

HIGH DESERT HEALTH SYSTEM AMBULATORY SURGICAL CENTER

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| SUBJECT: II-121 INFORMED CONSENT, iMED CONSENT | POLICY #: 1052 |
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| DATE APPROVED: 06/28/2016 | |

PURPOSE: To ensure that the patient, or the patient's legal representative, is provided information necessary to enable him/her to evaluate a proposed treatment before agreeing to the treatment.

POLICY: No medical care shall be provided at the Ambulatory Surgical Center (ASC) unless appropriate consent has been obtained from the patient or the patient's legal representative(s), except in medical emergencies.

PROCEDURE:

1. Surgical or invasive procedures shall be performed only with the consent of the patient or his/her legal representative, except in emergencies.
2. The appropriate iMed Consent, specific to the procedure, will be generated from the computer after the required fields have been completed.
3. When an iMed Consent specific to the procedure cannot be found on the menu of procedures, a consent form for a procedure most similar to the proposed procedure will be selected. The operating surgeon must review and revise the iMed consent form as needed, including the language about the proposed procedure, associated risks, potential complications and alternatives, and modify it manually, by drawing a line through the inaccurate or irrelevant portions of the form, to fit the proposed procedure. The revision will then be timed, dated and signed by the surgeon making the modification. Only then can the provider obtain the informed consent from the patient.
4. The consent form must include the name of the physician performing the procedure, his/her assistant (if applicable), the patient's name, date of birth, and medical record number.
5. The physician will discuss the following with the patient:
 - a. Name and type of procedure, described in simple terms
 - b. Expected benefits of the procedure
 - c. Likelihood of achieving treatment goals

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- d. Possible risks, or side effects, including potential problems related to recuperation
 - e. Reasonable alternatives to the procedure
 - f. Risk of alternate management
 - g. Risk of refusing treatment
6. It is the treating physician's responsibility to obtain informed consent, and it is the exclusive duty of the treating physician to convey the information necessary, in a language which the patient can understand, and respond to the patient's questions concerning the proposed procedure, in order to secure the patient's informed consent.
 7. Individual informed consent must be obtained for procedures not covered in the general consent.
 8. 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.
 9. The physician shall inform the patient whenever an assistant is required on a contemplated procedure and, in those cases; the correspondent names will appear on the consent noted above, or the MD will initial under "no" on the informed consent. Under this section the provider will also initial under "yes or "no", if an observer will be present.
 10. The provider must ask the patient for their authorization if photographs are to be taken during the procedure. The patient will initial next to "yes" or "no" on the informed consent.
 11. Following the informed consent process the patient/conservator/guardian will be asked to sign, date and time their consent to the procedure.
 12. 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.

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13. The provider will print his/her last name, sign, date, and time their discussion in the designated area. 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.
14. 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; that the patient or his/her legal representative fully understood the nature of the procedure; including the risks 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, that will be performing tasks related to the procedure.
15. The person witnessing the patient/conservator/guardian signature will sign in the designated area as the witness. One person should serve as the witness when the patient or the patient's legal representative signs the form. The original signed iMed consent form will be placed in the patient's medical record and a copy will be 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.
16. If a patient or legal representative cannot communicate with the physician because of language barriers, the physician must utilize an interpreter. If an interpreter is used, the interpreter will print is/her name, sign the informed consent and document his/her title in the designated area on the informed consent form. The physician must also ensure that the Translator Attestation Form is completed.
17. If the patient or his/her legal representative is physically unable to write his/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 his/her legal representative is physically unable to place a mark, two staff witnesses must verify that the patient has given verbal consent.
18. 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

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discussion should be witnessed by a second employee and noted on the iMed form. The patient's legal representative must be informed that two facility employees are on the phone.

19. In case of an unexpected emergency, when patient's signature is unobtainable (the patient is not alert and oriented, or is incompetent, unconscious, or is a minor), and the legal guardian cannot be reached, the physician must determine whether the treatment appears to be immediately necessary to alleviate pain or to diagnose and treat conditions that can lead to serious disability or death, if not immediately diagnosed and treated. In addition, the scope of the emergency treatment must be determined. The treatment provided may be either first aid, temporary medical care in lieu of surgery or an actual surgical procedure. The medical emergency must be documented in the progress note as well as the fact that the patient was not able to sign the appropriate consent. Neither the spouse nor any other relative can legally sign a consent for the patient without prior arrangements having been made, i.e., an Advance Directive. However, the need for the procedure should be discussed with the family, and documentation of this discussion should be placed in the progress note.
20. For minor or wards of the court, a parent or guardian must sign the consent.
 - a. There are certain conditions under which a minor may give consent to medical care. The following conditions must apply:
 - i. Emancipated minors (Family Section Code 7120).
 - ii. Minors under 18, married or previously married (Family Section Code 7002).
 - iii. When a minor or 15 years of age or older is living separate and apart from his or her parent (s) or legal guardian, whether living with or without the consent or acquiescence of his or her parent(s) or legal guardian, and manages his or her financial affairs, regardless of source of income, the minor is capable of giving a valid consent for medical care without parental or guardian consent knowledge or financial liability.
 - iv. The minor should affirm the above conditions are met and complete the "Self Sufficient Minor Information form." In the absence of evidence to the contrary, the ASC may reasonably believe that the affirmations made in the form are correct without independent verification.

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- b. The following conditions must apply in those instances when authorization is necessary for a third party to consent to the treatment of a minor:
 - i. “A non-parent adult relative with whom the minor is living may authorize medical care for the minor by signing a “Caregiver’s Authorization Affidavit”
 - ii. A minor must be living with the adult family member.
 - c. Authorization for care only applies to the child receiving medical care and:
 - i. The adult, who must be at least 18 years of age or older, must be a “qualified relative,” which is defined in the law as a spouse, parent, step parent, brother, sister, half-brother, half-sister, uncle, nephew, niece, first cousin or any person denoted by the prefix “grand” or “great,” or the spouse of any of the persons specified in the definition, even after the marriage has been terminated by death or dissolution.
 - ii. The adult must advise the parent(s) of the proposed medical treatment and the parent must have no objection thereto; or the adult must be able to contact the parent(s).
 - iii. The adult must complete a “Caregiver’s Authorization Affidavit” (CHA Form 2-2 or a similar form), in which he or she attests that the elements outlined above are true and correct. The affidavit is valid for one year from the date of the signature. The Affidavit becomes invalid when the health care provider learns that the minor no longer lives with the caregiver. Providers should be careful to require that the Affidavit is completed in its entirety, and that an attempt has been made to reach the minor’s parents prior to the care being delivered to the minor.
 - d. In the event that the patient is unable to continue to make healthcare decisions and has documented evidence of a Durable Power of Attorney for Healthcare, the individual named in this document shall be consulted regarding any invasive procedure and will be asked to give consent for the patient.
21. 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.

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22. If the consent for surgery or other invasive procedures is found to be incorrect after the premedication has been given, the following guidelines will apply:
 - a. For an adult patient who is determined by the physician to be alert and oriented to name, place, date, and circumstances, a new correct consent form will be made and signed by the patient. A note by the physician obtaining the new consent attesting to the circumstances involved must be written in the medical record.
 - b. For a patient who is not alert or oriented, a sufficient amount of time must elapse until the patient is alert and oriented before a new consent can be signed.
 - c. In the case of minors, a new consent must be obtained from parent/guardian.

23. In exceptional cases where the patients asks not to be informed and/or where discussion of the risk or complications might in the opinion of the attending physician cause greater harm to the patient than is warranted, the physician will discuss the risks, complications, benefits and alternative treatments, if any, with individuals who would be appropriate decision makers if the patient lacked the capacity to make care decisions; such a situation should be documented in the patients' medical record.

24. 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.

REFERENCES:

2014 California Hospital Association Consent Manual
 DHS policy # 314, Informed Consent
 DHS policy # 314.1, Providing Care to Minors in the Absence of Parent or Legal Guardian
 DHS policy# 314.2, Documenting Use of Interpretation Services during Informed Consent Discussions
 DHS policy # 318, Non-English and Limited English Proficiency
 Family Code Sections 7002 and 7120

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