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CHAPTER 1

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FORMS & APPENDIXES

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CHAPTER 1

PATIENTS’ RIGHTS AND THE BASIC PRINCIPLES OF CONSENT

State and federal laws grant patients certain rights. Foremost among these is the right for a competent adult to make his or her health care decisions. This chapter discusses the basic principles of consent, including when consent is necessary, the difference between “simple” consent and informed consent, how consent may be obtained, and penalties for failure to obtain consent. This chapter also discusses state and federal requirements to inform patients of their rights.

I. WHY CONSENT IS NECESSARY

Every competent adult has the fundamental right of self-determination over his or her body and property. Individuals who are unable to exercise this right, such as minors and incompetent adults, have the right to be represented by another person who will protect their interests and preserve their basic rights. (See chapter 2 regarding appropriate legal representatives.)

A. THE PATIENT’S RIGHT TO CONSENT TO, OR REFUSE, MEDICAL TREATMENT

A person does not give up the right to control what is done with his or her body and property when seeking care at a hospital. Indeed, a physician has both a legal and an ethical duty to obtain the patient’s consent, or the consent of the patient’s legal representative, to medical treatment.

Failure to obtain the proper consent to treatment in accordance with applicable legal standards may result in a charge of battery, professional negligence (malpractice), and/or unprofessional conduct against the physician, nurses, or other health care providers, for even the simplest of procedures.

If the nature of the treatment involved is complicated, the recognition of the patient’s right to self-determination may require that “informed” consent be obtained. [Cobbs v. Grant, 8 Cal.3d 229 (1972)] The distinction between “simple” consent and “informed” consent is described in III. “Informed Consent,” page 1.4.

FAILURE TO OBTAIN CONSENT: BATTERY

“Battery” is defined legally as an intentional touching of a person in a harmful or offensive manner without his or her consent. Consequently, a claim of battery may be made against a physician or other health care provider who performs a medical procedure on a patient without the patient’s consent. A battery may also arise if the patient consents to a particular procedure and the provider either exceeds the scope of the consent or performs a different procedure for which consent was not obtained. It is important to note that no wrongful intent need be present; a physician may sincerely intend to aid the patient, but still be liable for committing a battery. A medical procedure may be considered to be a “harmful touching” (a battery) even if it is performed competently with no adverse outcome.

FAILURE TO OBTAIN INFORMED CONSENT: MALPRACTICE

A patient’s right to decide whether or not to submit to medical treatment establishes the physician’s corresponding duty to inform the patient about the recommended care so that the patient’s decision is meaningful. The physician’s duty of disclosure arises from the fiduciary quality of the physician-patient relationship, which is based upon the patient’s dependence on the physician’s specialized knowledge. [Cobbs v. Grant, supra, at 242]

A physician who fails to adequately disclose the nature of the procedure and its risks and alternatives may be liable for negligence (malpractice). In Cobbs v. Grant, the California Supreme Court established guidelines regarding the physician’s duty of disclosure that are explained at length in III. “Informed Consent,” page 1.4. If the recommended treatment involves the performance of a “complicated” procedure, a physician must explain the nature of the treatment, the risks, possible complications, and expected benefits or effects of the treatment, as well as the alternatives to the treatment and their risks and benefits. The physician must also inform the patient of any potentially conflicting interests he or she may have, such as research or financial interests. (See II. “Use of Organs, Tissues and Fluids,” page 4.1, regarding potentially conflicting interests.) Informed consent is not required for the performance of “simple and common” procedures, where the related risks are commonly understood.

INFORMED REFUSAL

The California Supreme Court has specifically ruled that the physician’s duty of disclosure includes the responsibility to inform the patient of the risks of refusing to undergo a simple and common procedure that has been recommended [Truman v. Thomas, 27 Cal.3d 285 (1980)] (see chapter 5). In the Truman case, the court held that the defendant doctor
breached his duty to his patient by failing to inform her of the risks resulting from her failure to authorize and undergo a Pap smear test. The court stated:

If a patient indicates that he or she is going to decline a risk-free test or treatment, then the doctor has the additional duty of advising of all material risks of which a reasonable person would want to be informed before deciding not to undergo the procedure ... If the recommended test or treatment is itself risky, the physician should always explain the potential consequences of declining to follow the recommended course of action. [Id. at 292]

Consequently, depending upon the type of procedure involved, a physician may be liable for professional negligence (malpractice) if he or she fails to secure the patient’s “informed refusal.”

B. THE PATIENT’S RIGHT TO CONSENT TO HOSPITAL SERVICES

The patient’s personal and property rights may also be affected by certain activities conducted by the hospital and its personnel (as distinct from activities conducted by the physician). Examples include the release of patient-identifiable information, the transfer of a patient to another health facility, and the submission of patient claims to arbitration. These activities and related consent requirements are discussed in detail in subsequent chapters.

Although a hospital is not subject to the physician’s fiduciary duty to the patient and is not directly responsible for obtaining the patient’s informed consent to medical treatment, the hospital is responsible for the care of its patients and for obtaining their consent, or the consent of their legal representatives, to those hospital activities, which, without such consent, would impinge on patients’ rights. Examples of hospital activities that require consent (although not necessarily informed consent) include routine blood tests, chest X-rays and nursing services. Consent to these activities is included in the model “Conditions of Admission” form (CHA Form 8-1) (see chapter 8).

A hospital’s failure to obtain a patient’s consent may raise allegations of battery (as discussed above), false imprisonment (as discussed below) and possibly other charges.

FALSE IMPRISONMENT

Obtaining the patient’s consent to hospitalization will help protect the hospital and physician from the charge that they falsely imprisoned the patient, that is, compelled the patient to remain in the hospital against his or her will. (See also V. “Leaving the Hospital Against Medical Advice,” page 5.5, and chapter 12 regarding involuntary mental health evaluation and treatment.)

In summary, the patient’s consent to medical treatment and hospital services is necessary because, as a general rule, without such consent, the physician and the hospital have no authority to subject the patient to medical treatment or hospitalization and related services. Failure to obtain the consent of the patient or the patient’s legal representative may violate the patient’s common law rights discussed above as well as other patients’ rights established by the state and federal laws discussed in VI. “Patients’ Rights,” page 1.17.

II. WHEN CONSENT IS NECESSARY

The general rules for determining when consent is required are presented below. Subsequent chapters address the requirements that apply in specific situations. The exceptions to the general rule are described below. (See also chapter 12 regarding mental health evaluation and treatment.)

A. GENERAL RULE

The hospital may not permit any treatment, without the risk of liability, unless the patient, or a person legally authorized to act on the patient’s behalf, has consented to the treatment.

B. EMERGENCY TREATMENT EXCEPTION

STATEMENT OF PRINCIPLE

Treatment of a medical emergency may be provided without consent where the provider reasonably believes that a medical procedure should be undertaken immediately, and that there is insufficient time to obtain the consent of the patient or of a person authorized to consent for the patient. The law implies consent in these circumstances on the theory that if the patient were able, or if a qualified legal representative were present, the consent would be given. This exception applies to minors as well as to adult patients.

The location of the patient is not relevant to the determination of whether the patient has a medical emergency. A patient may be in the emergency department, yet may not have a medical emergency that obviates the necessity to obtain consent. Similarly, the patient may be located in a medical/surgical unit or outpatient department and develop a medical emergency that requires treatment to be provided without consent.

California law defines a medical emergency for certain purposes, such as the provision of immunity to physicians who provide treatment in emergency situations [Business and Professions Code Section 2397(c)(2) and (3)], the rendering of care to incompetent adults without court authorization [Probate Code Section 3210(b)], and the rendering of care to minors in custody of the juvenile court [Welfare and Institutions Code Section 369(d)]. According to these statutes, a medical emergency exists when:
1. Immediate services are required for the alleviation of severe pain; or
2. 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.

LIMITATIONS
It is important to note that only the emergency condition may be treated. Treatment that exceeds the necessary response to that needed for the emergency condition may not be rendered without consent from someone authorized to consent to treatment on a nonemergency basis.

As a general rule, if a patient or the patient’s legal representative has validly exercised his or her right to refuse particular medical treatment (see chapter 5), the treatment may not be provided. Since the emergency treatment exception is based on the theory of implied consent, it is not applicable when a patient has validly refused medical treatment, and the emergency arises from the fact that treatment was not given. However, if the medical emergency is the result of a condition or injury that is not specifically related to the condition or injury for which the patient previously refused treatment, the emergency treatment exception generally applies.

If evidence exists to indicate that the patient (or the patient’s legal representative) would refuse the treatment — such as a wallet card stating that the patient is a Jehovah’s Witness and refuses blood products — legal counsel should be consulted. (See chapter 5 regarding refusal of treatment.)

IMMUNITY FROM LIABILITY
The emergency treatment exception has been recognized in several statutes that provide immunity to a physician who does not inform a patient and obtain his or her consent to treatment under certain emergency circumstances. Business and Professions Code Section 2397 provides that a physician is not liable for civil damages for injury or death caused in an emergency situation occurring in his or her office or in a hospital on account of a failure to inform a patient of the possible consequences of a medical procedure where the failure to inform is caused by any of the following:

1. The patient was unconscious.
2. The medical procedure was undertaken without the consent of the patient because the physician reasonably believed that a medical procedure should be undertaken immediately and that there was insufficient time to fully inform the patient.
3. A medical procedure was performed on a person legally incapable of giving consent, and the physician reasonably believed that a medical procedure should be undertaken immediately and that there was insufficient time to obtain the informed consent of a person authorized to give such consent for the patient.

This law is applicable only to actions for damages for injuries or death arising because of a physician’s failure to inform, and not to actions for damages arising because of a physician’s negligence in rendering or failing to render treatment. Business and Professions Code Section 1627.7 provides similar protections for dentists.

In addition, Health and Safety Code Section 1317 provides immunity from liability for an act or omission (which includes the failure to obtain consent) that occurs while a rescue team established by a licensed health facility (or operated by the state or federal government, a county, or the Regents of the University of California) attempts to resuscitate a person who is in immediate danger of loss of life or serious injury or illness, if the rescue team acts in good faith. This immunity extends to the facility, its officers, staff, and employees, including members of the rescue team.

RECOMMENDED PROCEDURE FOR PROVIDING CARE PURSUANT TO THE EMERGENCY MEDICAL TREATMENT EXCEPTION

Determination of Existence and Nature of Emergency
The physician must initially determine whether the patient has the capacity to give consent, since the emergency exception applies only when consent cannot be given. In addition, the scope of the emergency must be determined, and any treatment provided must be limited to that necessary to alleviate the severe pain, or to prevent the patient’s severe disability or death. The treatment provided may be a matter of first aid, temporary medical care in lieu of surgery, or actual surgical procedures. However, only the emergency medical condition may be treated under this exception, since it is the existence of the emergency condition that establishes the implied consent.

Consultation
There is no legal requirement that the physician consult a second physician to confirm the existence of an emergency. However, such consultation may be required by hospital or medical staff policy. Otherwise, it is a matter of discretion for the treating physician to determine if consultation is advisable to confirm the existence of the emergency.

Otherwise Obtaining Consent
The possibility of obtaining the necessary consent from the patient, if he or she is able to give consent (e.g., a conscious adult with capacity), or another person legally capable of consenting, should be assessed and weighed against the
CONSENT TO SURGERY OR SPECIAL PROCEDURE

1. Your doctors have recommended the following operation or procedure: ________________________________

and the following type of anesthesia: ________________________________

Upon your authorization and consent, this operation or procedure, together with any different or further procedures which, in the opinion of the doctor(s) performing the procedure, may be indicated due to any emergency, will be performed on you. The operations or procedures will be performed by the doctor named below (or in the event the doctor is unable to perform or complete the procedure, a qualified substitute doctor), together with associates and assistants, including anesthesiologists, pathologists, and radiologists from the medical staff of (name of hospital) ________________________________ to whom the doctor(s) performing the procedure may assign designated responsibilities.

2. Name of the practitioner who is performing the procedure or administering the medical treatment:

The hospital maintains personnel and facilities to assist your doctors in their performance of various surgical operations and other special diagnostic or therapeutic procedures. However, your doctors, surgeons, and the persons in attendance for the purpose of performing specialized medical services such as anesthesia, radiology, or pathology are not employees, representatives or agents of the hospital or of doctor(s) performing the procedure. They are independent medical practitioners.

3. All operations and procedures carry the risk of unsuccessful results, complications, injury, or even death, from both known and unforeseen causes, and no warranty or guarantee is made as to result or cure. You have the right to be informed of:

- The nature of the operation or procedure, including other care, treatment or medications;
- Potential benefits, risks or side effects of the operation or procedure, including potential problems that might occur with the anesthesia to be used and during recuperation;
- The likelihood of achieving treatment goals;
- Reasonable alternatives and the relevant risks, benefits and side effects related to such alternatives, including the possible results of not receiving care or treatment; and
- Any independent medical research or significant economic interests your doctor may have related to the performance of the proposed operation or procedure.

Except in cases of emergency, operations or procedures are not performed until you have had the opportunity to receive this information and have given your consent. You have the right to give or refuse consent to any proposed operation or procedure at any time prior to its performance.

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1 CMS recommends that consent forms state, 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) and that qualified medical practitioners who are not physicians will perform important parts of the surgery or administration of anesthesia within their scope of practice, as determined under state law, and for which they have been granted privileges by the hospital.
4. If your doctor determines that there is a reasonable possibility that you may need a blood transfusion as a result of the surgery or procedure to which you are consenting, your doctor will inform you of this and will provide you with information concerning the benefits and risks of the various options for blood transfusion, including predonation by yourself or others. You also have the right to have adequate time before your procedure to arrange for predonation, but you can waive this right if you do not wish to wait.

Transfusion of blood or blood products involves certain risks, including the transmission of disease such as hepatitis or Human Immunodeficiency Virus (HIV), and you have a right to consent or refuse consent to any transfusion. You should discuss any questions that you may have about transfusions with your doctor.

5. By your signature below, you authorize the pathologist to use his or her discretion in disposition or use of any member, organ or tissue removed from your person during the operation or procedure set forth above, subject to the following conditions (if any): ______________________________

6. Your signature on this form indicates that:

▪ You have read and understand the information provided in this form;
▪ Your doctor has adequately explained to you the operation or procedure and the anesthesia set forth above, along with the risks, benefits, and alternatives, and the other information described above in this form;
▪ You have had a chance to ask your doctors questions;
▪ You have received all of the information you desire concerning the operation or procedure and the anesthesia; and
▪ You authorize and consent to the performance of the operation or procedure and the anesthesia.

Date: _____________________________ Time: _____________________________ AM / PM

Signature: ____________________________________________________________

(patient/legal representative)

If signed by someone other than patient, indicate relationship: _____________________________

Print name: ____________________________________________________________

(legal representative)
**PHYSICIAN CERTIFICATION**

I, the undersigned physician, hereby certify that I have discussed the procedure described in this consent form with this patient (or the patient’s legal representative), including:

- The risks and benefits of the procedure;
- Any adverse reactions that may reasonably be expected to occur;
- Any alternative efficacious methods of treatment which may be medically viable;
- The potential problems that may occur during recuperation; and
- Any research or economic interest I may have regarding this treatment.

I understand that I am responsible for filling in all blanks in paragraphs 1. and 2. above. I further certify that the patient was encouraged to ask questions and that all questions were answered.

Date: ________________________________ Time: __________________________ AM / PM

Signature: ________________________________

(physician)

Print name: ________________________________

(legal representative)

**CONSENT TO BLOOD TRANSFUSION**

Your signature below indicates that:

1. You have received a copy of the brochure, A Patient’s Guide to Blood Transfusion.
2. You have received information from your doctor concerning the risks and benefits of blood transfusion and of any alternative therapies and their risks and benefits.
3. You have had the opportunity to discuss this matter with your doctor, including predonation.
4. Subject to any special instructions listed below, you consent to such blood transfusion as your doctor may order in connection with the operation or procedure described in this consent form.

Special Instructions: ____________________________

*(Describe here any specific instructions for patient’s blood transfusion, e.g., predonation, direct donation, etc.)*

2 The Physician Certification is not a required element of this form but is one way of providing for physician documentation of the consent process. Other options include a progress note in the patient’s medical record, a note in the patient’s history and physical, or documentation provided from the physician’s office (e.g., an informed consent form signed by both the patient and the physician). **NOTE:** Even if the physician provides a copy of a consent form signed in the physician’s office, the patient should still be asked to sign the hospital’s consent form.
Form 1-1 Consent to Surgery or Special Procedure

Date: ___________________________ Time: _____________________________ AM / PM

Signature: ____________________________

(patient/legal representative)

If signed by someone other than patient, indicate relationship: ____________________________

Print name: ____________________________

(legal representative)

INTERPRETER’S STATEMENT

I have accurately and completely read the foregoing document to (patient or patient’s legal representative) ___________________________ in the patient’s or legal representative’s primary language (identify language) ___________________________. He/she understood all of the terms and conditions and acknowledged his/her agreement by signing the document in my presence.

Date: ___________________________ Time: _____________________________ AM / PM

Signature: ____________________________

(interpreter)

Print name: ____________________________

(interpreter)

Reference: CoP Interpretive Guidelines, Tags A-0466 and A-0955
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