MIEC Loss Prevention
# Claims Alert

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# Informed Consent Revisited: What is Expected of Physicians

## INSIDE

*Why we have consent laws . . . . 1*
*Implied consent for minor procedures and emergencies 1*
*Benefits of informed consent . . 2*
*When consent is withheld for religious reasons . . . . . 2*
*Answers to common questions about informed consent . . . 2*
*Documenting informed consent and refusal discussions . . . 3*
*Use audiovisual, written aids . 4*
*Summary of Recommendations . 4*

*Note: This Claims Alert summarizes the general principles of informed consent. An enclosed supplement addresses specific consent issues in California, Hawaii, Idaho, Alaska and Nevada*

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*"Informed consent" has generated many articles, legal opinions and court decisions, yet it is still a misunderstood legal doctrine. The failure to obtain an informed consent is a common allegation in cases that involve surgery, invasive diagnostic studies and medications. In some cases, defendants are absolved of negligence, but are held liable for not adequately disclosing the material risks of treatment which prevented the patient from giving an informed consent. Many physicians think "informed consent" is something they* ***give*** *to patients. In fact, doctors* ***obtain*** *consent from patients who give permission to proceed after they have been informed of a proposed procedure's risks, alternatives and their risks, and expected outcome. To protect themselves from liability, physicians need a consistent policy for informing patients, and for obtaining and documenting patients' informed consent.*

## Why we have consent laws

In 1914, New York State Supreme Court Justice Nathan Cardozo said, "Every human being of adult years and sound mind has a right to determine what shall be done with his own body." Every state's courts recognize this principle. Issues such as *what* a patient needs to know in order to give an informed consent, *who* must provide the information, and *how* to document that an informed consent was obtained are determined by state law and standards of practice in each medical specialty.

## Implied consent for minor procedures and for emergencies

Even though a patient may not sign a document or verbalize consent for a particular medical procedure, a patient's conduct will imply consent in some instances. The patient's acquiescence to medical procedures is evidence of consent. For example, the patient may hold out an arm to allow blood to be drawn without ever articulating consent, but consent to the blood test can reasonably be inferred from the patient's conduct. Implied consent is a legal recognition of the reliance on nonverbal communication in simple situations. Consent may not be routinely implied, however, where a medical procedure is complex or not commonly understood by a lay person.

**Emergencies**: The law generally assumes that a patient who is *in extremis* and unable to communicate would nonetheless desire that appropriate medical assistance be rendered. Unless it is known that the patient does not desire treatment, or unless the patient is able to communicate his or her conscious refusal, in an emergency one may render aid or care to prevent loss of life, serious injury or illness. The emergency doctrine is a form of implied consent. However, implied consent in this circumstance lasts only as long as the emergency, and formal consent must be obtained for procedures performed after the emergency has passed.

## Benefits of informed consent

Studies cite these benefits of informing patients and obtaining their consent: (1) informed patients are less likely to sue; (2) informed consent discussions deter nonmeritorious claims that result from unrealistic expectations or misunderstandings; (3) informed patients are more compliant with medical advice and recover faster; (4) informed consent discussions strengthen doctor-patient relationships and increase patients' confidence in their doctor.

## When consent is withheld for religious reasons

When a competent adult refuses treatment for religious or other reasons, there is little that a physician can do. The patient's decision cannot be ignored if the patient has made an informed decision, no matter how unwise. Courts usually respect the wishes of a competent adult to refuse treatment. A court may order medical treatment in very limited circumstances, such as for a mother where the welfare of an infant would be in jeopardy. Problems arise, however, if the patient is incompetent or of questionable competence, or is a minor whose parents refuse to consent to medical treatment in spite of serious medical consequences. If the adverse consequences to the patient are sufficiently grave, the physician may try to obtain consent by asking the family to convince the patient to consent to needed medical care. When persuasion fails, a court may order needed medical treatment directly or by through a temporary guardianship.

MIEC's Claims Department will attempt to assist an insured in situations in which a court order may be needed. See the state law insert for additional discussion of this topic.

## Answers to common questions about informed consent

***Does getting the patient's signature on a consent form suffice?*** Not always. A consent form is not the same as informed consent, and the signed consent form is not a substitute for an oral discussion. Even in states in which a signed consent form is regarded as evidence that the patient did give an informed consent, malpractice defense attorneys have considerable difficulty refuting a plaintiff's claim that he or she signed a consent form, but did not understand its contents. Plaintiffs' attorneys are aware that some patients are informed of risks and see a consent form for the first time just prior to surgery. Plaintiffs have successfully argued in court that they were unable to make informed choices minutes before being taken to the operating room. Others have claimed in litigation that even though they had questions or did not fully understand a proposed procedure, they signed the hospital's consent form "under duress," when told that unless they signed, the procedure would be canceled or rescheduled.

***Who is responsible for obtaining a patient's informed consent?*** In most jurisdictions, obtaining consent is the obligation of the physician who will perform a procedure. *(State law may allow consent to be obtained by another physician who is able to perform the procedure and is familiar with the benefits and risks, but who may not perform the procedure on the subject patient. This is a common practice among anesthesiologists and radiologists.)* Courts have recognized that, with respect to a specific patient, only a qualified physician can determine if a procedure is indicated and explain the risks for that patient. Nonphysicians, including nurses and medical assistants, can help educate patients in a general way about a procedure and answer basic questions. But the physician must "fine tune" this information, based on a specific patient's medical condition and history.

***How much information does a patient need to give an informed consent?*** This varies, but in general, physicians are required to tell patients the nature and purpose of a procedure or other recommended treatment, the "significant" or "material" risks, alternative treatments and their benefits and risks, including no treatment, and the expected outcome. "Significant" or "material risks" are those that involve potentially serious temporary or permanent injury or disability. For major surgery, significant risks may include death, paralysis, hemorrhage and infection. Certain procedures involve additional specific risks. For example, a significant potential risk of abdominal surgery is injury to adjacent tissues and organs. The failure of a procedure to resolve a medical condition, or the need to redo a surgery are significant risks of some neurological, ophthalmological and cardiothoracic surgeries. The more elective a procedure, the more physicians are obligated to disclose the risks and less risky alternatives. State laws generally embrace a "reasonable person standard," a "reputable physician standard," or both, for determining how much information a person needs to know for his or her consent to be an informed one. Under a "reasonable person standard," physicians must disclose what a reasonable person in the patient's situation would need to know in order to make an informed decision. Under the "reputable physician standard," a doctor must

disclose to patients what other reputable physicians who perform the same procedure ordinarily disclose to their patients. Both standards must be met in some states. Another guideline for what to disclose to patients is subjective: if the patient was your [the physician's] spouse or child, how much information would you and the patient want to have before consenting to the procedure?

***Doesn't telling patients about the risks of surgery frighten them away from needed treatment?*** Studies show more patients decline surgery because of a lack of information than because they were told the risks of necessary surgery.

In some states, the so-called "therapeutic privilege" permits a physician to withhold a discussion of potential serious risks if the physician has good reason to believe that disclosure would be so upsetting that the patient would not be able to make a rational decision. Physicians should use this therapeutic privilege judiciously. When a patient's emotional or physical condition makes the doctor reluctant to disclose significant risks, the discussion can take place with a spouse or other close relatives. If the patient has no available family, the physician might ask a colleague to evaluate the patient and concur that it would be prudent to not discuss the potential risks.

***Do risks have to be disclosed if the patient does not want to know?*** Patients can decline an informed consent discussion, a decision the physician should document. If the surgery is elective or if nonsurgical alternatives are possible, the physician should encourage the patient to listen to the choices and their risks. Prudent physicians often decline to do elective surgery if a patient is unwilling to be informed about potential risks, adverse outcomes or failure of the surgery. Such patients usually have unrealistic expectations.

California and other states have an **"informed refusal"** doctrine. This doctrine holds that competent adult patients have a right to refuse treatment, surgery, tests or referrals, even if they could suffer severe consequences as a result. Informed refusal requires physicians to disclose material information a patient needs to make an informed decision.

To help a patient understand, the physician should explain the likely, known consequences of not having a surgery, test, medication or referral. A patient who declines treatment for malignant cancer can be told the probable result of foregoing treatment. There is less certainty about what to tell a patient who refuses a test or X-ray the doctor needs to make a diagnosis. In such cases, the physician should explain why the test is needed and what problems could remain unidentified and untreated if the test is not done. How much to disclose depends on what a reasonable person in the patient's position would regard as significant.

## Document consent, refusal

For reasons noted earlier, a signed consent form is less likely to be questioned in litigation if it is backed up by a physician's handwritten or dictated note that verifies an informed consent was obtained. Defense attorneys recommend that physicians document their informed consent discussion with a note such as: "I advised patient of the purpose, benefits and significant risks of this procedure, including but not limited to bleeding, infection, [damage to adjacent structures or organs] [other specific, common risks]. I also discussed alternative treatments and their risks, and the risks of non-treatment. I answered patient's questions. (S)he expresses understanding of the risks of the procedure and gives his/her informed consent." Documentation of the informed consent discussion may be handwritten or dictated, and should be made in the physician's office progress record, the hospital admission history and physical report, or both, **but not in operative or procedure reports.** These reports are dictated **after** a surgery or procedure. If problems occur, notes about **preoperative** discussions of complications or adverse outcomes in these after-the-fact reports appear self-serving and may lack credibility in court.

Physicians are encouraged to ask patients to sign a plain-language consent form for office surgery when the procedure is discussed. Include statements on the form for the patient to initial such as: "Dr. *(name)* has explained to my satisfaction the purpose, benefits and alternatives to this procedure, the significant risks, and the consequences of not having the procedure. The doctor answered my questions about the procedure. I wish to proceed." *(A sample form to memorialize the informed consent discussion that takes place in the doctor's office, and which is signed after this discussion, is included with this newsletter.)*

Physicians should document a patient's informed refusal of surgery, diagnostic studies, treatment or referral to another physician. A brief chart note such as, "Patient refuses test [or procedure]; explained consequences of not having treatment [surgery; referral] and degree of urgency; patient expresses understanding of risks," generally suffices.

## Use audiovisual, written aids

It takes time for a physician to explain why a patient needs surgery, what the surgery will entail, alternatives, and the potential risks; it also takes time to listen to and answer the patient's questions. Using written materials and audiovisual aids to supplement, not replace, a physician's face-to-face informed consent discussion with patients facilitates the process and reduces the amount of time doctors must spend explaining procedures and answering questions. In most instances, written information is essential, as many patients cannot remember most of what the doctor told them after they heard the words, "You're going to need surgery." A handout that describes the procedure in plain language and summarizes the key points of the doctor's oral discussion gives the patient another opportunity to review the choices before making a decision. Equally important, patients can take written material home to educate and inform a spouse or other family members. Documentation that written information was dispensed strengthens the doctor's position in a malpractice case in which the patient does not remember preoperative discussions. A number of vendors market informed consent videotapes, computerized consent education programs, and other materials that reduce the amount of time the physician must spend explaining and reiterating.

## Summary of Recommendations

1. Understand your state's informed consent laws. Get advice from MIEC's Loss Prevention or Claims Departments if in doubt about what is required in specific situations.

2. Ask colleagues in your specialty what they disclose to patients about specific procedures; physicians in group practices should know how their colleagues obtain and document informed consent.

3. Use plain language to explain medical procedures to patients. The law does not require physicians to give patients a mini-course in medicine or to disclose every problem that could occur.

4. Encourage patients to ask questions. Consider asking the patient to invite a spouse or other relative to join in the informed consent discussion. Don't be offended if a patient seeks a second opinion about the surgery or tests you recommend. Third-party payers often require second opinions; support for your recommendation is a plus.

5. Train your staff to assist you to educate patients and families generally about treatment or surgery. Use written materials, models and audiovisual aids to supplement discussions. Document educational efforts.

6. At the conclusion of an informed consent discussion, ask the patient to sign a consent form, even if the hospital has its own. Sign the form yourself and give the patient a copy.

7. Document a summary of your informed consent discussions in your office chart and in the hospital admitting history and physical report **(not in the operative report)**; include the name and relationship of others who were present, and the name of foreign or sign language interpreters who participated in your discussions with the patient.

8. Don't wait until the last minute to discuss a surgery or procedure in order to obtain a patient's informed consent.

9. Don't delegate the task of obtaining a patient's informed consent to your staff or to hospital staff. Although these individuals can help educate patients in a general way about a planned surgery or procedure, a physician should explain to individual patients why they need surgery, what the risks are, and feasible alternatives for that patient.

10. Don't confuse "informed consent" with "consent form." In most jurisdictions, a signed consent form carries little weight if the physician has not discharged his or her obligation to inform a patient of the material risks of a surgery or procedure, as discussed in this newsletter.

11. Don't give guarantees, make exaggerated claims or minimize risks. Patients should understand that problems can occur under the best of circumstances and in the most skilled hands. Refer to the literature, and consider your own experience when responding to questions about the historical success of a surgical procedure.

**See supplement for informed consent laws in Alaska, California, Hawaii, Idaho or Nevada**