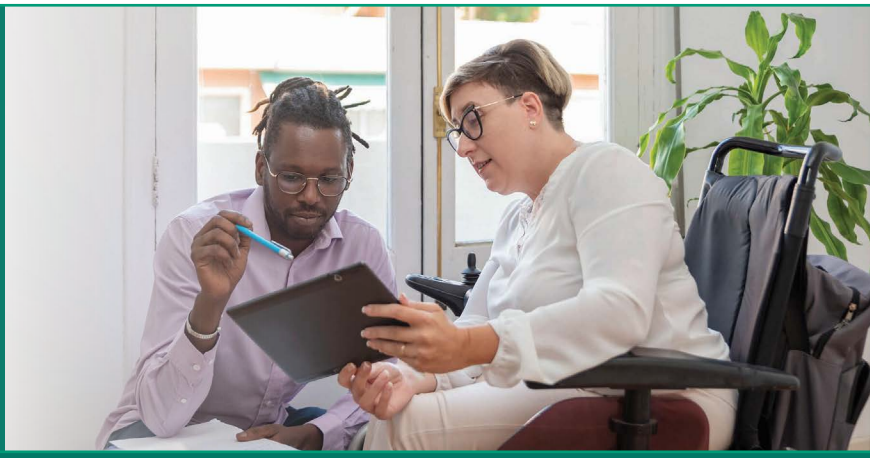
Patient Safety & Risk Management

Copiscope

Issue 231
4TH Quarter 2025

Informed Consent:

A Review of the Legal and Practical Aspects



Informed consent is a fundamental principle, ensuring a patient's right to make decisions regarding their medical care. It is also a process that entails balancing legal requirements and practical considerations. This article explores the legal standards for obtaining a patient's informed consent, the responsibilities of treating providers and facilities, and specific circumstances that affect the informed consent process.

Patient's Right to Informed Consent

The U.S. Supreme Court has held that a competent person has a constitutionally protected interest in refusing unwanted medical treatment.[1] In the Cruzan case, the Court stated that "no right is held more sacred, or more commonly guarded by the common law, than the right of every individual to the possession and control of his own person."

A patient's right to make an informed decision regarding their care is addressed from a regulatory standpoint under the "patient's rights" requirements of both the Centers for Medicare & Medicaid Services regulations and regulations that exist under state law for licensed health facilities.

Critical Factors for Informed Consent

Lack of informed consent is a type of negligence claim. To recover damages, a plaintiff must prove all of the following by a preponderance of the evidence (more likely than not that they are true):

1. The defendant performed a procedure or prescribed a treatment for the patient
2. The defendant negligently failed to obtain the patient's informed consent before the procedure or treatment
3. A reasonable person in the patient's position would not have consented to the procedure or treatment had the patient been given the information required for informed consent; and
4. The defendant's negligent failure caused the patient's injuries or losses.

Continued on page 2

INSIDE

5 When the Healer Hurts: The Toll of Medical Errors on Physicians

6 Risks Associated with Remote Patient Monitoring Systems

7 Safety and Risk Strategies: On-Site and Virtual Reviews

copic

Informed Consent (continued from page 1)

For a patient's consent to be informed, a physician must have discussed the following with them:

1. The nature of the medical condition
2. The nature of the treatment or procedure
3. The alternative treatments available, if any; and
4. The substantial risks, if any, involved in undergoing the treatment or procedure and the substantial risks, if any, of the alternative treatments.

The Two Standards of Informed Consent

While the legal requirements for the type of information that must be discussed with patients during the informed consent process is similar across states, there can be a difference in whether a state uses a "physician" or "professional" standard or a "patient" standard.

- **Professional standard** (reasonable physician)—Under this traditional standard, a patient must be informed to the extent a reasonable physician in the same specialty, at the same time, would have under the same or similar circumstances. Expert testimony is needed to establish the scope of a physician's duty of disclosure. The reasoning is that a lay person would generally not have the degree of knowledge and experience required to understand matters relating to medical diagnosis and treatment without the assistance of an expert.
- **Patient standard** (reasonable patient)—Many states have rejected the professional standard and instead have adopted the reasonable patient standard. In states like Iowa, a physician's duty to disclose is determined by whether a reasonable person in the patient's position would consider the information material to the decision of whether to undergo the proposed treatment. Information is material if it would be significant to a reasonable person in the patient's position in deciding whether to consent to the procedure or treatment. Deciding what information is material depends on the facts and circumstances of each case and is for the jury to decide.

The difference between these two standards is important from a practical standpoint because it's easier for a patient to bring a successful "uninformed consent" claim in jurisdictions using a patient standard. In addition, under the patient standard, a claim for lack of informed consent doesn't depend on whether the physician performed the procedure negligently, rather on whether the physician failed to obtain consent by failing to disclose material information. This is especially important to consider when obtaining a patient's informed consent to an elective procedure. One court explained that a patient who asserts that they were not given appropriate medical information, even if the physician was not negligent in performing the procedure, is asserting that the physician is liable for harmful results because the patient would have refused consent and avoided the harm had the patient been appropriately informed.

Responsibilities for Medical Providers and Facilities

It is always the legal obligation of the person doing a procedure to obtain the patient's informed consent for that procedure. Under the Centers for Medicare & Medicaid Services (CMS) regulations, though, a hospital must assure that the practitioner(s) responsible for the surgery obtain informed consent from patients in a manner consistent with the hospital's policies governing the informed consent process.

Most courts have concluded that, as a general matter, only the treating physician who performs the procedure has the duty to obtain the patient's informed consent and that a hospital or facility does not owe an independent duty to obtain the patient's informed consent. They reason that the physician, not the hospital or the facility, has the education, training, and experience necessary to advise each patient of risks associated with surgery and, by virtue of the physician/patient relationship, is in the best position to know the patient's medical history and to evaluate and explain the risks of a particular operation in light of the particular medical history.

CMS regulations for hospitals and ASCs require a properly executed informed consent form for an operation to be in the patient's chart before surgery, except in emergencies.[2] CMS guidance for ASCs recognizes that the informed consent process may take place outside the ASC:

> *It would be acceptable if the ASC required the physician(s) who perform procedures in the ASC to obtain the patient's informed consent outside of the ASC, prior to the date of the surgery, since this might allow more time for discussion between the patient and physician than would be feasible on the date of the surgery. In such cases, the physician must follow the ASC's informed consent process. In all cases, the ASC must ensure that the patient's informed consent is secured prior to the start of the surgical procedure, and that this consent is documented in the patient's medical record.*[3]

If there are additional requirements under state law for informed consent, the hospital/ASC must also comply with those requirements.

Continued on page 3

Informed Consent (continued from page 2)

In general, under CMS guidance, a hospital's or ASC's surgical informed consent policy should describe the following:

- Who may obtain the patient's informed consent
- Which procedures require informed consent
- The circumstances under which surgery is considered an emergency, and may be undertaken without an informed consent
- The circumstances when a patient's representative, rather than the patient, may give informed consent for a surgery
- The content of the informed consent form and instructions for completing it
- The process used to obtain informed consent, including how informed consent is to be documented in the medical record
- Mechanisms that ensure that the informed consent form is properly executed and is in the patient's medical record prior to the surgery (except in the case of emergency surgery); and
- If the informed consent process and informed consent form are obtained outside the hospital, how the properly executed informed consent form is incorporated into the patient's medical record prior to the surgery.

The Difference Between a "Consent to Treat" Form and Informed Consent

While there is an overlap between a facility's "consent to treatment" form and an "informed consent," there is a difference from a legal standpoint. A general consent-to-treat form often has notice provisions for patients, so it can be protective for a hospital to have this. For example, it gives patients notice of how their blood or tissue samples will be used, that photographs or other images might be used for treatment or other purposes, and the facility's visitor policies.

The informed consent process and any document used to memorialize the informed consent process, on the other hand, is generally the responsibility of a practitioner (e.g., a physician, podiatrist, or APRN) providing treatment or performing a procedure as opposed to the facility. Courts have held that written general consent to treatment forms, whether provided to a patient by a physician or hospital personnel, which do not specify any particular type of treatment to which a patient might be subjected, aren't adequate alone to satisfy a physician's duty to disclose certain information needed for a patient's informed consent.[4]

Specific Situations

Emergencies

All states recognize, either in case law or statute or both, the idea of implied consent in an emergency. A physician's defense is strongly supported when the following is shown:

- The defendant reasonably believed the plaintiff's life or health was in such danger that to delay surgery or treatment would further endanger the person's life or health,
- Under the same or similar circumstances, a reasonably careful physician would have believed the same thing; and
- The patient was in a mental or physical condition that prevented the person from being able to indicate the person's consent or lack of consent.

Unless it is clear from the clinical presentation, (e.g., an unconscious patient), the physician should affirmatively document that the patient's condition was emergent and they proceeded with reasonable care for that emergent condition. For minors with emergencies, there should be attempts to notify the responsible parent(s), but the treatment of the emergent medical condition should not be delayed pending that notification. Documentation of the emergent nature, the attempts to notify the parent(s), and the reasonable decision to proceed without delay is critical.

Minors

Unless it's an emergency or it meets an exception under state law where a minor can consent to his or her own care, a parent or guardian or someone acting under a temporary power of attorney must legally consent. If a parent signs a general authorization to treat form or one allowing the minor to be seen on their own without a parent, a provider will still need to go through a discussion of the indications, benefits, risks, and alternatives to a specific course of treatment. If it's a higher risk treatment, that discussion and shared decision-making should be documented in the record.

If a parent has given informed consent to a course of care, it would not require the parent to accompany the child for each visit. However, if the provider recommends a change in the treatment plan, this should be discussed with the parent even if this discussion occurs by phone rather than in person.

Mental Health

State mental health laws may vary considerably, but they all have a mechanism for a person to be placed into emergency protective custody when, as a result of mental illness, they are an imminent danger to themselves or others or gravely disabled. A patient can't refuse care in that situation. This is also recognized as an "emergency medical condition" under EMTALA.

Continued on page 4

Informed Consent (continued from page 3)

EMTALA

EMTALA has two sections relevant to informed consent that have specific documentation requirements.

The first situation is where the patient refuses to consent to further treatment. A hospital meets the EMTALA requirements for necessary stabilizing treatment for emergency medical conditions (EMCs) if it informs the individual (or a person acting on the individual's behalf) of the risks and benefits to the individual of the examination and treatment, but the individual (or a person acting on the individual's behalf) does not consent to the examination or treatment. The medical record must contain a description of the examination, treatment, or both if applicable, that was refused by or on behalf of the individual. The hospital must take all reasonable steps to secure the individual's written informed refusal (or that of the person acting on his or her behalf). The written document should indicate that the person has been informed of the risks and benefits of the examination or treatment, or both.[5]

The second situation is where it's a lateral transfer of a patient with an EMC where the patient gives informed written consent. These are cases where your hospital may have the capability to care for the patient, but the patient (or a legally responsible person acting on the patient's behalf) requests a transfer to another hospital. The patient has to give informed written consent.

- The patient should be advised of the hospital's EMTALA obligations to evaluate them and provide stabilizing treatment within its capability and capacity.
- They should be advised of the risks and benefits of transfer.
- The transfer request should be in writing, be signed by the patient, have the reason the patient requested the transfer, and should indicate that the patient is aware of the risks and benefits of the transfer.[6]

Conclusion

Informed consent is a vital aspect of medical practice, protecting patients' rights and minimizing liability risks. By adhering to legal standards and providing comprehensive information, healthcare providers can ensure that patients make informed decisions about their care.

Key Liability Areas and Best Practices

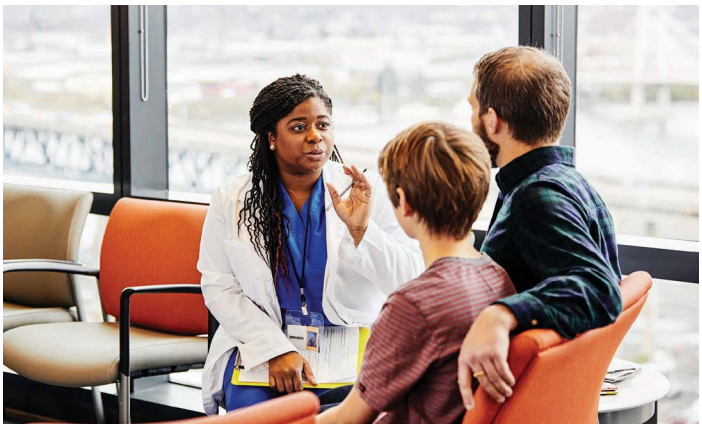
Based on a review of case law involving informed consent, the following are some areas where issues occurred:

- The consent was signed right before the procedure
- Risks were minimized
- Alternatives (including not doing anything) were not discussed
- The patient was sedated, so the patient lacked the full capacity to give informed consent, and
- The consent form was incomplete or wasn't signed

And finally, some of the best practices to consider with informed consent include:

- Using common language rather than, or in addition to, medical terms
- Use teaching aids and materials (and document what you used)
- Allow time for discussion before the patient signs the consent
- Ask open-ended questions and use the teach-back method to ensure that patients understand the indications, risks, benefits and alternatives to treatment
- Use medical interpreters for patients with limited English proficiency

A good resource is the 2022 Joint Commission advisory, "Informed consent: More than getting a signature"[7] as well as Copic's Patient Safety/Risk Management team.



[1] Cruzan v. Director, Mo. Dept. of Health, 497 U.S. 261, 278 (1990).
[2] 42 CFR § 482.51; 42 CFR § 416.47(b)(7).
[3] CMS State Operations Manual, Appendix L.
[4] Cross v. Trapp, 294 S.E.2d 446, 460 (W. Vir. 1982)
[5] 42 CFR § 489.24(d)(3).
[6] 42 CFR § 489.24(e)(1)(ii)(A).
[7] https://www.jointcommission.org/resources/news-and-multimedia/newsletters/newsletters/quick-safety/quick-safety--issue-21-informed--consent-more-than-getting-a-signature