Physicians: Don't Let Inadequate Informed Consent Raise Legal Problems

Many physicians fail to review or update their informed consent forms to ensure they comply with state laws, standards of practice, and specific regulations.

A physician client recently became the subject of an investigation by a state department of professional license enforcement when a patient suffered a side effect from a cosmetic injection.

Although the side effect is rare and unlikely to even have resulted from the injection, the licensing agency chose to fully investigate.

This got me thinking about the issue of informed consent for treatment. Physicians often use informed consent forms they receive from colleagues or directly from a manufacturer or a drug company providing the item or product that is the subject of such consent.

Typically, these consent forms will state the major potential side effects and concerns arising from the procedure, medication, etc. The standards for informal consents vary from state to state, making it difficult to create a uniform consent. Many physicians, however, fail to review these forms 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 these forms as laws change or new side effects are discovered.

The legal doctrine of informed consent has evolved over the years, but basically 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. Breach of the doctrine of informed consent may be viewed as a violation of the physician’s practice license (as in the case of my client) or, in some jurisdictions, deemed a criminal battery, an un-consented form of touching (not covered by liability insurance) or professional malpractice (covered by liability insurance).

Complete informed consent from a legal perspective generally requires discussion of 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.

Even an informed consent with all these components may not be adequate. In reality, how does the physician know a patient’s true understanding? What does constitute adequate disclosure of information? How much information needs to be disclosed? 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.
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. 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.

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 risk.

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