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Consent Forms v. Informed Consent

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Except in emergencies, healthcare practitioners must generally obtain the patient's informed consent before providing treatment.¹ If the patient lacks capacity due to age or incompetence, consent must be obtained from a personal representative authorized by law to provide consent.² Failure to obtain or properly document informed consent may subject practitioners to civil, administrative, and/or criminal liability. It is therefore important to periodically review consent processes and forms to ensure that they adequately establish and document valid informed consent.

Informed Consent. To be effective, a patient's consent must be informed, *i.e.*, the practitioner must explain the material facts related to the treatment so as to enable the patient to make an informed decision concerning the proposed treatment.³ Although state statutes, regulations, or case law may vary, material facts typically include the need for, nature of, and significant risks and benefits associated with the proposed treatment; alternatives to the proposed treatment along with associated risks and benefits; and the identity of practitioners rendering the care. For example, Medicare conditions of participation for hospitals relevant to surgeries state,

A well-designed informed consent process would include discussion of the following elements:

- A description of the proposed surgery, including the anesthesia to be used;
- The indications for the proposed surgery;
- Material risks and benefits for the patient related to the surgery and anesthesia, including the likelihood of each, based on the available clinical evidence, as informed by the responsible practitioner's clinical judgment. Material risks could include risks with a high degree of likelihood but a low degree of severity, as well as those with a very low degree of likelihood but high degree of severity;
- Treatment alternatives, including the attendant material risks and benefits;
- The probable consequences of declining recommended or alternative therapies;
- Who will conduct the surgical intervention and administer the anesthesia;
- Whether physicians other than the operating practitioner, including but not limited to residents, will be performing important tasks related to the surgery, in accordance with the hospital's policies.⁴

Absent specific statutory or regulatory requirements, the sufficiency of the

information provided to the patient is often measured by what other similar practitioners in the community would have disclosed or discussed.⁵

Effective Consent = Understanding. To be effective, consent requires communication and understanding: the practitioner must explain the material facts in a manner so that the patient understands them. To that end, it may be necessary for a practitioner to speak at the patient's educational level. If the patient does not understand the practitioner's language, the practitioner may need to engage a qualified interpreter or use translated documents to convey the facts. If the patient has a disability that interferes with effective communication, the practitioner may need to utilize auxiliary aids to ensure effective communication. Such accommodations are required by applicable nondiscrimination statutes⁶, but their use is even more important to obtain effective consent and render appropriate care.

Documenting Informed Consent. As a general matter, consent need not be written to be valid: it may be implied from the circumstances, obtained through oral communications, or documented in writing.⁷ Federal or state laws or regulations may require written consent in limited cases. For example, Medicare conditions of participation for hospitals generally require written consent for surgeries and other procedures identified by hospital policies and medical staff members.⁸ No matter how obtained, it is important to document the patient's capacity and informed consent (or refusal thereof) in the patient's medical record. To that end, a properly drafted informed consent form may help explain the facts relevant to the consent as well as document that the patient's consent was truly informed.

General v. Specific Consent. As part of the patient registration process, practitioners often ask the patient to sign a general consent form purportedly authorizing the practitioner to render care, including but not limited to performing labs, receiving diagnostic tests, etc. Such general consents may be helpful and are, as a practical matter, likely sufficient for basic care; however, if unaccompanied by communication of material risks and benefits, such general "consent forms" do not constitute effective informed consent and are subject to challenge. Remember: effective consent requires that the consent be informed, *i.e.*, that "the patient or patient representative is given the information, explanations, consequences and options needed" to allow them to make an informed decision.⁹ The more significant or risky the care, the more important it is to document specific informed consent; reliance on a general, generic consent form is dangerous.

Responsibility for Obtaining Informed Consent. The practitioner who performs or upon whose order the care is rendered is generally responsible for obtaining informed consent¹⁰; after all, she or he is the person with the knowledge necessary to explain the material facts and answer the patient's questions. Although the practitioner may use others such as nurses or registration personnel to assist in obtaining or documenting informed consent, the treating practitioner is ultimately responsible and potentially liable if effective informed consent is not obtained. Consequently, the treating practitioner should be actively involved in the consent process and not rely wholly on others to obtain

informed consent.

Requirements for Consent Forms. Practitioners should review their specific state laws and regulations and payer conditions to identify requirements for valid consent and consent forms. For example, the Medicare conditions of participation for hospitals state:

A properly executed informed consent form contains the following minimum elements:

- Name of the hospital where the procedure or other type of medical treatment is to take place;
- Name of the specific procedure, or other type of medical treatment for which consent is being given;
- Name of the responsible practitioner who is performing the procedure or administering the medical treatment;
- Statement that the procedure or treatment, including the anticipated benefits, material risks, and alternative therapies, was explained to the patient or the patient's legal representative; ...
- Signature of the patient or the patient's legal representative; and
- Date and time the informed consent form is signed by the patient or the patient's legal representative....

A well-designed informed consent form might also include the following additional information:

- Name of the practitioner who conducted the informed consent discussion with the patient or the patient's representative.
- Date, time, and signature of the person witnessing the patient or the patient's legal representative signing the consent form.
- Indication or listing of the material risks of the procedure or treatment that were discussed with the patient or the patient's representative;
- Statement, if applicable, that physicians other than the operating practitioner, including but not limited to residents, will be performing important tasks related to the surgery, in accordance with the hospital's policies and, in the case of residents, based on their skill set and under the supervision of the responsible practitioner.
- Statement, if applicable, that qualified medical practitioners who are not physicians who will perform important parts of the surgery or administration of anesthesia will be performing only tasks that are within their scope of practice, as determined under State law and regulation, and for which they have been granted privileges by the hospital.¹¹

The conditions of participation for critical access hospitals ("CAHs") require that consent forms contain at least the following:

- Name of patient, and when appropriate, patient's legal guardian;
- Name of CAH;

- Name of procedure(s);
- Name of practitioner(s) performing the procedures(s);
- Signature of patient or legal guardian;
- Date and time consent is obtained;
- Statement that procedure was explained to patient or guardian;
- Signature of professional person witnessing the consent;
- Name/signature of person who explained the procedure to the patient or guardian.¹²

States often have specific consent requirements for certain procedures, including but not limited to reproductive health (e.g., abortions, sterilization, etc.) and, more recently, telehealth.¹³

Conclusion. When it comes to informed consent, do not elevate form over substance: it is not enough to have the patient sign a consent form; the treating practitioner must ensure that (1) he or she has effectively communicated the material facts relevant to the treatment so as to ensure that consent is truly informed, and (2) such informed consent is properly documented in the medical record. The more significant the risks, the more important it is to ensure that informed consent is appropriately documented.

¹See, e.g., IC § 39-4503; 42 CFR § 482.13(b)(1)-(3).

²See, e.g., IC § 39-4504; 42 CFR § 482.13(b)(2).

³See, e.g., IC § 39-4506; 42 CFR § 482.13(b)(2).

⁴CMS State Operations Manual App. A, Interpretive Guidelines for Hospitals at A-0955.

⁵See, e.g., IC § 39-4506.

⁶See, e.g., 45 § CFR part 92. For more information concerning applicable anti-discrimination statutes, see our articles at <https://www.hollandhart.com/new-aca-anti-discrimination-rules-language-assistance-for-non-english-speakers> and <https://www.hollandhart.com/new-aca-anti-discrimination-rules-assistance-for-persons-with-disabilities>.

⁷See, e.g., IC § 39-4507.

⁸42 CFR §§ 482.24(c)(4)(v) and 482.51(b)(2); 42 CFR §§ 485.638(a)(4) and 485.639.

⁹CMS State Operations Manual App. W, Interpretive Guidelines for Critical Access Hospitals at C-0304.

¹⁰See, e.g., IC § 39-4508.

¹¹CMS State Operations Manual App. A, Interpretive Guidelines for Hospitals at A-0466.

¹²CMS State Operations Manual App. W, Interpretive Guidelines for Critical Access Hospitals at C-0304; see also *id.* at C-0320.

¹³See, e.g., IC § 54-5708; IDAPA 22.01.15.014.

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