understands. Font sizes should be adjustable to patient needs. Procedure information should be standardized enough to ensure that all applicable information is included for a given operation, but specific enough to cover the particulars of each individual patient's case.

Putting all of these factors into play to reinforce the requirements of informed consent will improve patient understanding of potential benefits and risks of procedures, and serve to properly document that understanding. With this foundation, patients are less likely to successfully accuse physicians of facility to property disclose risk in cases where outcomes are less than optimal.

Even an informed consent with all the proper components may not be adequate. In reality, how does the physician know a patient's true understanding? What constitutes adequate disclosure of information? How much information needs to be disclosed? What risks are reasonably foreseeable as opposed to improbable, and therefore, do not need to be communicated? There are three general approaches in response to these questions:

The "reasonable physician standard" places the duty on the physician to disclose information to a patient that any reasonably prudent physician with the same background, training and expertise, practicing in the same community would disclose to the patient in the same situation. While physicians may be most comfortable with this standard because it focuses on their perspective, what a "reasonably prudent physician" may disclose can vary greatly from what a reasonable person may expect to hear. Although a number of courts find the reasonable physician standard to be appealing (as it is the same standard applied to other types of malpractice claims) it often is viewed as inconsistent with the goal of informed consent, because the focus is on the physician and not what the patient needs to know.

The "reasonable patient standard" requires a physician to disclose information based on the point of view of the patient, rather than the physician. A growing number of state courts are applying the reasonable patient standard.

Finally, some courts use a "subjective patient standard" that asks what an individual patient, based on his or her particular set of circumstances, would need to know and understand to provide an informed consent. The standard is rarely applied given the difficulties of tailoring information to each patient; however, physicians may consider using this standard for patients with cognitive impairments or other medical issues that may affect their understanding.

Whatever approach is most common in your practice or area, it always is a good idea to have knowledgeable legal counsel review any written informed consent document to make certain it complies with local law and minimizes your legal risks ■