



POLICIES AND PROCEDURES

SUBJECT: INFORMED CONSENT

POLICY NO: 314

PURPOSE: To describe the Department of Health Services' requirements for informed consent.

POLICY: Medical care may only be provided at a Department of Health Services facility when appropriate consent has been obtained from the patient or the patient's legal representative, except in the case of a medical emergency.

In the case of a medical emergency, treatment may proceed without the patient's consent if no evidence exists to indicate the patient or the patient's legal representative would refuse the treatment. A medical emergency condition exists when:

- Immediate services are required for the alleviation of severe pain; or
- Immediate diagnosis and treatment of unforeseeable medical conditions are required, if such conditions would lead to serious disability or death if not immediately diagnosed and treated.

A complete informed consent process must include:

- the nature of the proposed care, treatment, services, medications, interventions or procedures;
- potential benefits, risks, or side effects, including potential problems that might occur during recuperation;
- the likelihood of achieving goals;
- reasonable alternatives;
- the relative risks, benefits, and side effects related to alternatives, including the possible result of not receiving care, treatment and services;
- when indicated, any limitations on the confidentiality of information learned from or about the patient; and

APPROVED BY:
REVIEW
DATES:

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- disclosure of the provider's potentially conflicting interests, such as research or financial interests.

It is the treating physician's responsibility to obtain informed consent. It is the exclusive duty of the treating physician or the legally authorized designee to provide the information necessary to secure the patient's informed consent, and respond to the patient's questions concerning the proposed procedure.

Individual informed consent must be obtained for procedures not covered in the general consent.

- The iMed informed consent program and associated printed form shall be used when informed consent is required. The form itself is not informed consent; it is evidence for both the organization and the physician that informed consent was obtained. The form is not a substitute for the role of the physician in the informed consent process.
- The physician obtaining the patient's informed consent shall also document, with a signed and dated note in the medical record that a discussion was held with the patient or his/her legal representative; the patient or his/her legal representative fully understood the nature of the procedure, including the risk and benefits of agreeing or refusing the procedure; and that informed consent was obtained. The iMed consent form will include the name of the practitioner performing the procedure and, if applicable, any other physicians or staff, including residents, that will be performing tasks related to the procedure.
- The time and date on the form should be the time and date the form is signed by the patient or the patient's legal representative, not the time and date of the procedure or operation.
- One person should serve as a witness when the patient or the patient's legal representative signs the form.
- The original signed iMed consent form shall be placed in the patient's medical record and a copy given to the patient. The informed consent must be made knowingly and given freely. The patient must be conscious and competent to understand the purpose and effect of the decision to be made and the form to be signed.

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- When a person other than the patient signs the iMed consent form, the relationship to the patient should be noted. If the patient's inability to sign is due to a temporary condition, informed consent from the patient should be attempted when the patient is able.
- A consent remains effective until the patient revokes it or until circumstances materially change. In such a situation, informed consent would need to be re-obtained.
- Consent should be obtained by telephone only if the person having the legal ability to consent for the patient is not otherwise available. If telephone consent is used, the physician must provide the patient's legal representative with all of the information the physician would disclose if the person were physically present. The iMed form shall also be used during telephone consent. The telephone discussion should be witnessed by a second employee and noted on the iMed form. The patient's legal representative must be informed that two hospital employees are on the phone.
- If a patient or legal representative cannot communicate with the physician because of language barriers, the physician must utilize an interpreter. The physician must also ensure that the Translator Attestation Form is completed.
- If the patient or their legal representative is physically unable to write his or her name, the person's mark must be obtained. This is done by the physician first writing the person's name in full and then having the person place an "X" beneath it. Two staff members must witness the signer place his or her mark on the consent form and then must sign the consent form themselves as witnesses. If a patient or their legal representative is physically unable to place a mark, two staff witnesses must verify that the patient has given verbal consent.

The principles set forth in the California Hospital Association Consent Manual shall serve as guidelines for obtaining and documenting appropriate consent for medical treatment and/or procedure.

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REFERENCE:

California Hospital Association Consent Manual

CROSS REFERENCE:

DHS Policy 314.2 DOCUMENTING USE OF INTERPRETATION SERVICES DURING
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