

Informed Consent and Risk Waivers

January 22, 2023
By Michael H. Cohen

The doctrine of informed consent is based on the principle that adults of sound mind should have the right to decide what can be done to their bodies. Before making a decision about what treatments or procedures to consider, a patient should understand the pros and cons of any treatment/procedure – the benefits and the risks. The risks include any side effects and any complications.

To ensure that the patient understands the benefits and dangers of any treatments or procedures, various states, agencies, and medical boards require that the doctor who is responsible for the treatments and procedures should obtain a written informed consent from the patient. The written document should list the benefits and risks of the treatment or procedure. By signing and dating the written informed consent, the patient is acknowledging he/she has been informed of the possible consequences – and agrees that the treatments and procedures can be provided to the patient.

The treatments and procedures that require a patient's informed consent include:

- Medical research. The Department of Health and Human Services (HHS) requires that researchers obtain the legally effective informed consent of the subject or the subject's legally authorized representative, unless:
 - The research is exempt under federal law
 - There are appropriate waivers -if waivers are permitted for the type of research being conducted
- FDA has its own set of informed consent requirements
- Treatments and procedures performed by a doctor or another type of health provider who has the legal authority to provide the treatment or procedure.

What is the relationship between informed consent and a risk waiver?

By signing the waiver (if properly worded), the patient does more than acknowledge his/her understanding of the pros and cons of the treatment or procedure. The signature on the informed consent form generally will be used by the doctor, hospital, or another healthcare provider to protect the doctor, hospital or another healthcare provider from liability. The liability protection is generally confined to complaints by the patient that an adverse consequence occurred during the treatment or procedure – that was identified on the informed consent document. Essentially, medical professionals use informed consent forms for more than just providing information. The professionals use the form as a waiver of liability claims by the patient.

Informed consent forms are also called liability waivers, risk waivers, medical release forms, release of liability forms, and

other similar names.

There is a reverse problem for doctors. The signing of an informed consent/risk waiver may protect the physician or healthcare provider that provides the treatment or procedure from a liability claim. Conversely, the physician or healthcare provider may be subject to a medical malpractice claim (for non-emergency treatments or procedures – if the patient suffers as a result of the treatment or procedure. The physician or healthcare provider may even be liable if the physician or healthcare provider does everything correctly – because the patient may argue he/she wouldn't have had the treatment or procedure if he/she had known of the possible dangers.

A physician or healthcare provider may also be liable – if there is a signed informed consent – if the treatment or procedure provided is different than what was identified in the informed consent document. Even with an informed consent, doctors may also be liable for other reasons – such as mistakes that were clearly avoidable such as leaving a surgical instrument in a patient after the surgery is complete.

AVOIDING MALPRACTICE THROUGH STRONG INFORMED CONSENT PRACTICES

Informed consent is critical in all areas of medicine; it takes on added importance with integrative medicine, functional medicine, anti-aging and aesthetic medicine, and non-mainstream [...]

When do healthcare providers use informed consent?

Some of the common types of informed consent uses include:

- **Surgeries.** Generally, doctors and hospitals require that a patient sign an informed consent form before any surgeries are performed.
- **Drug prescriptions.** Healthcare providers may also request that a patient sign an informed consent/risk waiver before nonsurgical remedies. For example, doctors and pharmacies regularly require informed consents from patients before the doctor prescribes any medications and the pharmacy fills the prescription. Common risks with drugs include the possible side effects, the dangers involved with taking the prescribed amounts, the dangers with taking amounts other than prescribed amounts, possible interactions with other drugs, and many other adverse consequences.
- **Research.** Many doctors, universities, hospitals, agencies, and other entities conduct research on the effectiveness of various drugs and various treatments. The people who volunteer to participate in these clinical studies have the right to be informed of the possible risks and dangers.

An informed consent may be required for many other types of reasons. Our experienced healthcare lawyers will explain when informed consents are advisable – whether a healthcare provider is performing surgery, conducting a telemedicine consultation, or for any other reason.

HOW TO DRAFT A TELEMEDICINE INFORMED CONSENT

In today's video, we discuss whether you need a specific type of consent form to offer patients telemedicine or telehealth services.

What happens if the patient cannot provide consent?

Patients may not be able to provide consent for different reasons:

- During emergencies when the patient is in too much pain or is otherwise unable to give his/her consent
- When the patient is not mentally competent

- If the patient is a minor

In these situations, the physician, hospital, or another healthcare provider will try to obtain the consent of someone with the authority to give their consent to the treatment or procedure for the patient. The authority may be based on:

- A power of attorney from the patient to another adult that authorizes an informed consent
- A guardian of the patient
- A parent of the patient
- Other people depending on the circumstances

Informed consent and California law

The duty to obtain an informed consent is generally defined by California case law – the decisions of judges in prior comparable cases. There are some statutes as well. For example, in our discussion of new healthcare laws for 2021, we discussed the following law:

AB-1280 California Hospice Licensure Act of 1990

This law was signed into law on October 4, 2021. The law sets new requirements for hospice referrals. The law prohibits:

Hospice providers (and hospice staff and agents for the hospice) from *“paying referral sources for the referral of patients to the hospice.”*

“A hospice salesperson, recruiter, agent, or employee who receives compensation or remuneration for hospice referrals or admissions from providing consultation on hospice services, hospice election, or informed consent to a patient, patient’s family, or patient’s representative.”

Certain authorized persons, such as a registered nurse or a medical social work can *“complete the election of hospice, informed consent, completed signatures, and counsel on the election of hospice with a patient, patient’s family, or patient’s representative.”*

The new law also requires that that hospice give a patient or his/her representative a verbal and written notice of the patient’s rights and responsibilities – in a language and manner the patient or representative can understand – before providing any care.

Doctors, nurses, and other healthcare providers should understand when an informed consent from a patient is required and the terms and explanations that must be set forth in the informed consent. The need for an informed consent doesn’t just apply to surgeons. The duty to obtain the medical consent doesn’t just apply to a doctor’s office. Nurses, acupuncturists, dentists, medical spas, and other types of health provider should review when an informed consent is necessary for their practice or business.

CALIFORNIA HEALTHCARE LAWS THAT WERE PASSED IN 2021

Pharmacies, hospitals, mental health facilities, hospices, and substance abuse facilities need to understand how the recently passed California healthcare laws apply to their practice

Physicians and other healthcare providers should contact Cohen Healthcare Law Group, PC to discuss the federal, state, and medical board requirements for obtaining an informed consent. Our experienced healthcare attorneys advise doctors and other types of healthcare providers about healthcare compliance laws and regulations.

Contact our healthcare law and FDA attorneys for legal advice relevant to your healthcare venture.