CONSENT MANUAL
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43rd Edition

CALIFORNIA HOSPITAL ASSOCIATION

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Mary Barker, Vice President, Publishing and Education
Lois J. Richardson, Esq., Vice President, Privacy and Legal Publications/Education
Bob Mion, Director, Publishing and Marketing
Emily Stone, Publishing Specialist

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QUICK REFERENCE GUIDE

LIST OF FORMS AND APPENDIXES

These documents are provided on the CD that accompanies the *Consent Manual*. Many forms are provided in English and Spanish.

1. PATIENTS' RIGHTS AND THE BASIC PRINCIPLES OF CONSENT

1-1[S] Consent to Surgery or Special Procedure
1-2[S] Informed Consent to Surgery or Special Procedure
1-A[S] Patient Rights *(Combines Title 22 and other California laws, The Joint Commission and Medicare Conditions of Participation requirements)**

2. WHO MAY GIVE CONSENT

2-1[S] Self-Sufficient Minor Information
2-2[S] Caregiver's Authorization Affidavit
2-3[S] Authorization for Third Party to Consent to Treatment of Minor Lacking Capacity to Consent
2-A Consent Requirements for Medical Treatment of Adults*
2-B Consent Requirements for Medical Treatment of Minors
2-C Selection of Health Care Surrogates with the Assistance of Health Care Professionals — Sample Policy
2-D Health Care Decisions for Unrepresented Patients*
2-E Considerations for Revising the Hospital's Policy and Procedure Regarding Decision Making for Unrepresented Patients*

3. ADVANCE HEALTH CARE DIRECTIVES

3-1[S] Advance Health Care Directive

4. PROCEDURES THAT REQUIRE SPECIAL CONSENT

4-1 Transfusion Information Form
4-3[S] Authorization for and Consent to Hysterectomy
4-4 Employee or Medical Staff Member Statement
4-5[S] Release from Responsibility for Treatment of Miscarriage or Partial Abortion
4-6[S] Consent to Reuse of Hemodialysis Filters
4-7[S] Consent to Receive Antipsychotic Medications
4-8[S] Consent to Donation of Sperm, Ova or Embryos
4-9[S] Consent to Implantation of Sperm, Ova or Embryos
4-11[S] Directive Regarding Embryo Disposition
4-A[S] A Patient's Guide to Blood Transfusion
4-B[S] Be Informed (Breast Cancer)*
4-C[S] Be Informed (Prostate Cancer)*

5. REFUSAL OF TREATMENT AND END-OF-LIFE ISSUES

5-1[S] Refusal to Permit Medical Treatment
5-2[S] Refusal of Blood Products
5-3[S] Leaving Hospital Against Medical Advice
5-4[S] Request Regarding Resuscitative Measures
5-5[S] Request for an Aid-In-Dying Drug to End My Life in a Humane and Dignified Manner*
5-6[S] Final Attestation for an Aid-In-Dying Drug to End My Life in a Humane and Dignified Manner*
5-7 End-of-Life Option Act Attending Physician Checklist & Compliance Form*
5-8 End-of-Life Option Act Consulting Physician Compliance Form*
5-9 End-of-Life Option Act Attending Physician Follow-Up Form*
5-A Guidelines for Policies Pertaining to Withholding and Withdrawing Life-Sustaining Treatment
5-B Physician Orders for Life-Sustaining Treatment (POLST)*

6. MEDICAL PROCEDURES AND INTERROGATIONS REQUESTED BY LAW ENFORCEMENT

6-1[S] Blood Test Request by Peace Officer
6-2 Medical Evaluation Request by Peace Officer
6-3 Warrantless Medical Search Request by Peace Officer (When Subject Refuses to Consent)
6-A Collection and Handling of Blood Samples (Pursuant to Vehicle Code Section 23612)

7. RESEARCH ON HUMAN SUBJECTS

7-1[S] Experimental Subject's Bill of Rights
7-2[S] Format for Informed Consent Form for Participation in a Medical Research Project
7-A Research Exempted under DHHS Regulations

8. CONDITIONS OF ADMISSION, ARBITRATION AND LIENS

8-1[S] Conditions of Admission
8-2[S] Notice of Lien
8-3[S] Assignment of Proceeds of Claim
8-4[S] Mutual Arbitration Agreement
8-5[S] Sample Arbitration Clause

"S" denotes that the form is provided in English and Spanish. Forms and Appendixes can be found on included CD.

* Indicates forms that are new or revised in this edition. Forms that begin with "MH" originated in CHA's *Mental Health Law* manual; forms that begin with "PR" originated in CHA's *California Health Information Privacy Manual*.

9. PATIENT TRANSFER, DISCHARGE, OR TEMPORARY ABSENCE

10. MATERNITY/NEWBORN ISSUES

11. DEATH, AUTOPSIES AND ANATOMICAL GIFTS

12. VOLUNTARY ADMISSION AND INVOLUNTARY DETAINMENT FOR MENTAL HEALTH TREATMENT

13. RIGHTS OF MENTAL HEALTH PATIENTS

14. THE MEDICAL RECORD

15. PRIVACY RIGHTS AND NOTICE OF PRIVACY PRACTICES

"S" denotes that the form is provided in English and Spanish. Forms and Appendixes can be found on included CD.

***** Indicates forms that are new or revised in this edition. Forms that begin with "MH" originated in CHA's *Mental Health Law* manual; forms that begin with "PR" originated in CHA's *California Health Information Privacy Manual*.

16. USE AND DISCLOSURE OF PHI: PATIENTS COVERED BY CMIA

17. USE AND DISCLOSURE OF PHI: PATIENTS COVERED BY LPS

18. USE AND DISCLOSURE OF PHI: SUBSTANCE ABUSE

19. ASSAULT AND ABUSE REPORTING REQUIREMENTS

20. OTHER STATUTORY REPORTING REQUIREMENTS

21. INCIDENT AND QUALITY ASSURANCE REPORTS

22. HOSPITAL LIABILITY FOR PATIENTS' BELONGINGS

No forms are associated with chapter 22.

23. HIV AND OTHER BLOODBORNE PATHOGENS

24. OTHER ISSUES

"S" denotes that the form is provided in English and Spanish. Forms and Appendixes can be found on included CD.

***** Indicates forms that are new or revised in this edition. Forms that begin with "MH" originated in CHA's *Mental Health Law* manual; forms that begin with "PR" originated in CHA's *California Health Information Privacy Manual*.

CHAPTER 1

PATIENTS' RIGHTS AND THE BASIC PRINCIPLES OF CONSENT

VI. PATIENTS' RIGHTS 1.19

FORMS & APPENDIXES

1-1[S] Consent to Surgery or Special Procedure
1-2[S] Informed Consent to Surgery or Special Procedure
1-A[S] Patient Rights *(Combines Title 22 and other California laws, The Joint Commission and Medicare Conditions of Participation requirements)*

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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 1.5.

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 1.5. 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 II. "When a Patient or Legal Representative Refuses Treatment," page 5.1)*. 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 1.19.

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. The consent may be simple or informed *(see B. "Identifying Procedures That Require Informed Consent," page 1.5)*. The exceptions to this general rule are described below. *(See also chapter 12 regarding involuntary mental health evaluation and 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 possibility that a delay in treatment in order to secure such consent would result in the patient's severe disability or death, or continuing severe pain. If a delay in treatment for purposes of obtaining consent would not jeopardize the condition of the patient, treatment must be delayed and consent obtained pursuant to the guidelines contained in this manual.

Documentation in the Medical Record

The medical determination that an emergency exists should be carefully documented by the physician (e.g., "The immediate treatment of the patient is necessary because ..."). The physician does not sign a consent form on behalf of the patient. Such consent is implied by law from the existence of the emergency.

If the physician has obtained a consultation, the consulting physician should similarly document his or her findings and opinion in the patient's medical record.

C. OTHER CIRCUMSTANCES IN WHICH A PHYSICIAN IS NOT REQUIRED TO OBTAIN INFORMED CONSENT

CIRCUMSTANCES

In *Cobbs v. Grant*, discussed above, the court noted two special circumstances in which a physician is not required to disclose all of the information that is required to secure the patient's informed consent.

First, the court indicated that a physician need not disclose the risks of the recommended treatment when the patient has requested that he or she not be so informed.

Second, a physician is not required to disclose information to the patient if such disclosure would seriously harm, rather than benefit, the patient. In this regard, the court explained:

> A disclosure need not be made beyond that required within the medical community when a doctor can prove by a preponderance of the evidence [that the doctor] relied upon facts which would demonstrate to a reasonable [person that] the disclosure would have so seriously upset the patient that the patient would not have been able to dispassionately weigh the risks of refusing to undergo the recommended treatment. [*Cobbs v. Grant*, 8 Cal.3d at 245-246]

This second exception to the physician's duty of disclosure is commonly known as the "therapeutic privilege."

Neither exception should be relied upon by the physician unless it is extremely clear that the facts and circumstances of the case justify invoking it. The court stated that these two exceptions constitute situations in which a physician who fails to make the disclosure required by law may defend his or her actions, and specified that any such defense "must be consistent with what has been termed the 'fiducial qualities' of the physician-patient relationship."

The physician's decision to not disclose information will be measured in terms of what "a reasonable person" would have done, not what another physician would have done. Also, the court's discussion about the exceptions generally referred to the disclosure of information about the potential risks of the recommended procedure and did not specifically state that a physician may be justified in not disclosing other information, such as that pertaining to the diagnosis, the nature of the recommended treatment, its expected benefits or effects, alternatives and any potentially conflicting interests of the physician (such as research or financial interests).

The use of these two exceptions should be very rare in the case of adult patients who have the capacity to make health care decisions. It is not clear that either exception is available in the case of a patient who lacks the legal authority to consent to his/her own care or the capacity to make a health care decision. If the parent, guardian, or other legal representative who ordinarily would make health care decisions for a minor or patient who lacks capacity requests not to be given certain information, or is not able to emotionally handle the information, legal counsel should be consulted. In such situations, it should be determined whether a different decision maker would be appropriate.

PROCEDURE

If the physician determines that the patient specifically asked to not receive information about the proposed procedure or treatment, or that the "therapeutic privilege" applies, the physician should fully document in the patient's medical record the facts that resulted in this conclusion. The physician should also document what, if any, information was disclosed to the patient. It may be appropriate for the physician to discuss the information that was not disclosed to the patient with the patient's closest available relative (if the patient consents to the release of medical information to, and the involvement of, the relative) and secure that person's approval for proceeding with the procedure in view of this full disclosure. The physician should document in the patient's medical record the nature and results of any such consultation with the patient's family.

The hospital's role is to verify, by checking the documentation in the medical record, that the physician's failure to disclose information resulted from a determination that one of the two exceptions applied. The hospital may wish to refer such cases to hospital administration, risk management, or legal counsel for review prior to beginning the procedure.

III. INFORMED CONSENT

A. ELEMENTS OF INFORMED CONSENT

As discussed above, the California Supreme Court held in *Cobbs v. Grant*, that a patient must give "informed consent" prior to certain medical treatment. The court stated that in order to give informed consent, the patient must be informed of:

1. The nature of the procedure;
2. The risks, complications, and expected benefits or effects of the procedure;
3. Any alternatives to the treatment and their risks and benefits.

In addition, a later court held that the patient must also be informed of any potentially conflicting interest the physician may have (such as research or financial interests). *(See II. "Use of Organs, Tissues and Fluids," page 4.1.)*

The *Cobbs* court explained that:

> The scope of the physician's communications to the patient, then, must be measured by the patient's need, and that need is whatever information is material to the decision. Thus the test for determining whether a potential peril must be divulged is its materiality to the patient's decision. [*Cobbs v. Grant*, supra, 8 Cal.3d 229, 245]

In a subsequent case, the court clarified its definition of "material information" as follows:

> [T]hat which the physician knows or should know would be regarded as significant by a reasonable person in the patient's position when deciding to accept or reject the recommended procedure … To be material, a fact must also be one that is not commonly appreciated ... If the physician knows or should know of a patient's unique concern or lack of familiarity with medical procedures, this may expand the scope of required disclosure. [*Truman v. Thomas*, 27 Cal.3d 285, 291 (1980)]

The Centers for Medicare & Medicaid Services (CMS) Conditions of Participation (CoP) *Interpretive Guidelines* (Tag A-0466) state that 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. The *Interpretive Guidelines* also state that hospitals are free to delegate to the responsible practitioner (the physician), who uses the available clinical evidence as informed by the practitioner's professional judgment, the determination of which material risks, benefits and alternatives will be discussed with the patient.

The *Interpretive Guidelines* can be found at www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.html, then Publication 100-07 State Operations Manual, then "Appendices Table of Contents." Appendix A (hospitals) is listed first.

For some procedures and treatments, the law requires the physician to give additional specified information. Some of these treatments include sterilization, hysterectomy, antipsychotic medications, reuse of hemodialysis filters, and electroconvulsive therapy. *(See chapter 4 for additional information about these procedures.)*

A physician need not inform a patient about treatment that cannot legally be administered in California [*Schiff v. Prados*, 92 Cal.App.4th 692 (2001)]. A physician must inform a patient about alternative treatments only to the extent that it is required for competent practice within the medical community. [*Vandi v. Permanente Medical Group*, 7 Cal.App.4th 1064 (1992)] For example, a physician need not discuss coffee enemas with patients.

In certain circumstances the patient's physician is not required to disclose all information which would otherwise be required to be given to the patient to secure the patient's informed consent. These circumstances are discussed in C. "Other Circumstances in Which a Physician is Not Required to Obtain Informed Consent," page 1.4. In other circumstances, the law requires that specified information be given to the patient. (These circumstances are discussed in chapter 4.)

B. IDENTIFYING PROCEDURES THAT REQUIRE INFORMED CONSENT

"Informed" consent, as distinguished from "simple" consent, is not required for all medical treatments. The *Cobbs* court held that treatments or procedures that are "complicated" require that informed consent (as described above) be obtained. Procedures that are "simple and common" do not require informed consent (although they still require consent, usually obtained in the "Conditions of Admission" form (CHA Form 8-1) *(see chapter 8)*). The court stated that a physician is not expected to explain risks that are commonly understood to be remote. The performance of a blood count was cited as an example of a "simple and common" procedure.

The determination of which procedures are "complicated" and, therefore, require informed consent, is medical in nature. It is the position of CMS that medical staff policies should address which procedures and treatments require written informed consent. *(See Hospital* Interpretive Guidelines*, Tag A-0466.)* The medical staff bylaws themselves would not seem to be the best place for this information. The rules and regulations or a policy and procedure would seem to be better choices. However it is done, it should be appropriately documented and

approved by the medical staff executive committee. The medical staff may wish to adopt a somewhat generic rule, requiring informed consent for any procedure performed in the operating room, cath lab, lithotripsy center, etc., and for radiology or cardiology procedures involving contrast material, for radiation therapy, etc. Each procedure need not be separately listed. Procedures for which the law specifically requires informed consent should also be included *(see chapters 4 and 7)*. To determine whether a procedure is "simple and common" or "complicated," the medical staff may wish to consider whether the average layperson would understand the nature of the procedure and its risks and benefits.

C. THE ROLE OF THE PHYSICIAN IN OBTAINING INFORMED CONSENT

It is the physician's responsibility to obtain informed consent. Generally, the physician who performs the procedure is responsible for obtaining the patient's consent. If a nonphysician will perform the procedure, then the ordering physician is responsible for obtaining consent. If more than one doctor is involved, they can determine together which one will obtain consent, or hospital policy may determine which physician will obtain consent. Hospital personnel should not be involved in providing the information necessary to secure the patient's informed consent or responding to the patient's questions concerning the procedure. The duty to provide this information and obtain informed consent is the exclusive duty of the treating physician.

PROCESS BY WHICH PHYSICIAN INFORMS PATIENT

Verbal discussion, written information, and audio and video recordings are typical methods by which physicians may impart the information to the patient necessary to obtain informed consent.

Although the physician may use written materials or audio or video recordings to provide information to the patient, it is recommended that the physician always give a personal explanation of the procedure or treatment, its possible complications, risks and alternatives. Such verbal discussion gives the patient the opportunity (as required by the legal doctrine of informed consent) to ask questions about the information presented by the physician. A patient's consent given after a discussion with the physician and the opportunity for inquiry is more likely to be truly "informed."

Physicians frequently develop patient information sheets that contain some or all of the information that must be given in order to secure a patient's informed consent. These information sheets may be an important part of the informed consent process since they give the patient the information in a written form which can be reviewed later. However, the use of the hospital's name or the distribution of such information sheets by hospital personnel might cause a patient to conclude that the hospital employs the physician and/or is responsible for the physician's provision of medical services, including the physician's duty to provide the patient with information about the procedure. Thus, any written information sheets, audio or video recordings, etc. which contain medical information that a physician is responsible for giving to a patient to secure the patient's informed consent should be designated as the physician's information. If the information contains the hospital's name or that of any hospital department, and hospital personnel are involved in distributing such information, describing the procedure to the patient, or responding to the patient's questions concerning the procedure or the information, this could easily suggest that the physician is a hospital agent or otherwise confuse a patient regarding the legal responsibility for obtaining informed consent. For these reasons, such involvement by the hospital or its staff is strongly discouraged. If a hospital chooses to distribute such information or put the hospital's name on information sheets, etc., it should be clearly noted that the form or information is being provided by the hospital as a courtesy and that the patient should review the information with his or her physician. It should also clearly state that the physician is not the employee or agent of the hospital (if that is the case). *(See C. "Legal Relationship Between Hospitals and Physicians," page 8.2, for more information regarding physicians as hospital agents.)*

INFORMED CONSENT FORMS THAT CONTAIN MEDICAL INFORMATION

Some physicians prefer to give patients an "informed consent" form that contains within it the medical information the patient must be provided. This procedure promotes complete disclosure and allows patients to study the information. While such forms should not be prepared or distributed by hospital personnel for the reasons discussed above, forms may be used by hospitals to verify and document that informed consent was given by each patient.

A physician who prepares an informed consent form that contains the medical information which must be provided to the patient may use as a guide the "Informed Consent to Surgery or Special Procedure" form (CHA Form 1-2). The physician should include medical information regarding the name of the procedure(s), nature of the treatment, its expected benefits or effects, its possible risks and complications, and any alternatives to the proposed treatment and their possible risks and complications. The physician should also include any potentially conflicting interests, such as research or financial interests. Usually it is not possible to include all information relevant to a

particular patient's condition on a written form; accordingly, the form must either be supplemented through verbal discussions with the patient and/or by written additions containing the information. For example, the risks of a simple appendectomy will differ depending upon whether the patient is a young, healthy person; a pregnant woman; or an elderly, brittle diabetic. A standardized list of risks may be used, but must be supplemented with any additional information pertinent to the particular patient.

These forms are helpful only if they are understood by the patient. Therefore, it is extremely important for the medical information included in the forms to be written in clear, simple, and easily understood terms. In addition, it is essential that the forms clearly state that the patient should ask any and all questions he or she may have concerning the proposed treatment. *(See V. "Securing Consent When Communication Barriers Exist," page 1.12.)*

Also, some physicians may ask patients to respond to questions such as: "Have you been given all the information you desire about the proposed treatment?" or "Do you understand the nature of the proposed treatment, its expected benefits and the possible risks and complications?" However, if this type of question is included in a consent form, the physician must verify it has been answered affirmatively on the form; otherwise, the patient will have established in the document that he or she did not give informed consent. The format provided in CHA Form 1-2 does not include such questions; rather, it requires the patient to acknowledge receipt of the relevant information.

PHYSICIAN DOCUMENTATION

It is recommended that the physician carefully document in the hospital medical record that a discussion was held with the patient and that informed consent was obtained. This documentation can be accomplished in a variety of ways — through a certification on the consent form itself (see the certifications on the "Consent to Surgery or Special Procedure" form (CHA Form 1-1)), through a progress note in the patient's record, through a note in the patient's history and physical, or through documentation provided from the physician's office (e.g., an informed consent form signed by both the patient and the physician). The physician should also place in the medical record a copy of any written material provided to the patient. Any special circumstances should also be documented.

D. THE ROLE OF THE HOSPITAL IN THE INFORMED CONSENT PROCESS

VERIFICATION THAT INFORMED CONSENT HAS BEEN OBTAINED

The hospital's role in the consent process should be limited to verifying that the physician obtained and properly documented the patient's informed consent before the physician is permitted to perform the medical procedure. The physician, not the hospital, has the duty to disclose all information relevant to the patient's decision and to obtain the patient's informed consent.

The obtaining of informed consent involves the practice of medicine, in which the hospital and its employees should not intervene. Hospital employees are not licensed or qualified to adequately explain the various types of medical procedures to the patient and to respond to the patient's potential questions. Only the physician has both the technical knowledge and the knowledge of the particular patient's history and current condition necessary to assure that an adequate disclosure of information, including that pertaining to the risks of treatment, has been given to the patient and that proper responses have been given to the patient's questions.

Although hospital personnel should not be responsible for securing the patient's informed consent (or for providing the information required to secure the patient's informed consent), it is foreseeable that a patient may ask questions of hospital employees who perform a procedure pursuant to the doctor's orders. Hospital personnel generally may answer such questions; however, if it appears that the patient has significant questions about the nature of the procedure, its benefits and risks which indicate that the patient may not have been given sufficient information about the procedure or did not understand the information, hospital personnel should contact the patient's physician to allow him or her to assure that the patient indeed gave informed consent to the procedure.

OBTAINING VERIFICATION

Except in those situations discussed under C. "Other Circumstances in Which a Physician is Not Required to Obtain Informed Consent," page 1.4, the form "Consent to Surgery or Special Procedure" (CHA Form 1-1) should be used after informed consent is given by the patient to the physician. This form serves the dual purposes of assuring that the physician obtained informed consent from the patient for the contemplated procedure or surgery, and indicating that the patient is aware of the right to give informed consent or refusal to the procedure recommended by the physician. By signing this form, the patient acknowledges that the physician adequately explained the operation or procedure to the patient and gave the patient all the information he or she desired concerning the operation or procedure. This form does not list the risks of the procedure nor alternative therapies; thus, if this form is used by the hospital, an additional form, prepared by the physician, which lists the risks and alternatives (signed by the patient and the physician) must also be included in the medical record.

NOTE: The form itself is not informed consent; it is evidence for both the hospital and the physician that

informed consent was obtained. The form is not a substitute for the critical role of the attending physician in the informed consent process.

RECOMMENDED PROCEDURE FOR COMPLETING THE HOSPITAL'S FORM

The consent form should include the name of the patient, and when appropriate, the patient's legal representative.

Identification of the Procedure or Treatment

The medical terminology for the procedure and the type of anesthesia to be used (if applicable) should be entered into the space provided on the form. In addition, it is recommended that a description of the procedure or treatment in lay terminology be entered in the space along with the medical terminology to provide a more meaningful description of the procedure. However, if lay terminology is used, there should be consistency within an institution in describing such procedures. Therefore it is recommended that the medical staff and nursing staff establish a glossary of lay terms which correspond to the medical terminology for procedures performed in the facility.

Identification of the Practitioner(s)

The Hospital *Interpretive Guidelines* require that the consent form include the name of the practitioner performing the procedure or administering the treatment. The Guidelines also recommend ("A well-designed informed consent form might also include …") that the form state, if applicable, that:

1. Physicians other than the operating practitioner, including but not limited to residents, will perform 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
2. 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 regulation, and for which they have been granted privileges by the hospital. *(See Hospital* Interpretive Guidelines*, Tags A-0466 and A-0955.)*

This supersedes CMS' previous position that informed consent forms must state the names of practitioners other than the primary surgeon who will perform important aspects of the surgical procedure.

Medical Information

The Hospital *Interpretive Guidelines* require that informed consent forms include a 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. The Guidelines also recommend ("A well-designed informed consent form might also include …") that the form include an indication or list of the material risks of the procedure or treatment that were discussed with the patient or the patient's legal representative. *(See Hospital* Interpretive Guidelines*, Tag A-0466.)* This reverses CMS' previous position that the form itself must include all information about the procedure or treatment and its alternatives.

Optional Clauses

The hospital may wish to add clauses to the sample form to obtain the patient's consent to photography or videotaping or to the presence of observers. *(See chapter 24.)*

PROCEDURE WHEN PHYSICIAN USES INFORMED CONSENT FORMS THAT CONTAIN MEDICAL INFORMATION

Review and Approval of Forms

Before a form is relied upon by the hospital as evidence that the physician secured the patient's informed consent, the hospital may wish to review it to see that it contains all the information that must be provided to the patient. Information that must be included in informed consent forms is discussed below.

When the physician uses an informed consent form that contains medical information that has been approved by the hospital and appropriate medical staff committees, the hospital may verify that the patient gave informed consent by relying on this form. The hospital should check the original form signed by the patient to ensure it is complete and that the patient or the patient's legal representative properly completed the document. The original consent form should be placed in the patient's medical record. The patient should be given a copy of the consent form if this has not already been done.

E. TWO-DOCTOR CONSENT

A common misconception related to consent law is that if two doctors agree that a patient would benefit from a particular procedure or treatment, the two doctors may consent on behalf of the patient. This is a myth.

There is no provision in California or federal law that permits two doctors to consent on behalf of a patient. This is true whether the patient has the capacity to make health care decisions or not. The patient or a legal representative must provide consent to medical treatment, except in an emergency or as otherwise permitted by law. In an emergency, patient consent is implied by law *(see II. "When Consent is Necessary," page 1.2)*.

F. DURATION OF INFORMED CONSENT

A consent remains effective until the patient revokes it or until circumstances change so as to materially affect the nature of, or the risks of, the procedure and/or the alternatives to the procedure to which the patient consented. For example, if a patient has been admitted for a specific course of treatment, including a specific operation, but in the course of studying the patient several days elapse and the anticipated operation changes considerably, the physician should obtain a new informed consent. Similarly, if the patient's condition changes or new information is learned about the patient's condition, resulting in increased or different risks to the patient from the contemplated procedure or treatment, a new consent should be obtained.

G. PATIENT DOUBT OR CONFUSION CONCERNING INFORMED CONSENT

If, when the informed consent form is presented to the patient, the patient voluntarily indicates doubt or confusion about the indicated procedure and consequently the question is raised whether an informed consent was obtained, the physician should be contacted immediately. Under no circumstances should an employee of the hospital attempt to obtain the patient's informed consent in such a situation.

IV. HOW CONSENT SHOULD BE OBTAINED

Obtaining informed consent is a communication process, not a signature on a paper form. Getting patients to sign consent forms does not mean they have read them or that they understand them. While documentation is important, and often required, the ultimate goal of patient understanding must also be met.

All requirements regarding translation and interpreter services must be followed *(see V. "Securing Consent When Communication Barriers Exist," page 1.12)*.

A. CONSENT MUST BE KNOWINGLY MADE AND FREELY GIVEN

To be effective, consent must be made knowingly and given freely. Consent must not be obtained through the exercise of duress or coercion. The patient (or representative) must be conscious and have the capacity to understand the purpose and effect of the decision to be made and the form to be signed. It is the treating physician's responsibility to determine whether the patient has this capacity. *(See A. "Adults With Capacity to Make Health Care Decisions," page 2.1.)*

B. THE NATURE OF CONSENT

Consent may be express (oral or written statement) or implied (for example, by voluntary submission to the procedure or by the existence of a medical emergency). Express consent should be obtained whenever possible.

C. CONSENT EVIDENCED IN WRITING

The "Conditions of Admission" form contains a clause that documents the patient's consent to noncomplicated procedures such as routine blood tests, X-rays, nursing and other services that may be performed during the patient's hospitalization, outpatient visit, or emergency room treatment. *(See chapter 8 regarding the "Conditions of Admission" form.)*

In certain instances, particularly when the patient is authorizing complicated medical treatment or refusing recommended care, it is recommended that the patient's consent (or refusal) be evidenced in writing. If a dispute arises as to whether consent was given, proof of consent is more readily established when it is in writing.

California law requires that consent for some procedures be documented in writing. These laws are discussed throughout this manual, particularly in chapters 4 and 7. In addition, Title 22, California Code of Regulations, Section 70223(d)(3) requires that, prior to nonemergency surgery, the person responsible for administering anesthesia, or the general surgeon if a general anesthetic will not be administered, must ascertain that a written informed consent form for the contemplated surgical procedure is in the medical record. Title 22, California Code of Regulations, Sections 70749, 70527(d) and 71549 require that all necessary consent forms be made a part of the medical record *(see chapter 14)*.

The Hospital *Interpretive Guidelines* — federal law — require each medical staff to review those procedures that are (or may be) performed at the facility and identify which require informed consent. For those procedures that are identified as requiring informed consent, written verification that informed consent was given should be obtained and placed in the patient's medical record. [Hospital *Interpretive Guidelines*, Tag A-0466] The CoP *Interpretive Guidelines* state that a properly executed informed consent form contains the signature of the patient or the patient's legal representative [Hospital *Interpretive Guidelines*, Tag A-0466].

RECOMMENDED FORMS

In order to provide written evidence of consent, various forms have been developed for use by hospitals and physicians. Such forms are included and discussed in this manual. In addition, as discussed in subsequent chapters, several statutes and regulations require specific information to be included in consent forms or require the use of prescribed forms under certain circumstances. The forms included in this manual fulfill such requirements.

INDEX

SYMBOLS

A

B

C

D

E

F

G

H

M

N

O

P

Q

R

S

T

U

V

W

X