



a risk management distance learning cme course

Informed Consent

strategies to minimize risk



Table of Contents

Introduction/CME Information	1
Section One: The Concept of Informed Consent	5
Section Two: The Informed Consent Process	12
Section Three: What to Disclose	20
Section Four: Exceptions to Disclosure Rules	26
Section Five: Who Can Give Consent	30
Section Six: Consent of Minors	38
Section Seven: Statutory Requirements for Informed Consent	48
References	58
Evaluation and CME Attestation Form	61

Introduction

CME Information

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NORCAL Mutual Insurance Company

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NORCAL Mutual Insurance Company designates this educational activity for a maximum of 2 *AMA PRA Category 1 Credits*[™]. Physicians should only claim credit commensurate with the extent of their participation in the activity

Identified Gaps/Educational Needs

Informed consent is an essential part of the physician-patient relationship. While it may not always be possible for physicians to meet all patient expectations, they must comply with certain requirements regarding a patient's participation in his or her own medical treatment, according to both good medical practice and the law. As treatment options have become more technical, the consequences of various treatment choices have become more difficult for a layperson to understand. Therefore, it is part of the physician's duty to help the patient understand the options so that the patient can make the choice appropriate for him or herself. Physicians' inconsistency in obtaining informed consent and informed refusal has surfaced as an important issue in malpractice allegations. This course addresses the gaps in physician

competence and performance related to the informed consent process in order to reduce malpractice claims and improve patient care.

Educational Objectives

With the goal of reducing liability exposure related to problems with informed consent/refusal, by implementing the risk management recommendations herein, participants will be able to:

- Consistently apply the four elements of proper consent (e.g., discussion, education, documentation and form).
- Utilize plain language in oral and written communication to facilitate consent with patients whose health literacy is limited.
- Differentiate needs and circumstances of patients and adapt the consent process based on patient legal status (as in the case of minors), severity of treatment, and capacity of consent giver.

Target Audience

This course is intended for treating physicians in any specialty.

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How the Course is Organized

This course contains seven sections that address aspects of informed consent that are of particular importance for healthcare professionals, from both a patient care and professional liability standpoint.

Section 1: The Concept of Informed Consent

Section 2: The Informed Consent Process

Section 3: What to Disclose

Section 4: Exceptions to Disclosure Rules

Section 5: Who Can Give Consent

Section 6: Consent of Minors

Section 7: Statutory Requirements for
Informed Consent

Each section has specific learning objectives. Each section also concludes with **Key Points**, which reinforce the topics addressed in that section.

NORCAL insures physicians in California, Alaska and Rhode Island. Thus, many examples of law are taken from these states, particularly California, where legislative summaries and analyses are available through the California Medical Association (CMA). In addition, many of the consent-related topics in this course delve into more state-specific detail than others; this reflects physician inquiries to NORCAL's Risk Management Department about these topics.

Instructions for Completing the Course and Receiving CME Credit

After reading through the closed cases and discussion, complete the Evaluation and CME Attestation Form.

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Section One

The Concept of Informed Consent

This section explores the connection between informed consent and patients' rights, describes situations in which a patient's informed consent is necessary and defines who is responsible for obtaining the patient's consent.

Learning Objectives

Upon completion of this section, you should be able to:

- recognize patients' rights in the medical decision-making process;
 - define the elements that constitute medical battery;
 - determine when an informed consent is necessary;
 - distinguish between implied consent and informed consent; and
 - identify who has the duty to obtain the patient's informed consent.
-

Informed Consent and Patients' Rights

The informed consent process is designed to honor patients' rights by ensuring that the patient is provided with the information necessary to make a *voluntary and rational decision* about a proposed treatment or procedure—even if that decision may not be in the patient's best interest.

The concept of informed consent to medical treatment is based on the following notions, as set forth in the landmark California informed consent case, *Cobbs v. Grant*:¹

- Patients are generally unlearned in the medical sciences.
- Adults of sound mind have the right to determine whether or not to submit to lawful medical treatment and decide what will happen to their own bodies.
- A patient's consent to treatment must be an informed consent.

- The patient has an abject trust and dependence upon his or her physician for the information upon which he or she relies during the decision-making process.

Physicians may incur liability for consent issues even when their medical care meets the standard of care. Consent issues are not usually the central focus of malpractice claims, but they often become important **associated issues or secondary allegations**. While a lack of informed consent or an insufficient disclosure may not necessarily have a causal connection to medical injuries in a malpractice case, those issues can and do discredit physicians at trial or during settlement discussions.

The patient's right to determine what shall be done with his or her own body is reflected, in part, within the legal concept of battery. Battery is the intentional, nonconsensual touching of another person. A **battery** claim by a patient would include one or both of these elements:

- An examination or treatment for which there was *no* express or implied consent
- The treatment provided constituted a substantially different form of care than that which was agreed upon by the patient and physician

A **negligence** claim by a patient for lack of informed consent would allege that the physician failed to disclose sufficient information that the patient should have had in order to make an informed decision about the treatment.

A patient's right to an informed consent to or refusal of medical treatment is enforced in a number of ways, for example, by state common law, federal and state statutes and regulations, medical ethics and The Joint Commission guidelines. The informed consent process is designed to ensure not only the satisfaction of legal, ethical and accreditation requirements, but also the quality and safety of patient treatment. The dual patient rights/quality and safety of care aspects of informed consent are apparent in the 2007 Center for Medicare and Medicaid Services (CMS) informed consent guidelines, which expand provider duties relative to obtaining informed consent for hospital surgical services.

Federal and State Laws Address Patients' Rights

Various state and federal laws have established patients' rights with specific requirements for consent. For example, patients' rights are a matter of federal law. On July 2, 1999, the Department of Health and Human Services published an interim final rule containing an addition to the Medicare Conditions of Participation (CoP) concerning patients' rights.² The interim rule became effective August 2, 1999. The regulation specifies that hospitals protect and promote each patient's rights. A patient's rights include being thoroughly informed of his or her status, being involved in the care planning and treatment, and being able to accept or refuse treatment.³

On April 13, 2007, the Centers for Medicare and Medicaid Services (CMS) issued a memo that completely supersedes the prior Interpretive Guidelines regarding informed consent and reads as follows: "The patient or his or her representative (as allowed under state law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate."⁴

CMS also requires that the medical staff of each hospital have a list of procedures at the hospital requiring an informed consent discussion and a signed consent form.

State-Specific Definitions of Informed Consent

California

- For detailed discussion regarding informed consent, please see the California Medical Association (CMA) On-Call Document #0415: Informed Consent.
- For a detailed discussion regarding informed consent for inpatient procedures, please see the California Medical Association (CMA) On-Call Document #0430: Informed Consent: Inpatient Procedures.

See www.cmanet.org

Rhode Island

It is important to note that, under Rhode Island law, the informed consent standard is a subjective one, not an objective, “reasonable person” standard. When evaluating whether, for example, a known risk or complication of a procedure ought to be disclosed to a patient, a physician should not assume that it need not be discussed because most people or “a reasonable person” would not find the information necessary to their decision. Instead, the pertinent question from the court’s perspective is whether this information would be material to the decisions of the particular patient with whom the physician is speaking.

Alaska

The state of Alaska defines informed consent as follows: A healthcare provider is liable for failure to obtain the informed consent of a patient if the claimant establishes, by preponderance of evidence, that the provider has failed to inform the patient of the common risks and reasonable alternatives to the proposed treatment or procedure, and but for that failure the claimant would not have consented to the proposed treatment or procedure.⁵

When Informed Consent Is Necessary

An informed consent is necessary in situations where a patient could not or would not be aware of the potential consequences of a given treatment decision without obtaining specific information from the physician.

When determining whether an informed consent is necessary, physicians should consider the following questions:

- What would a person expect to know about the risks and possible complications of the procedure?

- Is the patient at risk for a serious complication from the problem or treatment?

When the treatment or procedure involves risks commonly understood to be remote, such as a routine x-ray, informed consent is not needed. The patient must agree to the treatment or procedure, but the physician need not discuss risks and benefits of, and alternatives to, the procedure. Consent for simple and common procedures that involve little risk is considered **implied consent**, which does not require the discussion necessary for informed consent.

Examples of simple and common procedures that do not require the physician to obtain an informed consent include the following:

- Physical examinations
- X-rays
- Pregnancy tests
- Administration of routine medications

As mentioned before, CMS and The Joint Commission require that hospital policies describe which procedures or care require informed consent and are designated in the medical staff bylaws.

Who Should Obtain Informed Consent

The duty to obtain informed consent rests with the clinician/practitioner performing the procedure, diagnostic test or other treatment modality. This duty should not be delegated to another practitioner. Depending on the treatment and associated risks, another practitioner such as a nurse, therapist or technician can obtain the patient's signature on the form *after* the clinician who will perform the treatment or procedure has had the informed consent discussion with the patient.

CMS agrees that the practitioner performing the procedure in the hospital must obtain the informed consent from the patient: "Hospitals must assure that the practitioner(s) responsible for the surgery obtain informed consent from patients in a manner consistent with the hospital's policies governing the informed consent process."

Case Example⁷

Patient's Informed Consent Allegation

During a manipulation under anesthesia (MUA) procedure, the patient suffered a fractured shoulder and a torn rotator cuff. He claimed that Provider #1 (a physician who did not perform the procedure but had consulted on it) failed to inform him of the risks of the procedure, and that had he known he might suffer the injuries that he did, he never would have undergone the procedure.

The Event

The patient was a wheelchair-bound man. He had been rendered paraplegic during a spinal surgery ten years earlier. He presented to Provider #1 (a physical and rehabilitative medicine specialist and clinical director of the facility where the examination and subsequent treatment took place) for evaluation and treatment of adhesive capsulitis in his shoulder. After evaluating the patient, Provider #1 recommended physical therapy in the facility. He also discussed MUA, which would involve putting the patient to sleep and then manipulating the arm to break up the adhesive capsulitis.

Provider #2 (a chiropractor) provided the prescribed physical therapy. He also recommended MUA. Provider #3 (a chiropractor) also discussed MUA with the patient. After a number of physical therapy sessions, the patient made another appointment with Provider #1 to discuss MUA. He brought his mother with him because he was anxious (based on the prior paralysis during surgery) about undergoing the procedure.

Three days after the appointment, the patient presented to the facility for the procedure, which was to be performed by Provider #3. Provider #1, who was to administer a Toradol[®] injection and stabilize the patient on the table during the procedure, greeted the patient prior to surgery. Provider #1 had the patient sign a consent form covering the risks of the Toradol[®] injection.

During the procedure, the patient suffered a fractured shoulder and a torn rotator cuff. He would later testify that these risks were never revealed to him.

Discussion: Who Is Responsible for Obtaining Informed Consent?

Generally, the duty to obtain informed consent rests with the provider performing the procedure. In this case, the patient claimed that he believed Provider #1 was responsible for the procedure and thus responsible for obtaining consent. Provider #1, on the other hand, considered himself a consulting specialist with no obligation to engage in informed consent discussions since he

was not going to be the person conducting the procedure. The appellate court did not agree with Provider #1.

The opinion for this case lists a number of factors that the court considered indicative of an informed consent duty on Provider #1's part, including the following:

- The patient had two direct consultations with Provider #1.
- Provider #1 was the first one to introduce the idea of the procedure.
- Provider #1 was the clinical director of the facility.
- Provider #1 was present before and during the procedure.

In the current healthcare environment, patients may consult with a variety of providers during the process of being treated for a particular condition. As this case indicates, depending on another provider to ensure that a patient understands the risks and alternatives of a procedure may increase liability exposure.

When Lack of Documentation Undermines a Medical Liability Defense

The best defense to a claim of lack of informed consent is a medical record that carefully details successful discussions with the patient. Memories of discussions with patients fade with the passage of time. For example, when testifying about the patient's second appointment (when the patient was accompanied by his mother), Provider #1 stated, "I don't recall a lot about the conversation. Certainly [they were] both inquisitive, I'm sure. I did the best to answer them."⁷ Although Provider #3's procedure notes indicated that informed consent took place, the notes included no details of which risks had been discussed, and there was no signed consent form. The patient in this case only needed to give his informed consent for the MUA procedure once. Unfortunately for Provider #1, there was no way to show that the patient had been informed of the risks and alternatives associated with the procedure by someone other than himself. Had Provider #1 confirmed with Provider #3 that an informed consent process had occurred and charted the risks and alternatives that had been discussed, he might have avoided involvement in this claim.

Referring, On-Call and Substitute Physicians and Anesthesiologists

The duty of the treating physician to obtain informed consent holds true for referring, on-call and substitute physicians, as well as for anesthesiologists.

Referring Physicians

A referring doctor may indicate generally what type of treatment he or she expects for a patient, but the practitioner who will actually perform the procedure or administer the treatment is considered the expert. *Therefore, that person is responsible for informing the patient and obtaining consent.* The referring physician remains liable for obtaining consent only if he or she retains more than a "degree of participation" in the care of the patient.⁸

On-Call and Covering Physicians

Physicians who are on-call or covering for other physicians should be aware that they may be held liable for a lack of informed consent if they go beyond the treatment already begun by the original physician. In addition, a covering physician is responsible for advising of the risks of a continuing treatment.

Referring, On-Call and Substitute Physicians and Anesthesiologists (continued)

In order to avoid potential claims alleging a lack of informed consent, the on-call or covering physician should read the patient's chart, if available, to check for documentation of an informed consent discussion. In addition, he or she should question the patient to ensure that the patient understands and agrees to the procedure.

In an ongoing treatment situation, the covering physician should screen patients for risks that may have arisen since the last visit. If the patient asks a lot of questions or expresses reservations regarding the treatment, it is important to reopen the consent discussion.

Anesthesiologists

The issue of informed consent is especially crucial for anesthesiologists because often they have not developed an ongoing physician-patient relationship. The lack of an ongoing rapport with the patient makes it logistically more difficult to obtain the patient's informed consent. At times, the anesthesia consent is incorporated into the surgical consent form. However, obtaining the patient's signature on such a form may fall short of satisfying the anesthesiologist's duty to obtain informed consent for several reasons:

- Since the duty to obtain informed consent rests with the physician performing the procedure, anesthesiologists have a duty to communicate with their patients about the planned anesthesia, just as surgeons have a duty to communicate about the surgical procedure.
- The surgeon is trained and licensed to perform surgery, not to administer anesthesia. Therefore, he or she may not be fully aware of, or may not fully discuss, the particulars involved in administering an anesthetic.
- Because the anesthesiologist is the expert in administering anesthetic agents and has knowledge of associated side effects and complications, the anesthesiologist can best address any concerns the patient has.

Federal Medicare Conditions of Participation Interpretive Guidelines comment that a hospital's anesthesia services department should consider providing an informed consent form in addition to that of the surgical services department. *It is therefore recommended that anesthesiologists obtain and **document** a separate informed consent for anesthesia from the patient.* Although there is often resistance to using a separate consent form, it is still important that anesthesiologists discuss the anesthesia with their patients in order to communicate concerns, answer questions and thereby allow the patient to make an informed decision based on that discussion.⁶ The patient's ability to understand risks and benefits is most likely better when he or she is not pre-medicated; therefore, it is optimal to have the discussion prior to medication being administered. This approach reinforces the idea that consent is not simply a form but a process.

Key Points – Section One

- ✓ Providing a patient with the information to make a voluntary and rational decision about a proposed treatment or procedure honors that patient's rights.
- ✓ A patient's informed consent is necessary when a patient could not or would not be aware of the consequences of a given treatment or procedure without first obtaining specific information about that treatment or procedure.
- ✓ The clinician or practitioner performing the procedure or administering the treatment is responsible for having the informed consent discussion with the patient and obtaining and documenting the patient's consent.

Section Two

The Informed Consent Process

This section emphasizes that informed consent is a process that incorporates four key elements, only one of which is the consent form. Central to the process is the discussion between the physician and the patient and the physician's documentation of that discussion.

Learning Objectives

Upon completion of this section, you should be able to:

- recognize and implement the four elements of the informed consent process;
 - identify ways in which the physician ensures that a patient has sufficient information to make an informed decision;
 - describe how the informed consent process improves the physician-patient relationship;
 - effectively document the informed consent discussion; and
 - distinguish between the informed consent discussion and the informed consent form.
-

Elements of the Informed Consent Process

Four key elements help physicians accomplish the duty of helping patients reach an informed decision regarding a proposed treatment or procedure:

1. Discussion
2. Education
3. Documentation
4. Consent form

1. Discussion

Beneficial Effect on the Physician-Patient Relationship

The discussion is the most important element in the informed consent process. Informed consent is an extension of good communication techniques and helps to strengthen the physician-patient relationship in the following ways:

- The patient becomes an *active* participant in his or her own treatment.
- The patient and his or her family are better prepared for certain medical realities.
- When patients participate in their own medical treatment, they feel a sense of responsibility for the outcome and are more likely to cooperate and follow medical advice.
- When patients are educated about the realities and potential consequences of their treatments, they have more realistic expectations and are less likely to blame the doctor if the ideal result is not achieved.
- Patients understand that the physician is genuinely concerned about their welfare and treatment outcomes.

Office Setting Is Best Place for the Discussion to Take Place

Ideally, if the doctor recommends an operation, treatment or medication, the discussion of risks,

benefits and alternatives should occur in the office setting rather than the hospital for the following reasons:

- The patient needs time to make a well-considered, rational decision whether to proceed with the doctor's recommendations. The patient loses the opportunity to make that decision if he or she waits until the time of hospital admission.
- The hospital can be a very intimidating place. Many patients report that they feel they have no power to go against the "medical machine" once it is in gear.
- Most patients do not want to hear about risks the night before or just prior to a surgery or procedure; it may be too threatening and the patient may block out relevant information.

However, if the procedure or treatment is ordered after the patient has been admitted to the hospital, the discussion must take place in the hospital, most likely at the patient's bedside. Try to ensure as much privacy as possible from other patients. It is very important that the patient is awake, and the physician should be confident that the patient has the capacity to understand the consequences of his or her healthcare decision. If the patient agrees, inviting a family member to the discussion can provide support for the patient and help him or her understand the urgency and/or consequences of the procedure. If a patient lacks capacity to understand the risks, benefits, and alternatives at the time of the discussion, a surrogate healthcare decision maker must be located with whom to hold the discussion.

Proposed Steps for Discussion

A face-to-face discussion with the patient allows the physician to observe body language and tone of voice, as well as to listen to the content of the patient's remarks. In educating the patient about risks and benefits of the proposed treatment, the provider is bridging the gap between the patient's expectations of a perfect outcome and the uncertainty inherent in the practice of medicine. The following steps are recommended in

communicating with patients during an informed consent discussion.

- Empathize with the patient's wishes for certainty in medicine (e.g., "I wish I could prescribe a medication that had no potential side effects.").
- Attempt to move the patient away from the concept of certainty in the practice of medicine (e.g., "There could be complications associated with this treatment...").
- Assure the patient of your commitment to good medicine, including ongoing communication throughout the proposed course of treatment. Guide the patient as needed (e.g., "Many people who are about to have this procedure often want to know about...Is that something that you'd like to know more about?").
 - Implement "teach-back" techniques, in which the physician works with the patient to increase understanding by having the patient re-state key points of the conversation in his or her own words. (For examples of "teach-back" methods, see Section 3: *What to Disclose*.)⁹
- Focus on the *discussion* rather than the informed consent form you are using.

2. Education

Patients are often relatively unaware of the nature of their medical problems. They tend to put faith and trust in their physicians, which leaves little latitude for patients to cope with less-than-optimal treatment outcomes.

Patients often do not understand that a less-than-optimal outcome may not be caused by substandard medical care. Therefore, the physician, as the expert consultant, bears the burden of educating the patient on certain medical realities. Additionally, as treatment options become more technical, potential consequences of a given treatment become more difficult for a layperson to understand. This places a heavier responsibility on the physician to help the patient comprehend what options are possible and the implications of a given choice.

Health Literacy and Informed Consent¹⁰

Health literacy, according to the Institute of Medicine, is the ability to obtain, process and understand basic health information and services needed to make appropriate health decisions and follow instructions for treatment. With so much complex medical care it is more important than ever for clinicians to confirm that patients understand what they need to know.

According to the 2003 National Assessment of Adult Literacy (NAAL), 40 to 50 percent of American adults have limited health literacy skills. Among survey respondents, associated problems manifested themselves as follows:

- Twenty-six percent did not understand when their next appointment was scheduled.
- Forty-two percent did not understand instructions to “take medication on an empty stomach.”
- Up to 78 percent misinterpreted warnings on prescription labels.
- Eighty-six percent could not understand the rights and responsibilities section of a Medicaid application.

It is important to appreciate that limited understanding of health concepts and health information is not only a problem for people with limited literacy skills. Even patients with average reading levels are often unable to understand consent forms for research studies on cancer drugs and may not comprehend medication instructions, such as those on what to do about missed oral contraceptive pills. Other examples:

- Fifty percent of ED patients are unable to read standard documents.
- Similar results have been shown for surgical consent, smoking cessation and OB/GYN materials.
- ED patients with limited literacy are twice as likely to be hospitalized as those with adequate literacy.

Common medical words and phrases that could be misunderstood by a person with limited health literacy skills include:

- Blood in the stool
- Bowel
- Colon
- Growth
- Oral
- Polyp
- Rectum
- Referral
- Screening
- Tumor

With 40 to 50 percent of people in the United States having limited health literacy skills, it is probable that a physician will encounter these people often, if not daily. Therefore, good communication is necessary for clinicians to have successful physician-patient relationships and improved patient care outcomes.

The informed consent discussion can be enhanced and reinforced by using a consent form that is written in plain language (i.e., uses common words and terms that people already know or explains words that they need to learn).

Plain Language Resources

www.plainlanguagenetwork.org/

www.plainlanguage.gov

Educational Materials Complement and Reinforce the Discussion

Because patients may only remember a small percentage of verbal information, quality educational material complements and reinforces the informed consent discussion.

Educational pamphlets, written handouts and preoperative and postoperative instructions will help the patient make an informed decision and remember possible complications involved in the procedure. Office staff can help the doctor obtain, select and prepare educational materials for the patient. The patient and the physician can look at the educational material together during the discussion. Documenting in the patient's record that the patient received these materials is helpful, particularly if educational materials provided are called into question at a later date.

Besides written materials for patient education consider using graphic illustrations (pictures, pictographs, models), audiotapes and compact discs, and/or videotapes as part of the informed consent process.

3. Documentation

Documenting the informed consent discussion is crucial. Documentation offers objective proof that the informed consent process occurred when the patient claims that it did not, or claims that information necessary to make an informed decision was not disclosed.

Documentation in the medical record should include the following:

- A notation in the progress notes that the informed consent discussion took place and the patient either consented or declined to consent. If the patient declined, informed refusal should be documented. *Merely placing a signed consent form in the record does not meet this objective; the notation in the record should emphasize the **discussion** rather than the form.*
 - A 2005 study by Bhattacharyya, et al, examined the connection between the method of documenting informed consent and indemnity paid in a small sample of 28 orthopedic surgery cases. These authors suggested that the presence of documentation in the surgeon's notes could be associated with a reduced risk of indemnity payment. The authors reported that in two cases where there was no consent *form*—but where the surgeon had *dictated notes in the chart* reflecting that an informed consent discussion had occurred—the claims were successfully defended.¹¹
- A notation regarding what items specific to that patient were discussed and any items that received special emphasis. For example, “Discussed with patient the nature of problem, proposed procedure, risks, benefits and alternatives. Emphasized specific risks related to obesity, alcoholism.” It is important to record that the discussion was tailored to the patient's clinical presentation, and to note the patient's specific questions.
- A notation or copy of any written material given to the patient. Even when the written material is comprehensive, the physician must discuss it with the patient in order to be sure the patient understands the information and to answer any questions. Documentation that written material was distributed is helpful if the material is called into question at a later date.
- The signed and dated consent form, if applicable
- The originals of educational handouts or information sheets that the physician gave to the patient
- Notation that the physician gave the patient any videotape, DVD, CD-ROM, or other visual aids
- Notation of the patient's language if not English, and the name and relationship of the translator
- Under CMS rules, a properly executed informed consent form for an operation in the patient's chart before surgery, except in emergencies.

Case Example¹²

This case involves the prenatal care and treatment of a woman who came under the care of an OB/GYN group in her fourth pregnancy. The then 35-year-old plaintiff mother alleged that she was not informed about AFP testing and was never given the opportunity to accept such testing, which more likely than not would have detected the fetus' affliction with Down syndrome. The plaintiff additionally alleged that the delivering obstetrician performed a tubal ligation at the end of the delivery, without the plaintiffs' informed consent.

The plaintiffs contended that they would have opted to abort the pregnancy had the mother been given the AFP test. The plaintiffs supported their claim that they were not told of the opportunity to have AFP testing by noting the lack of the standard written declination. The trial was bifurcated, so the issues before the jury in the subject phase were those of standard of care and causation.

The defendant countered that the AFP testing was offered to the plaintiff, who declined to undergo prenatal diagnostic study. This declination was recorded in the patient's chart. Additionally, timely and appropriate ultrasounds were performed, which did not reveal any abnormalities. Finally, the defendants maintained that the plaintiff consented to a tubal ligation, which was appropriately timed and documented.

The jury found for the defendant because the physician was able to provide documentation of the informed consent process.¹²

4. The Consent Form

Purpose of the Form

The consent form is a *record* of the discussion and should never *replace* the discussion. A consent form is helpful to ensure that none of the disclosure items is inadvertently missed. The use of an informed consent form should supplement or enhance the discussion between the physician and patient. Obtaining the patient's signature

should not be delegated to the staff assistant. Most attorneys do not consider a witness necessary; however, some physicians prefer to have a witness signature.

The doctor should give the patient a copy of the signed and dated consent form and keep one copy in the chart, which accomplishes several purposes:

- The consent form provides written information to help the patient absorb and remember the risks, benefits and alternatives discussed.
- If the patient has a copy of the form following an adverse outcome, the evidence it provides may help the patient decide against filing a claim against the physician.
- Physicians may incur liability for consent issues even when their medical care met the standard of care. Consent issues are not usually the *central* focus of malpractice claims, but they often become important *associated issues* or *secondary allegations*. While a lack of informed consent or an insufficient disclosure may not necessarily have a causal connection to medical injuries in a malpractice case, those issues can and do discredit physicians at trial or during settlement discussions. The form serves as documentation to be used in the doctor's defense if a claim is filed.
- The hospital consent form protects the hospital by ensuring that the patient has agreed to the procedure or treatment. This differs from the physician's consent form in that the hospital consent form is not intended to fully document the physician's informed consent discussions with the patient.

Content of the Form

The consent form should include the same elements as the consent discussion (see Section 3: *What to Disclose*) and should be written in plain language (i.e., using common words and terms that people already know or explaining words that they need to learn). The elements on the form include:

- Any explanation of the patient’s problem and proposed procedure
- Disclosure of information that a reasonable person would regard as significant in deciding to accept or reject a recommended procedure, including the following:
 - Possible complications (e.g., bleeding, possibility of additional procedures)
 - Severity of possible complications (e.g., death, paralysis, and loss of function)
 - Incidence of risks (e.g., 1 in 1,000 experience this complication), which helps the patient put the risk, including loss of life or limb, in perspective
 - Information about common side effects (e.g., swelling or pain)
- An explanation of the benefits of the procedure.
- A discussion of alternative treatments with their risks, benefits, and side effects.
- The likelihood of achieving the goal, but no guarantees of 100% success.
- Information about potential outcomes if treatment is refused.
- Encouragement of the patient to ask questions. Including “key points,” followed by lines or spaces to insert the patient’s questions, can serve as a good record that the discussion was tailored to the individual patient.
- Acknowledgment that the patient can withdraw consent.
- The offer of a second opinion.
- The patient’s signature with a statement(s) that he/she consents to the procedure, understands the risks, benefits and alternatives, and has had the opportunity to ask the physician all of his/her questions and had them answered to his/her satisfaction.
- In the hospital setting under CMS rules, a properly executed written informed consent form for procedures and treatments specified by the medical staff, or by federal or state law, with the patient’s written consent.¹³ This form must be in the patient’s chart before surgery, except in emergencies.¹⁴ Considering the facts that the informed consent form must be in the patient’s chart before a hospital procedure and that it must meet CMS regulations, a physician should consider obtaining the hospital’s approval of the form.

CMS Informed Consent Elements

There are six minimum elements that CMS requires for a properly executed informed consent form:

1. Name of the hospital where the procedure or other type of medical treatment is to take place
2. Name of the specific procedure or other type of medical treatment for which consent is being given
3. Name of the responsible practitioner who is performing the procedure or administering the medical treatment
4. 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 (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. Hospitals are free to delegate to the responsible practitioner... the determination of which material risks, benefits and alternatives will be discussed with the patient.)
5. Signature of the patient or the patient's legal representative
6. Date and time the informed consent form is signed by the patient or the patient's legal representative

CMS comments that a well-designed informed consent form might include five additional elements, though *not required by the agency*.¹³

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

Certain types of treatment and procedures are subject to state or federal laws that require specific forms and information to be covered in the

informed consent discussions. Section 7 of this course (*Statutory Requirements for Informed Consent*) reviews these requirements.

Key Points – Section Two

- ✓ Informed consent is a process, not a form. This process incorporates educating the patient through discussion, documenting the discussion in the medical record and using a form to record the discussion.
- ✓ The consent form should never replace the discussion.
- ✓ Merely placing the consent form in the medical record does not meet the obligation to document the informed consent discussion. The record notation should emphasize the discussion rather than the form.

Section Three

What to Disclose

This section outlines the information that must be disclosed to the patient in order for the patient to make an informed decision about a treatment or procedure.

Learning Objectives

Upon completion of this section, you should be able to:

- describe the categories of information that need to be disclosed to the patient in the informed consent discussion;
 - appropriately inform the patient of the risks and/or consequences of foregoing tests, procedures, treatment or consultation with a specialist; and
 - document a patient's informed refusal.
-

What to Disclose During the Informed Consent Process

Courts have found it necessary for the physician to divulge to his or her patient all information relevant to the patient to make a meaningful medical care decision. That information includes the following:

- Diagnosis
- Nature and purpose of proposed treatment
- Risks and benefits of proposed treatment
- Probability of success
- Alternatives to proposed treatment
- Risks of foregoing treatment

Diagnosis

Use Language the Patient Can Understand

Physicians need to communicate a patient's diagnosis in plain language. For example, "Mrs. Rodriguez, your bones are very thin and can break easily. I want you to take this medicine to keep your bones strong and make them thicker"

instead of "to prevent osteoporosis." (However, physicians could use these opportunities to teach their patients the meaning of words that they need to learn, such as "osteoporosis." This can be accomplished by drawing a picture or by reviewing educational material (DVD, CD-ROM, pamphlet with illustrations, etc.).

Physicians must ensure that patients with limited English proficiency (LEP) understand the nature of the proposed health care or medication instructions. There are increasing numbers of specific rules that may apply depending on the circumstances. Physicians who receive Medicare Advantage, Medicaid or other "federal financial assistance" must take "reasonable steps" to ensure "meaningful access" to the services the physician provides, at no cost to the LEP patient. For guidance on "reasonable steps," a physician should refer to the revised federal policy titled "Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting LEP Persons," located at: www.hhs.gov/ocr/lep.

There are several ways to provide interpreters, but it is necessary that the physician ensure that any persons used are competent to provide interpretation services. The policy warns that there must be no implication that LEP patients must bring their own interpreters or otherwise be responsible for translation services.

The Americans with Disabilities Act (ADA) prohibits a place of public accommodation (e.g., a physician's office or a hospital) from discriminating against an individual on the basis of disability. One example of ADA compliance would be to ensure that the deaf and hearing impaired can communicate with their physician. There are several relevant aids and services, but choosing the appropriate one will depend on the individual circumstances. If in doubt, the physician should contact his or her lawyer or professional liability carrier.

Allow Time for the Discussion

Because patients are often frightened and overwhelmed by the technical aspects of medicine, it can be difficult for the doctor to be sure that the patient understands what the doctor is saying. It takes time to process information that may be emotionally difficult to hear, and patients may not be able to think of appropriate questions immediately. Physicians can ensure better patient understanding of the diagnosis by allowing sufficient time for the discussion and by having a second discussion once the patient has had time to consider the information.¹⁵

- Create a “shame-free” environment in which patients can seek help without feeling stigmatized.
- Implement “teach-back” techniques that allow for true two-way conversation between clinicians and patients.
- Slow down and take time to listen to a patient's concerns. Create an atmosphere of respect and comfort. Build trust with the patient.
- Limit the information that patients receive at each visit to between three and five key points. Remember that patients retain less than half of the information provided during each visit.

“Teach-Back” Is an Effective Way to Confirm Patient Comprehension

Asking open-ended questions such as, “What will this mean to your lifestyle?” or, “How do you feel about this?” might help some patients think more clearly about the diagnostic information in practical terms. This approach is certainly more effective than closing the discussion with, “Do you have any questions?” However, even with open-ended questions some patients might feel embarrassed and be unresponsive, then go home and start panicking.

The teach-back method engages patients and can give physicians more than one opportunity to confirm understanding. After summarizing three to five key points of a treatment or procedure, the physician can ask the patient to restate his or her understanding of the proposed plan (e.g., “Can you tell me in your own words what we have discussed?”)

In a 1999 *Boston Globe* article, health literacy expert Helen Osborne offered specific suggestions for teach-back from Joanne G. Schwartzberg, MD, of the American Medical Association:⁹

- Ask the patient, “When you go home, what will you tell your [spouse, friend] about the [discussion points, instructions, procedure, treatment, etc.]?” If the patient is not able to restate instructions, try to simplify the language or draw a picture/show an illustration, and ask again.
- When the patient restates instructions, confirm understanding by saying, “I want to make sure I heard you correctly and didn't miss something. When you said [xyz], did you mean [xyz]?”
- Practice teach-back with the last patient of the day, once or twice a week, in order to build skills.

Nature and Purpose of Proposed Treatment

A physician can determine the framework for this explanation by thinking of the proposed treatment plan within the context of the patient's life. The patient may not need to know exactly how the treatment will work, unless such detailed knowledge

is necessary for the patient to cooperate with the treatment. For example, tailoring medication schedules to fit a patient's daily routine, color coding medicines, and using daily events as reminders can help increase compliance. Illustrations help patients visualize instructions, e.g., for a heart surgery patient demonstrate breathing and coughing by hugging a pillow to your stomach and instruct the patient: "After several deep breaths, breathe in slowly through your nose. Open your mouth, stick out your tongue, and cough hard three times as you breathe out."¹⁵ Understanding drug doses/dosing intervals, learning how a medical device works, knowing how to keep an incision site clean, and making and keeping regular appointments will increase patient compliance and decrease risks of complications due to inadvertent non-compliance.

Risks and Consequences

The risks and potential complications of a given treatment will be of varying importance to different patients, which can help determine what the physician should emphasize. This is not to say that the physician should disclose some risks to certain patients and not to others.

A physician must always disclose a known risk of death or serious bodily harm and explain the complications that might occur. These include the risks of death, blindness, brain damage, loss or impairment of any of the special senses (e.g., hearing and sight), paraplegia or hemiplegia, loss of sexual or reproductive function or organs, incontinence and cosmetic or functional mutilation. Beyond that, physicians should discuss additional information that a reasonable person would need to know in order to make an informed decision.

Other risks that are less serious but more likely to occur should be disclosed, such as infection or hair loss. Never assume that a patient is aware of a risk.

Probability of Success

Patients and their families want to be assured that their medical treatments will be successful.

An optimistic approach is important, but do not ignore the possibility that the patient may have unrealistic expectations. These unrealistic expectations need to be addressed before the consent process can be effective.

Patients and their families need to understand first that there are no guarantees in medicine. The informed consent process allows the physician to prepare the patient not only for the treatment or procedure itself, but also for the possibility that it may not provide the desired results. If the practitioner provides a good explanation of the possible results and the results are less than optimal, the patient will be prepared. Conversely, patients unprepared for an unexpected outcome tend to become frightened and angry when the unexpected outcome occurs. Frightened and angry patients are far more likely to sue their doctors even if the doctor has done nothing wrong.

The following is an example of how an inappropriate guarantee resulted in unrealistic expectations and a devastating outcome. A patient was discussing surgery for his peptic ulcer with his physician, who presented the following scenario:¹⁶

"Having this operation will take care of all your troubles. You can eat as you want, drink as you want, do as you please. We're specialists. There's nothing to it at all. It's a very simple operation. After the operation, you can throw away your pillbox. In 20 years, if you figure out what you spent for Maalox pills and doctor calls, you could buy an awful lot. Weigh that against having the operation."

The patient was convinced. During surgery, however, his esophagus was ruptured. He needed three subsequent operations for the insertion of tubes to drain excess fluid from his body. He developed hepatitis from one of the blood transfusions he received and lost 82 pounds. One of his infections could recur as much as 20 years later. The patient sued, not for negligence or battery, but for breach of contract because the physician had guaranteed the results of the operation. He won at trial and on appeal.¹⁷

How can the physician explain that a treatment may not work perfectly without frightening the patient into refusing? It is appropriate to use statistics, as long as they are correct and portray the treatment in a realistic light. Be cautious when using percentages, however. Patients often misunderstand them and mistakenly lower the risks; for example, some patients believe a 1 percent chance means one out of a thousand, rather than one out of a hundred. It is not helpful to tell a patient that the chances of failure are about the same as those of getting hit by a car. It is useful for the physician to tell the patient about how many times he or she has used the treatment and with what success. A further explanation, which takes into account the patient's specific clinical factors (e.g., diabetes, COPD), which make that patient a better or worse candidate for the treatment, is additionally helpful.

Alternatives

A large part of personal freedom to choose arises from being aware of reasonable alternatives. In helping a patient choose a course of treatment, the physician must explain to the patient the reasonable treatment alternatives and their risks and benefits. Most patients are guided by their physician's advice, but sometimes a patient will have a very cogent reason for choosing one treatment over another—contrary to the doctor's opinion.

Patients' lifestyles have everything to do with their choices; so do their cultural, ethical and religious beliefs. The physician has a responsibility to consider these. Through open-ended questioning, the physician can discover the patient's needs and perhaps address them in a way that is agreeable to the patient without compromising the quality of medical care.

Risks of Foregoing Treatment – Informed Refusal

Courts recognize the patient's right to refuse recommended treatment. For example, in 1980, the California Supreme Court in *Truman v. Thomas* expanded the doctrine of informed consent to include the concept of informed refusal. The court decided the following:¹⁸

“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. A physician should document the patient's informed refusal in the patient's medical record.”

Thus, informed refusal is an integral part of the consent process, in which the physician must also disclose what is likely to happen if the patient declines treatment or does not follow up for additional treatment or diagnostic tests. The risks to the patient, including death, should be discussed, and the physician must ensure that the patient understands the seriousness of his or her condition.

The informed refusal obligation applies equally to all tests and procedures that the physician believes are medically indicated, including a physician's recommendation that a patient see a specialist. In that case, the doctor must inform the patient of the possible consequences of failing to see a specialist.

Case Example: The Importance of Documenting Informed Refusal¹⁹

A patient told the surgeon that he had occasional bleeding after bowel movements. The surgeon performed an initial office test that indicated the presence of blood. The patient then underwent a barium enema, and results were reported as “unremarkable.” Months later, the patient again reported seeing blood. Notes in the patient's chart indicate that the surgeon discussed the need to test for blood in the patient's stool but that the patient refused, convinced that the blood he saw was not in his stool. Six months later, the surgeon recorded in the chart that the patient called and told her that he was ill from radiation and chemotherapy to treat a rectal tumor. She also noted that the patient declined further work-up when under her care and that he later saw another physician.

To support his claim, the patient prepared an affidavit attesting that the surgeon never mentioned the word “colonoscopy” or told him that his symptoms could be a sign of cancer. The surgeon testified in deposition that she had recommended a proctoscopy or colonoscopy. The court noted that the lack of documented informed refusal in the chart created a genuine issue of material fact for a jury to determine and bore directly on whether the surgeon breached the accepted standard of care. Had the patient’s informed refusal been documented in the medical chart or had the patient signed an informed refusal form, the case would not have made it to trial.

Documenting Informed Refusal

Documentation in the patient’s medical record concerning refusal of treatment should include the following points:

- Information that the physician gave to the patient concerning the condition and treatment, including reasons for treatment or referral to a specialist and possible alternatives
- Statement that the patient was advised of the risks and consequences (including loss of life or limb) of failing to undergo the test or see a specialist
- Statement that the patient’s refusal of treatment plan or advice and/or patient’s signature has been obtained on an informed refusal form. Use of the form is optional but helpful
- Physician’s referral of patient to obtain treatment from a specialist (if applicable)
- Verification that the patient did or did not keep an appointment with a specialist (if applicable)
- Physician’s attempt to contact patient after referral to a specialist (if applicable)

Withdrawal of Consent

Both patients and physicians need to be aware that the patient may withdraw his or her consent to a procedure at any time. Patients sometimes become so frightened and overwhelmed by certain procedures, or their pain is so great, that they do not wish to continue with the proposed or current regimen. In those cases, the physician must ensure that the patient is not coerced into proceeding against his or her will.

Withdrawal of Consent²⁰

A patient might consent to both a VBAC and a repeat c-section in the event the VBAC has to be abandoned. However, a 1998 Wisconsin Court of Appeals decision should alert physicians that completing these consents before labor may not be the end of the story—a second consent discussion may need to take place during labor.

The patient in this case signed consents for a VBAC and a c-section upon admission to the hospital. During labor, the patient complained of abdominal pain and requested a repeat c-section three different times, but her obstetrician did not grant her request. After 12 hours of labor, her uterus ruptured and the baby was delivered by an emergency c-section. The oxygen deprivation that the infant suffered resulted in spastic quadriplegia. The Wisconsin Court of Appeals held that the patient’s request for a repeat c-section constituted a withdrawal of her consent to a VBAC, and that this withdrawal required the physician to perform a new informed consent discussion of all available treatment options, including continuing with the VBAC or performing a repeat c-section. The Wisconsin Supreme Court affirmed the appellate court’s decision.

Key Points – Section Three

- ✓ In order for a patient to make an informed decision about a treatment, procedure or test, the physician must discuss the diagnosis, nature and purpose of the proposed treatment, risks and benefits of the proposed treatment, the probability of success, alternatives to the proposed treatment, and the risks of foregoing treatment.
- ✓ Physicians can ensure better patient understanding of the diagnosis and proposed treatment by allowing sufficient time for the initial discussion and for a second discussion once the patient has had time to consider the information. Language, health literacy, culture, disability, age and emotion are factors that influence successful communication that leads to patient understanding.
- ✓ A patient may withdraw his or her consent to a procedure at any time.

Section Four

Exceptions to Disclosure Rules

This section reviews situations that generally do not require disclosure of the information outlined in Section Three.

Learning Objectives

Upon completion of this section, you should be able to:

- identify exceptions to informed consent disclosure; and
 - treat conditions within these exceptions appropriately.
-

Emergency Exception

When a patient presents with an emergency condition, consent is unnecessary if the patient is incapacitated and is either permanently or temporarily unable to make an informed decision. This condition could be due to an injury or sudden illness, alcohol or drug intoxication, shock or trauma, or an underlying mental or physical disease or disability.

Emergency Exception Is Based on Implied Consent

Medical treatment for emergencies is based on the legal concept of *implied consent*. Implied consent to emergency treatment differs from a general implied consent (which is considered for most simple treatments), since *in an emergency the patient may be unable to give or deny consent*. The theory is that if the patient were able to consent to treatment, the consent would be given. However, the healthcare team should make continuing efforts to locate the patient's family and/or legal representatives prior to ongoing care.

Implied consent may also be applied to a life- or health-threatening incident that occurs during an authorized operation. When a surgeon is confronted

with an emergency (not just something unexpected), he or she is justified in extending the operation without the express consent of the patient. In *Wheeler v. Barker*, a California court found that the condition of the patient's internal organs was not ascertainable positively until the incision had been made. The existence of a large fibroid tumor on the uterus and multiple tumors and nodules on the inner walls "constituted an emergency that required the surgeons, in light of their experience, to determine at once whether the removal of the diseased portion of the uterus was necessary for the protection of the plaintiff's health."²² The emergency treatment exception does not apply, however, if the patient has refused treatment because of his or her religious beliefs.

Still Important to Keep Communication Lines Open

Although the full consent process may not be undertaken due to the urgency of care and events, the physician must keep the patient informed as much as is practical while treatment is being rendered. Not only will the patient be more cooperative if he or she is aware of what is happening, but the patient may also be able to provide additional information that will assist the physician's diagnosis and treatment.

Determining the Emergency Exception

California

In California, the emergency exception may be relied upon when:

- a medical emergency exists;
- the patient cannot communicate or participate in the consent process; and
- securing treatment authorization from a patient's spouse, closest relative or legal representative would delay treatment and jeopardize the patient's condition.

A medical emergency exists when:²¹

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

If possible, the physician should still attempt to obtain consent from the patient's spouse, closest relative or legal representative.

Treatment Must Be Limited to the Emergency

Once the physician has determined that an emergency condition exists, the treatment rendered must be "limited to that which is necessary to prevent the patient's death or severe disability, or to alleviate severe pain."²¹

Rhode Island

In Rhode Island, medical professionals may administer treatment without consent in those emergency situations in which a patient is unconscious or incapable of giving consent and where it is also necessary to treat or operate before consent can be obtained from the patient or legal guardian. Physician and medical team judgment is key in this situation and careful documentation as to reasons for treatment without consent must be outlined objectively in the medical record.

Alaska

In Alaska, a person who administers emergency medical services to a sick or injured person is not liable for civil damages as a result of an act or omission in administering those services if done in good faith and the injured or sick person reasonably seems to be in immediate danger of serious harm or death. This does not preclude liability for civil damages that are the proximate result of gross negligence or intentional misconduct.⁵

Consultation

While there is no requirement that a physician obtain a consultation when he or she performs emergency treatment, it is a good idea to get a consultation

if that is reasonable under the circumstances.

Physicians should be aware that a hospital policy in the facility may require or recommend a consultation to determine if an emergency exists.

Physicians, Hospitals and Ambulances Can Share Information for Treatment Purposes

According to the Centers for Medicaid and Medicare Services (CMS):²³

HIPAA does not require patients to sign consent forms before doctors, hospitals or ambulances can share information for treatment purposes.

Providers can freely share information with other providers where treatment is concerned, without getting a signed patient authorization or jumping through other hoops. Clear guidance on this topic can be found in a number of places:

- Review the answers to frequently asked questions (FAQs) in the “Treatment/Payment/Health Care Operations” subcategory, or search the FAQs on a likely word or phrase such as “treatment.” The link to the FAQs may be found at <http://www.hhs.gov/hipaafaq/> on the HHS Web site.
- Consult the Fact Sheet, “Uses and Disclosures for Treatment, Payment, and Health Care Operations,” which is at <http://www.hhs.gov/ocr/hipaa/guidelines/sharingfortpo.pdf> on the HHS Web site.
- Review the “Summary of the HIPAA Privacy Rule” at <http://www.hhs.gov/ocr/privacysummary.pdf> on the HHS Web site.

Documentation

Documentation is essential in the following areas:

- The physician should document consent given by the patient’s spouse, closest relative or legal representative.
- If obtaining consent from one of these people is not possible, any attempt to obtain that consent should be documented.
- The physician must document his or her determination that an emergency exists (e.g., “The immediate treatment of this patient is necessary because...”).
- Regarding treatment rendered, the physician should document what happened after the fact, including the “facts” of what was done and the patient’s condition.
- If consultation is obtained, the consulting physician should document similar information regarding his or her findings.

Patient Waiver Exception

When a patient, of his or her own volition, tells the physician that he or she would prefer not to be informed regarding a particular procedure, the doctor may agree to proceed without the informed consent discussion. *When the patient requests this exception, it should be documented in the medical record with the patient’s signature and a notation of the date and time.* The physician may wish to explain certain portions of the procedure, depending upon patient wishes; it is better to err on the side of more disclosure than less.

Therapeutic Privilege

Therapeutic privilege constitutes a valid exception to a full informed consent discussion, but it is a *narrow* exception and should be used with extreme caution. For the therapeutic privilege exception to apply, the doctor must be able to prove that disclosure would upset the patient so seriously as to

render him or her unable to make a rational decision. The use of the privilege must take into account the patient's circumstances.²⁴ The physician may be able to disclose information in a more general way than usual, if he or she feels

that the patient is incapable of coping with the facts. If the physician decides not to disclose information, it is best if he or she discusses the situation with the patient's closest relative and discloses the information to that person.

Key Points – Section Four

- ✓ Once the physician determines that an emergency condition exists, treatment rendered must be limited to that condition.
- ✓ If a patient requests not to be informed about a test, procedure or treatment, the physician should document this and include the patient's signature, and the date and time of the discussion.
- ✓ The therapeutic privilege is a narrow exception to informed consent and should be used with extreme caution.
- ✓ If a physician exercises the therapeutic privilege, he or she needs to make a detailed chart notation explaining the rationale for lack of disclosure

Section Five

Who Can Give Consent

This section explores how various types of adult patients can consent to treatment.

Learning Objectives

Upon completion of this section, you should be able to:

- identify who can give consent for an adult who lacks medical decision-making capacity;
 - document determination of a patient's decision-making capacity;
 - make a reasonable effort to discover a patient's desires and document the results of the effort;
 - identify types of advance directives;
 - identify the scope of a surrogate decision maker's consent; and
 - document decisions made by surrogates regarding treatments, procedures and the withholding or withdrawing of life-sustaining treatment.
-

Adults Capable of Making Medical Decisions

Adult patients are generally presumed to have the capacity to make a decision regarding medical care, including the withholding or withdrawing of life-sustaining treatment. Capacity is the medical concept that implies that a patient has the ability to understand and weigh medical information and make decisions. The patient's right to refuse treatment supersedes the physician's interest in the treatment. If an attending physician or health-care practitioner objects to a patient's declaration to forego life-sustaining treatment and therefore declines to act upon that decision, "appropriate steps" must be taken to transfer care of the patient to another physician who will comply with the patient's formal request.²⁵

Scenario

The condition of an 85 year-old retired teacher who was not previously your patient but is now

under your care, is deteriorating in the ICU. A decision must be made about further care, including resuscitation. The patient is alert, cooperative and appears to have the capacity to make any necessary decisions. You discuss with the patient the treatment options, risks and benefits and, after much discussion, you ask him what he would prefer that you do.

Take-Away Point

It is important to note that while a patient has the right to make decisions about further treatment, he or she is not required to make those decisions. The patient may prefer that his or her family or others make such decisions on the patient's behalf. Also, such refusal to make a decision does not, in turn, mean that the patient is no longer competent to consent or withhold consent for treatment.

Adults Unable to Make Medical Decisions

Lack of capacity to consent to medical treatment can be the result of a patient's unconsciousness, influence of drugs or alcohol, mental illness or other temporary or permanent impairment of reasoning ability.

The physician determines the patient's capacity to consent to proposed medical treatment—that is, whether the patient can reasonably understand his or her condition, the nature and effect of the proposed treatment, the risks of the treatment and the risks of refusing treatment.

If a patient lacks decision-making capacity, there are several avenues through which he or she may execute a legally valid decision to accept or refuse medical treatment, or withhold or withdraw life-sustaining treatment.

Advance Directives

An advance directive is a tool that addresses medical decisions should an adult patient become incompetent to consent to his or her

own medical care. In an advance directive, a patient gives written instructions regarding his or her medical care and, depending on the type of directive, may give another person (a surrogate decision-maker) authority to consent to certain procedures or treatment. A copy of the patient's advance directive should be placed in the patient's medical record.

All states have some form of the following directives:²⁶

- Durable Power of Attorney for Health Care (DPAHC) or, in California, Health Care Decisions Law
- Living Will
- Declaration to Physicians, pursuant to a state's Natural Death Act

Because the scope of these directives may vary in each jurisdiction, physicians should familiarize themselves with the types of directives available in their states and the provisions afforded by those directives.

Advance Directives – State-Specific Considerations

California

Health Care Decisions Law

Effective July 1, 2000, California's Health Care Decisions Law delineates the requirements for executing advance healthcare directives and how physicians should implement them. This law replaces the Natural Death Act and laws governing the Durable Power of Attorney for Healthcare (DPAHC). Existing DPAHC and Natural Death Act Declaration forms remain effective after July 1, 2000. This law does not negate the validity of directives signed by patients under prior laws; its intent is to improve the value and implementation of advance directives. Under California law, five valid types of advance directives for healthcare decisions still exist:

1. Advance healthcare directives pursuant to the Health Care Decisions Law
2. Durable Power of Attorney for Healthcare (DPAHC)
3. Natural Death Act Declaration
4. Emergency medical services (EMS) pre-hospital do-not-resuscitate (DNR) forms
5. Other non-statutory living wills

The new law does not address provisions for identifying surrogates if the patient has not identified someone to make healthcare decisions on his or her behalf. Assuming existing law would apply, the "closest available relative" could act as surrogate decision maker.

Advance Directives – State-Specific Considerations (continued)

The use of EMS pre-hospital DNR forms still remains the best means for insuring that paramedics do not undertake unwanted resuscitation efforts.

Intent and Use of Advance Directives (Effective July 1, 2000)

Under California law, completing an “Advance Healthcare Directive” form would allow a patient or “principal” to do either or both of two things:²⁷

1. Appoint an “agent” to make healthcare decisions when he or she becomes incapacitated. The law also authorizes the appointment of a healthcare agent to make decisions relating to personal care and further allows a directive to specify that the agent’s power becomes effective before the principal becomes incapacitated.
2. Document the healthcare instructions in the form of an advance directive. For example, patients may state that they do not wish to receive treatment that only prolongs the dying process in situations of terminal illness.

Legal authority to make decisions about a patient’s care would be granted to the patient-designated agent. Unless otherwise specified in the advance directive, the primary physician shall make a determination that the patient lacks capacity.²⁸ The definition of capacity is “a patient’s ability to understand the nature and consequences of a decision and to make and communicate a decision, and includes, in the case of proposed health care, the ability to understand its significant benefits, risks and alternatives.”²⁹

Key points to note concerning the Healthcare Decisions Law:

- Patients with existing advance directives do not have to execute new ones. However, physicians should encourage patients to execute the forms available under this law to prevent ambiguity concerning use of forms.
- Patients, physicians, families and healthcare facilities do not have to go to court to withhold or withdraw treatment.
- In the absence of controversy, a court is normally not the proper forum in which to make healthcare decisions regarding life-sustaining treatment.³⁰
- Unless otherwise specified in a written advance healthcare directive, a determination that a patient lacks or has recovered capacity—or that another condition exists that affects an individual healthcare instruction or authority as agent or surrogate—shall be made by the primary physician.²⁸

California Durable Power of Attorney for Health Care (DPAHC) (Repealed as of July 1, 2000)

California legislation supports the continued use of the DPAHC form, since most of its statutory language has been incorporated in the new Health Care Decisions Law. The “Advance Health Care Directive” has now replaced the “Durable Power of Attorney for Health Care,” even though DPAHC forms prior to the change are still recognized as valid. As stated earlier, using the new form for advance healthcare directives is encouraged since it is now the legally recognized document for appointing a healthcare agent.

Advance Directives – State-Specific Considerations (continued)

Consent of the “attorney-in-fact” (this person does not have to be an attorney) named in a DPAHC is obtained only if the patient is currently incompetent. The DPAHC remains valid until the patient regains capacity to make healthcare decisions. The patient may also revoke a DPAHC. (Regulations regarding the validity and revocation of a DPAHC may vary from state to state.)

The parameters of the attorney-in-fact’s consent may also vary from state to state, but the following generally apply:³¹

- An attorney-in-fact may consent to affirmative medical treatment and also, in limited situations, to the withholding or withdrawing of life-sustaining procedures.
- An attorney-in-fact may *not* consent on behalf of a patient to the following: commitment to or placement in a mental health facility, convulsive treatment, psychosurgery, sterilization or abortion.
- An attorney-in-fact may authorize withholding or withdrawing of life-sustaining treatment as long as the following rules are observed:
 - *Above all, the patient’s desires must be upheld.* Treatment may not be withdrawn or withheld if the patient objects or expresses a desire to have the treatment continued.
 - If the patient has also issued a declaration to physicians under a state’s Natural Death Act, the physician should be aware of which document takes precedence.
 - The authority to direct withholding or withdrawing of life-sustaining treatment is only extended to permit the natural process of dying.
 - *The physician must make a reasonable effort to discover his or her patient’s desires, and the results of the effort must be documented in the patient’s chart.*

The California Medical Association (CMA) offers an Advance Health Care Directive Kit. Contact CMA Publications at 1-800-882-1CMA to order a kit. CMA members may access this kit at www.cmanet.org. The California Health Care Association Web site (www.calhospital.org) also contains a sample Advanced Health Care Directive form. Physicians in states other than California may want to refer to the American Medical Association’s Web site, which provides an example of a generic advance directive.

Limitations on Surrogate/Agent Role

California Assembly Bill (AB) 1278, effective January 1, 2002, amends Probate Code §4659 and prohibits a supervising healthcare provider from being a surrogate/agent for healthcare decisions if the provider is an employee of an institution where the patient is receiving care. Additionally, AB1278 amends Probate Code §4711 to limit the duration of the oral designation of a surrogate healthcare decision maker to be the shorter of:

- the course of treatment or illness;
- the stay in the healthcare facility when the designation is made; or
- 60 days.

Advance Directives – State-Specific Considerations (continued)

The expiration of an orally designated surrogate does not affect the role the designee may have in making healthcare decisions under any other law or standards of practice. Additionally, an orally designated surrogate takes priority over an agent under the Power of Attorney for Healthcare Decisions while the designation is in effect, but does not revoke the Power of Attorney for Healthcare Decisions.

Rhode Island

Health Care Power of Attorney

Rhode Island legislators have enacted a law titled “Health Care Power of Attorney,” which allows an individual to declare his or her life sustaining measures in the event of a terminal illness or injury.³² The physician or other healthcare provider should note in the medical record the existence of the Health Care Power of Attorney, particularly if a DNR (do-not-resuscitate) order is included. In the event that the healthcare provider does not wish to comply with the Power of Attorney document, he or she should make necessary arrangements to transfer care of the patient to another practitioner.

Rights of Terminally Ill Act

The Rights of the Terminally Ill Act declares that Rhode Island state laws must recognize the right of an adult person to make a written declaration instructing his or her physician to withhold or withdraw life-sustaining procedures in the event of a terminal condition. “Life-sustaining procedure” means any medical procedure or intervention that, when administered to a qualified patient, will serve only to prolong the dying process. “Life-sustaining procedure” shall not include any medical procedure or intervention considered necessary by the attending physician to provide comfort and care or alleviate pain.³³ “Terminal condition” is defined as an incurable or irreversible condition that, without the administration of life sustaining procedures, will, in the opinion of the attending physician, result in death.³⁴

Alaska

In Alaska.³⁵

An adult may execute a durable power of attorney for healthcare, which may authorize the agent to make any health care decision the principal could have made while having capacity. The power remains in effect notwithstanding the principals’ later incapacity and may include individual instructions. The power must be in writing, contain the date of execution, be signed by the principal, and be witnessed by one of the following methods:

- 1. signed by at least two individuals who are personally known by the principal, each of whom has witnessed the signing either of the instrument by the principal or of the principal’s acknowledgment of the signature on the instrument; or*
- 2. acknowledged before a notary public at a place in the state.*

Living Will

A living will allows a patient to refuse life-sustaining treatment when the patient is terminally ill.³⁶ Living wills often only apply to terminally ill patients and not to those who are in an irreversible coma or permanent vegetative state. Living wills primarily refer only to withdrawing or withholding care and they do not designate a surrogate decision-maker to make all healthcare decisions that apply to any type of illness or injury.

Declarations to Physicians under a State's Natural Death Act

Pursuant to a state's Natural Death Act, a competent adult may issue a "Declaration to Physicians," which directs healthcare providers to withhold or withdraw life-sustaining procedures, including nutrition and hydration. A Declaration does not provide a means for a patient to appoint an agent to make medical decisions on his or her behalf, nor does it state the patient's desires to receive life-sustaining or other types of treatment. *Physicians need to be aware of any state-specific regulations that define the following:*

- The validity of a Declaration to Physicians
- The time frame between when the patient must be informed of the diagnosis of terminal illness and the signing of the declaration
- Any requirement that the patient be certified by a physician(s) to be in a terminal condition and imminently close to death in order for the directive to be carried out
- A patient's or a physician's ability to withhold or withdraw treatment in the absence of a declaration

These situations necessitate documentation of the date and time of the physician's communication with the patient.

Others Who May Consent on the Patient's Behalf

Court-Appointed Legal Representatives

A patient may have a court-appointed legal representative, such as a conservator (in California),³⁷

who can consent to treatment on behalf of the patient. Some patients (conservatees) in this arrangement are judged to have the capacity to consent to their own medical treatment and some are judged to lack capacity to give consent. Documentation, such as the patient's letters of conservatorship, may state whether the conservatee has been found lacking capacity to give consent. *A copy of the letters of conservatorship should be retained in the medical record.*

Physicians should be aware of the limitations on the legal representative's ability to consent for the patient, pursuant to their state laws.

Close Relatives

If the patient is incapable of consenting for himself or herself and has no attorney-in-fact or court-appointed legal representative, consent from the closest available relative may be legally acceptable.³⁸ The relative should state his or her relationship to the patient on the consent form.

The courts generally use the following order of preference among relatives for consent:

1. Spouse (or, in California, domestic partner)
2. Adult child
3. Either parent
4. Adult sibling
5. Grandparent
6. Adult aunt/uncle
7. Adult niece/nephew

Consent from the closest available relative should *not* be accepted if:

- the relative's competence or motives are questionable;
- there is a question as to whether the patient would consent, were the patient competent; or
- the relatives disagree among themselves regarding the treatment.

In these cases, if there is time to seek a court order for treatment of the patient, such action

should be attempted. In some states, the court appoints a *guardian ad litem* to represent the interests of the patient and investigate the situation. The *guardian ad litem* meets with the patient to observe whether the patient is lucid and aware of his or her medical condition, the recommended treatment, its benefits and consequences and the alternatives to that treatment. The *guardian ad litem* then makes a recommendation to the court regarding the patient's mental capacity to consent and the court renders the decision.³⁹

In California, if a patient consents to treatment during a lucid period, then changes his or her mind while confused, it is appropriate to continue the treatment. Careful documentation in the record of nurse's notes, psychiatric consultations, pertinent observations and any conversations with the patient's relatives is necessary to avoid the appearance of coercion or battery. When the patient regains lucidity, it is important to ensure that he or she is still willing to continue treatment.

Documentation of Decisions Regarding Life-Sustaining Treatment

California

Decisions to forego life-sustaining treatment can become controversial, so physicians should be sure to include the following documentation in the patient's medical record:⁴⁰

- Clear written evidence of the diagnosis and prognosis, including test results or other evidence to support the findings.
- Attending physician's statement that the patient or surrogate has been fully informed of the diagnosis and prognosis, their bases and the consequences of withdrawing or withholding life-sustaining treatment.
- The patient's or surrogate's consent, including all applicable advance healthcare directives.
- The patient's verbal desires or the patient's incapacity to give consent. In the event of incapacity, a record of conversations with the closest available relative or the surrogate regarding the patient's wishes and his or her consent to withhold or withdraw life-sustaining treatment.
- A statement that the attending physician believes that the best interests of the patient have guided the surrogate in his or her decision. Copies of certified letters of conservatorship or guardianship, if applicable.
- Express written orders stating which treatment modalities to withhold or withdraw.

The Joint Commission has established standards that apply to foregoing life-sustaining treatment. The *2001 Accreditation Manual for Hospitals* notes that the decision-making process should be applied consistently and the lines of accountability should be clear. A "guiding process" should be formally developed and approved by the hospital's medical staff and should be in place to insure the consistent application of advance directives. Standards RI.1.2.3. through 1.2.8 address hospital policies that must do the following:⁴¹

1. Help the hospital identify its position on initiating resuscitative services and using and removing life-sustaining treatment
2. Ensure that the hospital conforms to the legal requirements of its jurisdiction
3. Address situations in which these decisions are modified during the course of care
4. Offer guidance to health professionals on the ethical and legal issues involved in these decisions and reduce their uncertainty about the practices permitted by the hospital

Key Points – Section Five

- ✓ A physician has a duty to make a reasonable effort to discover and uphold a patient's desires regarding a treatment or procedure. The results of this effort must be documented in the patient's medical record.
- ✓ An advance directive is a tool that allows a patient to give written instructions regarding his or her medical care. An advance directive may designate a surrogate decision-maker to consent to certain procedures and treatments.
- ✓ Healthcare decisions made by the patient directly or through a surrogate decision-maker designated in an advance directive must be documented in the patient's medical record.

Section Six

Consent of Minors

This section addresses consent issues related to minors, including: who can consent for a minor, the legal statuses of minors that allow them to consent to their own treatment and the medical conditions that allow minors to consent to their own treatment.

Learning Objectives

Upon completion of this section, you should be able to:

- identify who can consent for minors;
- identify which minors can legally consent to their own treatment, as determined by the age and status of the minor; and
- identify conditions for which minors can give consent.

Persons Who May Give Consent for a Minor's Treatment

The following information, based on California, Rhode Island and Alaska law, is intended to be illustrative. Since specific laws regarding these areas of minor consent vary from state to state, physicians should check their state laws for further guidance.

In general, the legal age of majority is 18. (Physicians should be aware of the legal age of majority in their states). As a general rule, a minor may not give consent for his or her own medical treatment. Consent must be given by either a parent or by someone authorized to stand in place of a parent. Legal guardians, divorced parents and caregivers who are responsible for the minor in the parents' absence are among the people that may be in the position to consent to a minor's treatment.

In Rhode Island, "Any person age sixteen (16) or over or married may consent to routine emergency medical or surgical care. A minor parent may consent to treatment of his or her child."⁴² The general age of majority in Rhode Island is 18.

Although there is a direct confidential relationship between the physician and the minor patient, physicians and healthcare team members are encouraged to have minors discuss serious medical issues with parents or guardians. Along with the minor's right to consent to treatment, physicians must consider confidentiality of medical information and responsibility for payment of medical bills.

Case Example⁴³

The Event

A four-year-old patient had wart-like lesions on her neck, and was taken to the defendant clinic after her parents saw a TV ad claiming that the clinic could treat skin problems. The defendant physician, a general surgeon, performed laser therapy, and the patient subsequently developed a large keloid scar.

The plaintiffs alleged that the physician did not attain proper informed consent and did not warn of possible risks and complications of the procedure. Plaintiffs also alleged that the surgeon's

treatment fell below the standard of care because it was administered to a Hispanic patient, who would have a greater chance of developing keloid scarring than a lighter-skinned person. However, the physician's records indicated that he had discussed various treatment alternatives with the parents, and had informed them of the risk of scarring, which was less than 5 percent.

Comment

This case demonstrates not only the need for a full informed consent discussion with the parents of a minor patient, but also the importance of documenting the informed consent discussion.

Married Parents of Minors

Except in an emergency, parental consent is necessary to treat a minor. Unless there is disagreement, either parent can consent to treatment of a minor.

In an ongoing treatment situation, such as that for a fractured arm or a series of allergy shots, a physician may consider a parent's original consent for the course of treatment sufficient to continue; in other words, there is no need for consent at every stage. However, if complications arise or the demands of the situation change the physician's treatment plan, the physician must contact the parents again to obtain consent.

Divorced Parents of Minors

If one parent has sole legal custody, then that parent has the right and responsibility to make decisions regarding medical care for the child.⁴⁴

If both parents have joint legal custody, either parent has the right to make healthcare decisions for the child unless the court has specified in its custody order that the consent of both parents is required, or that one is the designated healthcare decision maker.⁴⁵

Should parents who share joint legal custody of a minor disagree about the minor's treatment, the physician should advise them to secure a court order resolving the disagreement before care is provided. If a delay in treatment might harm the minor, the physician may decide to treat the minor, notwithstanding one parent's objection. *The physician's decision-making should be based on good patient care and should be thoroughly documented in the medical record.* Where appropriate in complex matters, legal counsel should be obtained.

Legal Guardians of Minors

The legal guardian of a minor can consent to treatment on the minor's behalf in the same manner as a parent would have, unless the court has narrowed or specified the authority of guardianship. A copy of the letters of guardianship should be placed in the medical record. If the minor is 14 years or older and requires surgery:

1. consent of both the minor and guardian is required; or
2. a court order must authorize the surgery.

(Exception to the above: the guardian can consent to surgery if the minor faces loss of life or limb.)

A guardian *cannot* consent to treatment of a minor for the following types of treatment:⁴⁶

- Placing the patient in a mental health facility involuntarily
- Prescribing or administering an experimental drug
- Administering convulsive shock treatment
- Performing elective sterilization
- Performing psychosurgery

California: Caregivers of Minors: Non-Parent/Adult Relative

A non-parent caregiver, who is an adult relative with whom the minor is living, has the same rights as a parent or guardian to authorize medical care for a minor by signing a *Caregiver's Authorization Affidavit*.

California Family Codes §§6550 and 6552 allow an adult relative who is not the parent, guardian or conservator of a minor to consent to treatment for the minor. The code sections do not identify the types of medical treatment for which consent may be allowed. However, effective January 1, 1997, a caregiver who is a relative can authorize mental health treatment, except for involuntary commitment.

The *Caregiver's Authorization Affidavit* has the following requirements:

- The minor must reside with the adult family member.
- The adult caregiver must be a “qualified relative,” which is specified as spouse, parent, stepparent, brother, sister, stepbrother, stepsister, half-brother, half-sister, uncle, aunt, niece, nephew, first cousin, or any person denoted by the prefix “grand” or “great,” or the spouse of any of the persons specified in this definition, even after the marriage has been terminated by death or dissolution.
- The caregiver must make an attempt to contact and advise the parents of the medical treatment and have received no objection, or the caregiver must be unable to contact the parents.
- The caregiver must complete an affidavit form and attest to all items on the form as being true.
- The affidavit is valid for one year from the date signed by the caregiver.
- A copy of the signed form should be kept in the child's medical record.

Physicians can provide parents or guardians with blank authorization forms, which they may use to designate who may consent to the child's treatment in their absence. California Medical Association (CMA) members may access the form through the CMA at www.cmanet.org. NORCAL policyholders may contact the Risk Management Department at (800) 652-1051, ext. 2244.

Third-Party Authorization to Consent

Third parties such as babysitters, relatives, neighbors, day care providers, camp counselors, etc., often provide care to minors for most of the day. The parent or guardian of a minor may authorize an adult caring for a minor to consent to medical or dental care. Such an authorization must be in writing.⁴⁷ Absent an emergency, when a third party presents at the office requesting medical care for a minor, a copy of the written authorization should be available in the minor's medical record. However, physicians should still attempt

to contact the parent to confirm consent and to inform the parent of the minor's status.

Organized Sports and Other Institutional Child Care Situations

Certain types of institutional child care custodians such as sports teams, day care facilities, pre-schools, camps, clubs, etc., provide parents with medical authorization forms to be signed before a minor can be enrolled. This is allowed under the law as long as the administrator of the program that consents on behalf of the minor is an

adult. Physicians should exercise caution regarding the type of care requested for a minor.

Physicians should familiarize themselves with the laws in their states that set forth consent guidelines for situations involving treatment of minors when one or both parents are unavailable.

A Minor’s Legal Ability to Consent to Treatment

While minors are generally deemed incapable of exercising sufficient judgment to consent to their own treatment, circumstances may exist under which minors have statutory rights to consent to their own treatment. These statutory rights are granted for several reasons, among them the consideration that minors are entitled to certain rights, particularly as they approach the age of majority. Many minors are also mature and self-sufficient enough to comprehend and consent to their own medical care. Finally, a public health concern encourages minors to obtain medical care they might not seek if it were necessary to involve their parents or guardians.

California

Minors Who Can Consent to Their Own Treatment (According to the Minor’s Age and Status)

In California, four categories of minors who may be able to consent to their own medical treatment exist. These minors are treated exactly as adults and, depending on state-specific laws, their parents or guardians may not be responsible for their medical bills. These categories are as follows:

1. **Minors on active duty with the U.S. Armed Forces**
2. **Married or divorced minors**
3. **Emancipated minors:** emancipation is achieved by evidence of a court order; a copy of the court order should be kept in the minor’s medical record.
4. **Self-sufficient minors:** defined as 15 years or older, living away from home and managing their own financial affairs. The minor should be asked to complete a form that provides information demonstrating that the minor falls within the statute. The form should be placed in the minor’s medical record.

The following chart summarizes the ability of these categories of minors to consent to their own treatment in California. The information was taken in part from the California Hospital Association (CHA) Consent Manual. The CHA has granted NORCAL permission to use this material.

If the Patient Is:	Is parental consent required?	Is minor’s consent sufficient?	Are parents responsible for cost?	Can the physician inform parents without the minor’s consent?
Under 18, on active duty with Armed Forces	No	Yes	No	No
Under 18, married or previously married	No	Yes	No	No
Emancipated minor (declared by court, ID card from DMV)	No	Yes	No	No
Self-sufficient minor (over 15, not living at home and managing own financial affairs)	No	Yes	No	Yes

Medical Conditions That Allow Minors to Consent to Their Own Treatment

The following are situations in which minors can consent to their own treatment in California:

- 1. Pregnancy, contraception, and abortion:** A minor of any age may consent to care for the prevention or treatment of pregnancy, including contraception and abortion, but *cannot* consent to sterilization.⁴⁸
- 2. Sexually transmitted diseases/contagious or communicable diseases:** If the minor is 12 years or older, he or she can consent to treatment of a sexually transmitted disease, or any contagious or communicable disease of the categories that are required to be reported to the local health officer.⁴⁹
- 3. Rape:** A minor who is 12 years or older, and who is alleged to have been raped, may consent to medical care related to the diagnosis and treatment following the alleged rape. (Family Code §6927).⁵⁰
- 4. Sexual Assault:** A minor of any age can consent to medical care related to the diagnosis and treatment of sexual assault. The healthcare provider should attempt to contact the minor's parent or guardian unless the physician believes that the minor's parent or guardian committed the sexual assault on the minor.
- 5. Drug and Alcohol Abuse:** In certain circumstances, a minor who is 12 years or older can consent to treatment and counseling services by a provider, excluding treatment with methadone or levoalphacetylmethadol. The physician must contact the parents to involve them in the treatment plan unless the physician believes that contacting the parent or guardian would not be appropriate. Effective January 1, 1997, parents have the right to seek treatment for their child and have access to medical information even if the minor objects.⁵¹ Since successful treatment cannot be provided to an

objecting patient, it is important for the physician to communicate to the minor the importance of parental involvement in the minor's treatment and to reach a resolution that is satisfactory to all. NOTE: There are conflicting federal and state laws regarding the treatment of minors for drug and alcohol abuse. Physicians are advised to refer to the CMA's On-Call Document #0425, *Minor Consent*, available at www.cmanet.org, for further discussion of this topic. Personal attorneys should be consulted with any specific questions.

- 6. Mental Health:** A minor who is 12 years or older may consent to mental health treatment on an outpatient basis (excluding convulsive shock therapy, psychosurgery or psychotropic drugs) or residential shelter services if the minor is 12 years or older and mature enough to participate and either (1) the minor is an alleged victim of incest or child abuse or (2) there is danger of serious physical or psychological harm to the minor without the treatment. The physician should involve the parents or legal guardians unless the physician believes the parent or legal guardian is the perpetrator of the abuse. Either the attempts to contact the parents or the rationale for not contacting them should be documented in the medical record.⁵²

The following chart summarizes the ability of minors to consent to their own treatment for the medical conditions listed above. The information was taken in part from the California Hospital Association (CHA) *Consent Manual*. The CHA has granted NORCAL permission to use this material. The California Medical Association's *California Physician's Legal Handbook* also contains guidance on the issue of drug testing of minors.

Physicians should familiarize themselves with the laws in their state that set forth consent guidelines for situations involving treatment of minors who have a legal status allowing them to consent to their own treatment.

	Is parental consent required?	Is minor's consent sufficient?	Are parents responsible for cost?	Can the physician inform parents without the minor's consent?
If the Patient Is:				
Under 18, unmarried, care related to prevention or treatment of pregnancy, except sterilization	No	Yes	Yes ¹	No
Under 18, unmarried, pregnant, seeking abortion	No	Yes	Yes ¹	No
Under 18, over 12, care for contagious reportable disease or condition	No	Yes	No	Probably not
Under 18, over 12, care for rape	No	Yes	Yes ¹	Yes, usually
Under 18, care for sexual assault	No ²	Yes	Yes ¹	Yes, usually
Under 18, over 12, care for alcohol or drug abuse	No ³	Not Always ⁴	Only if parents participate in counseling	Yes, usually ⁴
Under 18, over 12, care for outpatient mental health treatment	No	Not Always ⁴	Only if parents participate in counseling	Yes, usually ⁴

For a more comprehensive treatment of this topic, consult additional resources such as the *California Physician's Legal Handbook*, published by the California Medical Association, and the *Consent Manual*, published by the CHA.

Chart Endnotes

- ¹ The minor's parents or legal guardians are legally responsible for payment, even though the law allows the minor to give consent for this treatment. *However, health care practitioners must realize that confidentiality of medical information may prevent them from seeking payment from the minor's parents or guardians.*
- ² Health care practitioners must make an attempt to contact the parents, unless the physician reasonably believes that one of the parents committed the sexual assault on the minor.
- ³ Parental consent is required for a minor's participation in replacement narcotic abuse treatment using methadone or levoalphacetylmethadol in a program licensed under Health & Safety Code §11875, *et seq.*
- ⁴ For treatment related to mental health or drug or alcohol abuse, the decision whether or not to inform the child's parents requires more information from the minor and possibly the minor's parents. When minors request treatment for mental health or drug or alcohol abuse, the physician may inform the parents of the treatment without the minor's consent, *as long as, in the physician's best judgment, it will not be detrimental to the child's treatment or the physician-patient relationship.* If the physician feels it is in the minor's best interest to inform the parents of the treatment, it is best to discuss the situation with the patient first and attempt to obtain his or her agreement to inform the parents. At the very least, the patient should be informed that his or her parents will be informed, regardless of whether or not the patient agrees with this disclosure. Attempts to contact the parents or guardians and the outcome must be documented in the medical record. If no such attempt is made, the reason should be documented. (See above information for California laws that do not allow minors to have exclusive rights to consent to alcohol, drug or mental health treatment.)

Be Aware of Confidentiality, Payment and Parental Involvement Issues

Some states may provide exceptions that allow minors to consent to their own treatment related to the following conditions:

- Pregnancy prevention or treatment (except for sterilization procedures)
- Contagious, reportable diseases
- Rape
- Sexual assault
- Alcohol or drug abuse
- Mental health treatment

In these situations, *depending on state law*, a minor *may* be able to obtain confidential treatment without parental consent. In addition to being aware of these situations, physicians are advised to check regulations in their jurisdiction and seek legal counsel regarding confidentiality of medical information and responsibility for payment of medical bills.

If a parent or legal guardian demands confidential information that may be covered under these situations, physicians can explain that they are bound by law and medical ethics not to divulge certain information. They must discuss the matter with the minor patients and attempt to obtain their consent to discuss the situation with their parents. Alaska Rule 504 provides for physician and psychotherapist privilege.

For treatment related to mental health or drug or alcohol abuse, the decision whether or not to inform the child's parents requires more information from the minor and possibly the minor's parents. For example, in Alaska, minors do not have the exclusive authority to consent to alcohol and drug treatment. Since successful treatment cannot be provided to an objecting patient, it is important for the physician to communicate to the minor the importance of parental involvement in the minor's treatment and to reach a resolution that is satisfactory to all.

In California, when minors request treatment for mental health or drug or alcohol abuse, the physician may inform the parents of the treatment without the minor's consent *as long as, in the physician's best judgment, it will not be detrimental to the child's treatment or the physician-patient relationship*. If the physician feels it is in the minor's best interest to inform the parents of the treatment, it is best to discuss the situation with the minor patient first and attempt to obtain his or her agreement to inform the parents. Additionally, in California, the parents are responsible for treatment costs only if they participate in counseling. Attempts to contact the parents or guardians and the outcome must be documented in the medical record. If no such attempt is made, the reason should be documented.

When minor patients seek treatment for mental health or drug or alcohol abuse, the physician may want to inform those patients that although their parents may be legally responsible for medical bills, confidentiality issues may prevent the physician from attempting to collect on the bill. The minor may not be aware that if he or she uses a parent's insurance plan to pay the medical bills, payments for medical appointments and/or tests will almost certainly be shown on the parent's statement. Therefore, the patient may wish to choose an alternative payment method.

Physicians need to check the laws in their state for clarification on specifics regarding these conditions, the age at which the minor can consent for him or herself and whether or not the minor's parents can be informed.

Alaska

Consent Requirements for Medical Treatment of Minors in Various Circumstances

As with the California chart, this chart is intended to clarify those situations in which a minor can consent for him or herself and whether or not the minor's parents can be informed.

	Is parental consent required?	Is minor's consent sufficient?	Are parents responsible for cost?	Can the physician inform parents without the minor's consent?
If the Patient Is:				
Under 18, unmarried, no special circumstances	Yes ¹	No	Yes	Yes
Under 18, married or previously married	No	Yes	No	No
Under 18, no special circumstances, emergency, and parents not available	No	Yes, if capable	Yes	Yes
Emancipated minor (declaration by court)	No (AS09.55.590)	Yes	No	No
Self-sufficient minor (not living at home, manager own financial affairs)	No ² AS25.20.025	Yes	No	No
Not married, pregnant, under 18, care related to prevention or treatment of pregnancy	No AS25.20.025	Yes	No	No
Not married, pregnant, under 18, abortion sought	Yes ³ AS18.16.020	No	Yes	Yes
Not married, pregnant, under 18, care not related to prevention or treatment of pregnancy, no other special circumstances	Yes Exception on AS18.16.020	No	Yes	Yes
Under 18, on active duty with Armed Forces	No	Yes	No	No
Under 18, care for sexually transmitted diseases	No AS25.20.025	Yes	No	No
Under 18, care for sexual assault, rape	No ⁴	Yes	Possibly	Possibly
Under 18, care for alcohol or drug abuse (outpatient only)	No ⁵	Probably	Yes, if consent given and/or involved in treatment	Probably ⁶
Under 18, care for mental health treatment (outpatient only)	Probably	Possibly	Yes, if consent given and/or involved in treatment	Probably ⁶

Section Six: Consent of Minors

It should be recognized that although the minor's parents or guardian are legally responsible for payment (even though the law allows the minor to give consent as a practical matter), other considerations such as confidentiality of medical information may prevent the care provider from seeking payment from the minor's parent or guardian.

Chart Endnotes

- ¹ While Alaska law does not directly mandate the securing of parental consent for the treatment of a child under 18 (a minor), it does require parents to provide their children with medical care. In addition, AS 09.55.556 makes a health care provider potentially liable for failure to obtain the informed consent of a patient. Absent an emergency, parental consent therefore should be secured before medical care is provided to a minor.
- ² Under AS 25.20.025, a minor's consent is sufficient for medical and dental care if the minor is living apart from the minor's parents and managing his or her own finances, if the minor's parents are either unavailable or withhold consent, if the minor is seeking treatment of pregnancy or venereal disease, or if the minor is a parent. Under these circumstances, the parents are relieved of financial obligations.
- ³ Under AS 18.16.020 and 12 AAC 40.060, parental permission is required for the termination of a pregnancy of an unmarried, unemancipated woman under 18 years of age. If parental consent is sought and obtained for an abortion, the parents are legally responsible for payment and can be informed of treatment without the minor's consent. **Judicial Bypass:** Under 18.16.030 a court can issue an order permitting the minor to consent to the abortion without first obtaining consent of a parent or guardian. Complaints must be filed in superior court. Complaints must be under oath and include a statement that the complainant is pregnant, unmarried, under 18, unemancipated, and wishes to have an abortion without parental consent. In addition, the complainant must allege that she is sufficiently mature and well informed to make an abortion decision without parental consent and/or that one or both of her parents or her guardian is abusing the complainant physically, sexually, or emotionally; or that securing consent is otherwise not in the woman's best interest. Sec. 18.16.030 also sets time limits for hearing complaints; establishes an appeals process; requires appointment of an attorney; provides for anonymity. If the court does not act within the time limits, it shall be considered a "constructive order" allowing the minor to consent to the abortion without the consent of a parent or guardian.
- ⁴ Treatment for rape or sexual assault are presumed here to be emergency situations. As above, in non-emergency situations AS 25.20.025 might apply.
- ⁵ Consent of an unemancipated minor is probably sufficient for outpatient drug or alcohol treatment, although the parent will probably be held responsible for the costs of such only if the parent has consented and/or is involved in the counseling process.
- ⁶ Although parents may be entitled to notification of treatment, consideration of the confidentiality of such treatment should be made. AS 47.30.590 requires that entities develop and provide for disclosure of confidential information to parents and guardians, to mental health professionals providing services to a recipient, and to other appropriate service agencies when it is in the *defined* best interests of the patient.

Rhode Island

There is little or no Rhode Island law in the area of consent of minors to medical treatment. There is no case law and very little statutory law to guide practitioners in this issue. *The general rule, however, is that one must obtain consent of a minor's parent or legal guardian before performing medical or surgical care on that minor.* The age of majority in Rhode Island is 18.

Rhode Island law does carve out one exception to this rule. Rhode Island General Laws Title 23 Section 4.6-1 states, "Any person of the age of sixteen (16) or over or married may consent to

routine emergency medical or surgical care. A minor may consent to treatment of his or her child." Although neither the statute nor any reported Rhode Island cases define "routine emergency medical or surgical care," it appears to refer to emergency care that does not involve immediately life-threatening situations.

Under the rule, a person who (a) has reached the age of sixteen or (b) is married may give consent to his or her own routine emergency medical or surgical care. Conversely, consent must be given by either a parent or by someone authorized to stand in place of a parent for an unmarried minor under the age of sixteen.

Abortion

There are several specific provisions and exceptions in Chapter 23-4.7 of the Rhode Island General Laws regarding minors consenting to an abortion. Generally, in the case of an unmarried pregnant woman, consent of at least one of her parents would be required. The pregnant woman's parent(s) should consider only the best interests of their child. If both parents have died or are otherwise unavailable to the physician within a reasonable time and in a reasonable manner, consent of the pregnant woman's legal guardian shall be sufficient.

An unmarried, pregnant minor may choose not to seek consent of either her parents or guardian, or consent may be denied by her parents or guardian. Upon a petition or motion, and after a proper

hearing, a judge of the family court may authorize a physician to perform the abortion if the judge determines that the pregnant woman is mature and capable of giving informed consent. If the judge determines that the woman is not mature, but that the performance of an abortion would be in her best interests, she may participate in proceedings in family court represented by a guardian *ad litem*. Proceedings such as this are given precedence over other pending matters, are kept confidential, and decisions are reached without delay so as to serve the best interests of the pregnant woman. The judge records specific factual findings and legal conclusions regarding the decision. The same provisions listed above from RI General Laws Chapter 23-4.7-3 would apply for the consent process.

Key Points – Section Six

- ✓ While minors are generally deemed incapable of exercising sufficient judgment to consent to their own medical treatment, circumstances may exist in which minors have statutory rights to consent to their own treatment.
- ✓ A public health concern encourages minors to obtain medical care they might not seek if it were necessary to involve their parents or guardians.
- ✓ Physicians generally need to be aware of **who** can give consent for a minor, the various **legal statuses of minors** that allow them to consent to their own treatment, and the various **medical conditions** that allow minors to consent to their own treatment.

Section Seven

Statutory Requirements for Informed Consent

This section reviews certain procedures for which informed consent is governed by state-specific statute.

Learning Objectives

Upon completion of this section, you should be able to:

- recognize the types of treatment that may require special consent under state or federal law; and
 - give the patient sufficient information about the risks and benefits as required by law.
-

State Statutory Requirements for Informed Consent

Some states have specific statutory requirements for obtaining informed consent for tests, treatments or procedures related to certain diseases or conditions. Examples include the following:

- Blood transfusions
- Breast cancer treatment
- Prostate cancer treatment
- Hysterectomies
- Sterilization
- HIV testing
- Abortion
- Telemedicine

Requirements for statutorily imposed informed consent will likely address, at minimum: 1) the physician's obligation to inform the patient of the risks, benefits and complications of a test, treatment or procedure; 2) whether the consent is verbal, written or both; 3) whether the physician must use standardized written summaries to convey information to the patient; 4) the need for documentation in the medical record; 5) applicable

time frames from the date consent is obtained to the date of the procedure; and 6) confidentiality provisions.

Also, statutory requirements in California for specific procedures may be obtained from the California Medical Association's (CMA) *Physician's Legal Handbook* and On-Call documents, as well as the CHA's *Consent Manual*.

Physicians should consult with an attorney familiar with this area of law for informed consent statutory requirements specific to their state.

Consent for Vaccines

Federal Law

Federal law—the National Childhood Vaccine Injury Act⁴⁰—requires healthcare providers to give patients (or their parents or legal representatives) written information about the benefits and risks of certain vaccines before each administration:

- Diphtheria, tetanus, pertussis (DTP, DTaP, Tdap, DT, Td, or TT)
- *Haemophilus influenzae* type b (Hib)

- Hepatitis A (HAV)
- Hepatitis B (HBV)
- Human papillomavirus (HPV)
- Influenza (TIV, LAIV) (Given each year during the flu season)
- Measles, mumps, rubella (MMR, MR, M, R)
- Meningococcal (MCV4, MPSV4)
- Polio (OPV or IPV)
- Pneumococcal conjugate (PCV)
- Rotavirus (RV)
- Varicella (VZV)

Information must include the following:⁵³

- A description of the vaccine's benefits
- A description of the vaccine's risks
- A statement of the availability of the National Vaccine Injury Compensation Program (VICP)
- A copy of the CDC Vaccine Information Statement (VIS) for each administered vaccine

(More information about the VICP can be found at: <http://www.hrsa.gov/vaccinecompensation/>)

The CDC Vaccine Information Statements (VISs) provide written information about a vaccine's risks and benefits and are intended as a tool for physicians to obtain informed consent; however, *they are not intended to be used as informed consent documents or forms*. Although physicians *must use these CDC-developed materials*, they can supplement them with other visual aids or verbal explanations, where appropriate, in order to enhance the informed consent discussion.⁵³

Healthcare providers are not required to obtain the signature of the patient, parent or legal representative acknowledging receipt of the VIS. However, the healthcare provider must document the following information in the patient's medical record:⁵³

- The VIS was provided
- The risks and benefits of the vaccine were explained to the patient (or the patient's parent or legal representative)

- The patient (or parent or legal representative) either consented to or refused administration of the vaccine

In addition, the following information must be documented in the patient's medical record:⁵³

- The date that the vaccine was administered
- The manufacturer and lot number of the vaccine
- The name, address and, if appropriate, the title of the healthcare provider who administered the vaccine

Abortion

California

California physicians should refer to the *California Therapeutic Abortion Act* (California Health & Safety Code §§123400-123450) for information.

Rhode Island

The following are required disclosures by the person who is to perform the abortion in Rhode Island:⁵⁴

- Inform the woman that she is pregnant and the estimated gestational age of the fetus at the time the abortion is to be performed.
- Explain to the woman the medical nature of an abortion, including probable gestational age of fetus at the time the abortion is performed.
- Explain to the woman all known material risks associated with the particular abortion procedure to be employed. If the physician or authorized agent determines that disclosure of a known material risk should not be made, that risk need not be disclosed, provided that the medical basis for nondisclosure is certified in writing in the patient's medical record.

The following standard information must be recorded on a form in order to properly document an adult woman's consent to an abortion:

- Disclosures (as required by Rhode Island General Laws Chapter 23 §4.7-3)
- Acknowledgment that she has received information (as required by Rhode Island General Laws Chapter 23 §4.7-3)

- A statement that reads, “If you decide to carry your pregnancy to term but not to keep the child, you may be able to place the child with either a relative or with another family through foster care or adoption.”

Partial-Birth Abortion

In Rhode Island, “Partial-Birth Abortion” is an abortion in which the person performing the abortion vaginally delivers a living human fetus before killing the infant and completing the delivery.⁵⁵ Performance of a partial birth abortion deliberately and intentionally is a violation of Rhode Island law and is considered a felony. The woman upon whom a partial birth abortion is performed may not be prosecuted for violating this law or for conspiracy to violate the law.

Life of the Mother Exception

Rhode Island General Laws §23 §4.12-2 shall not apply to a partial birth abortion that is necessary to save the life of a mother because her life is endangered by a physical disorder, physical illness or physical injury, including a life-endangering condition caused by or arising from the pregnancy itself, provided that no other medical procedure would suffice for that purpose.

Alaska

According to the State of Alaska Department of Health and Human Services:⁵⁶

“State law and associated regulations address the required content of information to patients considered to constitute informed consent for abortion procedures. There are two major stipulations in the law. First, the Department of Health and Social Services (DHSS) is required to maintain an informational Web site covering the required information on fetal development, abortion, pregnancy, and family planning. The Web site also has resources related to pregnancy-related social and health services in Alaska. The informed consent Web site is located at www.hss.state.ak.us/dph/wcfh/informedconsent/default.htm. Second, use of the informational Web site will be anonymously monitored with the Bureau of Vital Statistics.

There is a downloadable form (http://www.hss.state.ak.us/dph/wcfh/informedconsent/docs/SIGNATURE_FORM.pdf) for documenting that the patient has received or reviewed the informed consent materials on the Web site. Once the patient has signed the form, it should remain as part of his or her permanent medical record. You should not forward this form to the state, as it contains identifying information about your patient. If you choose to not use the information on the Web site you must have a form indicating that informed consent was obtained and that record must remain as part of your patient’s permanent medical record.

All abortion procedures must be reported to the state. The form to use is titled *Report Of Induced Termination Of Pregnancy* (ITOP form) and can be found at the Bureau of Vital Statistics Web site: http://www.hss.state.ak.us/dph/bvs/PDFs/itop/ITOP_form.pdf. The original copy of this completed form must be sent to the bureau within 30 days of the abortion or termination of pregnancy. However, the ITOP form will ask you whether your patient requested and received the information contained on the Web site.”

Physicians should consult with an attorney familiar with this area of law for informed consent statutory requirements specific to their state.

Blood Tests of Pregnant Women

California

Every licensed physician or surgeon responsible for prenatal care of pregnant women in California, or attending such women at the time of delivery, must obtain a blood specimen at the time of the first professional visit or within 10 days thereafter, and submit it to a laboratory to be tested for syphilis. A violation of this code section is considered a misdemeanor unless the patient refuses. The patient’s refusal should be documented in the chart. Other statutory requirements for blood tests of pregnant women include blood type and hepatitis B surface Antigen. *Tests that must be offered include HIV, alpha-fetal protein (AFP) and genetic testing.*

Blood Transfusions

California

The Paul Gann Blood Safety Act (California Health and Safety Code §1645) imposes certain requirements on physicians regarding blood transfusions. The code section stipulates that whenever there is a reasonable possibility, as determined by a physician or surgeon, that a blood transfusion may be necessary as a result of a medical or surgical procedure, the physician or surgeon must use a standardized written summary developed by the California Department of Health Services. It is the physician or surgeon's duty to inform the patient of the positive and negative aspects of receiving autologous blood or directed and nondirected homologous blood from volunteers. Additionally, the physician or surgeon should note on the patient's medical record that the standardized written summary was given to the patient. This documentation is considered the physician's responsibility. It is not a delegated task or the hospital's responsibility. Absent a life-threatening emergency and medical contraindications, the physician or surgeon must allow adequate time prior to the procedure for pre-donation to occur.

Physicians outside California should consult with an attorney familiar with this area of law for informed consent statutory requirements specific to their state.

HIV Test Results

California

Physicians must obtain a *written* informed consent from patients (including those minors who are 12 years or older) in order to perform an HIV test. (Note that under prior law, an informed consent, but not written consent, was required.)⁵⁷

Rhode Island

The state of Rhode Island requires consent for HIV testing as a general rule. The written informed consent shall include at least the following information:⁵⁸

- Name and signature of party(s) seeking and consenting to AIDS test
- Name and nature of the test
- Reasons for conducting the test
- The fact that the test results shall remain confidential except as required by law
- Explanation of how test results will affect the tested person's ability to obtain services from the party requesting the test, or those for whom he or she is acting

Exceptions for drawing blood to secure a test for the presence of the AIDS virus without informed consent are as follows:

- When the person to be tested is under one year of age
- When the person to be tested is between one and thirteen (13) years of age and appears to be symptomatic for AIDS
- When the person to be tested is a minor under the care and authority of the Department of Children, Youth and Families (DCF) and the director of the DCF certifies that an AIDS test is necessary to secure health or human services for that person
- When a person (the complainant) can document significant exposure to blood or other bodily fluids of another person (the individual to be tested), during performance of the complainant's occupation, providing:
 - a) the complainant completes an incident report within 48 hours of the exposure, identifying the parties to the exposure, witnesses, time, place and nature of the event;
 - b) the complainant submits to a baseline AIDS test and is negative on that test for the presence of the AIDS virus, within seventy-two (72) hours of the exposure; and
 - c) the complainant has experienced a significant percutaneous or mucus membrane exposure (e.g., needlestick; bite; splash over an open wound, broken skin, or mucus membrane) to blood or bodily fluids

of the person to be tested, of a type and in sufficient concentration to permit transmission of the AIDS virus if present in those fluids.

- In a licensed healthcare facility or in the private office of a physician in the event that an occupational health representative or physician, registered nurse practitioner, physician assistant, or nurse-midwife not directly involved in the exposure, determines that a healthcare provider, other than one in a supervisory position to the person making the determination, had a significant exposure to the blood and/or body fluids of a patient and the patient or the patient's guardian refuses to grant consent for an HIV test to determine whether the patient has HIV. In such cases, if a sample of the patient's blood is available, that blood shall be tested for HIV.
 - a) If a sample of the patient's blood is not available and the patient refuses to grant informed consent, the healthcare worker may petition for a court order mandating that the test be performed.
 - b) Before a patient or a sample of a patient's blood is required to undergo an HIV test, the healthcare provider must submit to a baseline AIDS test within 72 hours of the exposure.
 - c) No member of the exposure evaluation group that determines that a health care worker has sustained a significant exposure and authorizes the HIV testing of a patient, or any person or health care facility that relies, in good faith, on the group's determination and performs the test, shall have any liability as a result of their actions.
- In an emergency, where due to a grave medical or psychiatric condition, it is impossible to obtain consent from the patient or the patient's parent, guardian or agent.
- There are other provisions in the law including Chapter 23 §18.6-12, Chapter 23 §1-38 and 23 §8-1.1

Department of Corrections and AIDS Testing

All persons who are committed to the Rhode Island Adult Correctional Institution (ACI) for any criminal offense are tested for HIV after conviction, at time of release, and at other times deemed appropriate by a physician. Consent for testing is not required. Pre-and post-test counseling shall be provided to all inmates.

Alaska

The State of Alaska requires specific informed consent for HIV testing as a general rule. Post-test counseling about measures for preventing transmission and the need for treatment is required for individuals who have been or may have been exposed. There are no specific provisions regarding the notification of sexual partners or contacts. There are no specific provisions regarding prenatal or neonatal testing. Minors may consent to HIV testing, except as explicitly excluded by law.⁵⁹

Cancer Information Requirements

California

Breast Cancer Information

According to Health and Safety Code §109275, physicians have a duty to inform patients of risks, benefits and alternative methods of breast cancer treatment by means of a written summary.⁶⁰ Specifically, physicians must document in the medical record that the written summary was given to the patient. The timeliness of the information is important in that physicians need to give the written brochure to patients prior to the performance of a biopsy. This is to be done even if a breast biopsy is not followed by treatment for breast cancer. To comply with the informational requirements, physicians may distribute the brochure, *A Woman's Guide to Breast Cancer Diagnosis and Treatment*, prepared by the California Department of Health Services. Physicians may want to refer to the CHA's website (www.hospital.org), where a copy of the *Be Informed* poster for breast cancer is available.

If a physician does not comply with the statutory requirements for breast cancer information, his or her actions may be considered unprofessional conduct subject to disciplinary action by the Medical Board.⁶¹

Gynecological Cancer Treatments

Physicians are required to comply with Health and Safety Code §109278, which mandates that physicians who provide annual gynecological exams to patients distribute a written summary of symptoms and diagnostic methods for gynecological cancers. Physicians can comply with the code section by distributing to patients the pamphlet titled *Gynecologic Cancers...What Women Need to Know*, published by the California Department of Health Services.⁶² The pamphlet is available at www.dhs.ca.gov/director/owh.

Prostate Cancer Detection

Any time a physician examines a patient for prostate cancer, the physician must provide information to the patient about the availability of appropriate diagnostic procedures, including, but not limited to the prostate antigen (PSA) test, if any of the following conditions are present:

1. The patient is over 50 years of age
2. The patient manifests clinical symptomology
3. The patient is at an increased risk of prostate cancer
4. The provision of the information to the patient is medically necessary, in the opinion of the physician

Violation of this code section constitutes unprofessional conduct.⁶³ Screening guidelines are available through the American Cancer Society at www.cancer.org, 800-ACS-2345. Currently, there is a lack of consensus regarding prostate screening guidelines, but physicians must still provide the information to their patients.

Prostate Cancer Standardized Summary

Health and Safety Code §109280 recommends but does not require physicians to provide written

information to patients regarding prostate cancer.⁶⁴ However, it is highly recommended that written information be given to patients. Forms and summaries on this topic, as well as the brochure *What You Need to Know About Prostate Cancer*, may be obtained from the National Institutes of Health, National Cancer Institute, at www.nci.nih.gov and Cancernet at <http://cancernet.nci.nih.gov/health.htm>.

Physicians outside California should consult with an attorney familiar with this area of law for informed consent statutory requirements specific to their state.

Sterilization

California

Physicians must adhere to specific legal requirements prior to proceeding with sterilization procedures. These are noted below with a separate explanation of consent information required when a physician performs hysterectomies.

Consent of Competent Patients

A competent, “private pay” person must be 18 years old to consent to sterilization. If a patient under 18 requests sterilization, the laws allow the patient to consent if one of the following conditions is met:

1. The person has entered into a valid marriage, even if the marriage was terminated by dissolution
2. The person is on active duty with the United States Armed Services
3. The person is over 15, lives apart from his or her parents or guardians and manages his or her own financial affairs
4. The person has received a judicial declaration of emancipation (pursuant to Family Code §7120)

Of special note: physicians should seek legal advice or contact their medical malpractice carriers prior to performing a sterilization procedure on a minor patient.

Medi-Cal Patients

A competent person who accepts benefits under Medi-Cal must be at least 21 to consent to sterilization.

Comprehension

A patient must be able to understand the content and nature of the informed consent process as detailed by law.

Consent Forms and Pamphlets

Physicians must provide patients with a specific type of consent form and patient pamphlet on sterilization, published by the Department of Health Services in Spanish and English. The required materials for Medi-Cal and non-Medi-Cal are different, but the legal requirement applies to all patients.

The required sterilization pamphlets are: *Understanding Sterilization and Understanding Vasectomy*. The required consent forms are *Medi-Cal/Federally Funded Patients Consent Form* (PM 330) and *Consent Form: Non-Federally Funded* (PM284). The pamphlets and consent forms can be obtained at no cost to physicians from the Department of Health Services Warehouse, 1037 N. Market Blvd., Suite 9, Sacramento, CA 95834. Physicians can request forms by a letter written on their letterhead or by using a form indicating the code and quantity.

Offer to Answer Questions

The physician must offer to answer any questions the individual to be sterilized may have prior to the procedure.

Provide Certain Information Orally

Physicians must orally provide all of the following to the individual to be sterilized:

1. Advice that the individual is free to withhold or withdraw consent to the procedure at any time before the sterilization without affecting the right to future care or treatment and without loss or withdrawal of any federally funded program benefits to which the individual might be otherwise entitled

2. A full description of available alternative methods of family planning and birth control
3. Advice that the sterilization procedure is considered to be irreversible
4. A thorough explanation of the specific sterilization procedure to be performed
5. A full description of the discomforts and risks that may accompany or follow the performance of the procedure, including an explanation of the type and possible effects of an anesthetic to be used
6. A full description of the benefits or advantages that may be expected as a result of the sterilization
7. Approximate length of hospital stay, if any
8. Approximate length of time for recovery
9. Financial cost to the patient
10. Information that the procedure is established or new
11. Advice that the sterilization will not be performed for at least 30 days, unless the procedure meets the emergency condition exception as noted by other laws
12. The name of the physician performing the procedure. If another physician is to be substituted, the patient shall be notified, prior to administering of pre-anesthetic medication, of the physician's name and the reason for the change in physician.

A copy of the signed consent form must be provided to the patient.

If the patient is blind, deaf or otherwise disabled, arrangements must be made to ensure the information is appropriately communicated to the patient. An interpreter must be provided if the patient does not understand the language of the person obtaining consent. For more information on the use of interpreters, refer to NORCAL's Communication CME course. Additionally, informed consent may not be obtained while the individual to be sterilized is seeking to obtain an abortion, is in labor, or within 24 hours postpartum or post-abortion.⁶⁵

Physicians outside California should consult with an attorney familiar with this area of law for informed consent statutory requirements specific to their state.

Hysterectomies

California

Health and Safety Code §1690 requires physicians to obtain verbal and written informed consent prior to performing a hysterectomy on any patient, as outlined below:⁶⁶

1. The patient is free to withhold or withdraw consent at any time prior to the hysterectomy. The withdrawal will not affect the patient's right to future care or treatment or result in loss or withdrawal of any state or federally funded program benefits to which the individual might be otherwise entitled.
2. The patient must receive a description of the type or types of surgery and other procedures involved in the proposed hysterectomy and a description of any known available and appropriate alternatives to the hysterectomy itself.
3. The patient must be advised that the hysterectomy procedure is considered to be irreversible and that infertility will result.

4. The patient must receive a description of the discomforts and risks that may accompany or follow the performance of the procedure, including an explanation of the type and possible effects of any anesthetic to be used.
5. The physician must provide the patient with a description of the benefits of the surgery.
6. The patient must be aware of the approximate length of hospital stay and approximate length of time for recovery.

The patient must sign a written statement prior to the performance of the hysterectomy procedure, indicating she has read and understood the written information, and that her physician or surgeon, or his or her designee, has discussed the information with her. Unless the patient is sterile or postmenopausal, the statement must indicate that her physician or the physician's designee has advised her that the hysterectomy will render her permanently sterile and incapable of having children.

Physicians outside California should consult with an attorney familiar with this area of law for informed consent statutory requirements specific to their state.

Telemedicine

Specific informed consent requirements exist for the practice of telemedicine in California.⁶⁷ Telemedicine is defined as the practice of healthcare delivery, diagnosis, consultation, treatment, transfer of medical data and education using interactive audio, video or data communications. Interactive means an audio, video or data communication involving a real time (synchronous) or near real time (asynchronous) two-way transfer of medical data and information.

Prior to the delivery of healthcare via telemedicine, the healthcare practitioner who has ultimate authority over the care or primary diagnosis of the patient shall obtain verbal and written informed consent from the patient or the patient's legal representative.

The informed consent process must ensure that all of the following information is given to the patient or the patient's legal representative both verbally and in writing:

- The patient or the patient's legal representative retains the option to withhold or withdraw consent at any time without affecting the right to future care or treatment or risking the loss or withdrawal of any program benefits to which the patient or the patient's legal representative would otherwise be entitled.
- A description of the potential risks, consequences and benefits of telemedicine techniques.
- All existing confidentiality protections apply.
- All existing laws regarding patient access to medical information and copies of medical records apply.
- Dissemination of any patient-identifiable images or information from the telemedicine interaction to researchers or other entities will not occur without the consent of the patient.
- The patient or the patient's legal representative shall sign a written statement prior to the delivery of healthcare via telemedicine, indicating that the patient or the patient's legal representative understands the written information provided and that the risks and benefits of, as well as the alternatives to, the procedure or treatment have been discussed with the health practitioner.
- The written consent statement will become part of the patient's medical record.

All existing laws regarding surrogate decision-making will apply. For purposes of this section, "surrogate decision-making" means any decision made in the practice of medicine by a parent or legal representative of a minor or adult lacking decision-making capacity. The failure of a healthcare practitioner to comply with informed consent requirements for use of telemedicine technology is considered unprofessional conduct.

Telemedicine informed consent requirements would *not* apply under the following circumstances:

- When the patient is not directly involved in the telemedicine interaction; for example, when one healthcare practitioner consults with another healthcare practitioner
- In an emergency situation in which a patient is unable to give informed consent and the representative of that patient is not available in a timely manner
- A patient who is under the jurisdiction of the Department of Corrections or any other correctional facility

A sample telemedicine informed consent form can be obtained from the California Medical Association (CMA) at www.cmanet.org. NORCAL policyholders can contact the Risk Management Department at (800) 652-1051, ext. 2244.

NORCAL's *Communication & Follow-Up* CME course contains information about liability exposures associated with the Internet and websites.

Key Points – Section Seven

- ✓ Some states have specific statutory requirements for obtaining informed consent. Examples include informed consent for the following:
 - Blood transfusions
 - Breast cancer treatment
 - Prostate cancer treatment
 - Hysterectomies
 - Sterilization
 - HIV testing
 - Abortion
 - Telemedicine
- ✓ Requirements for statutorily imposed informed consent will likely address, at minimum:
 - The physician's obligation to inform the patient of the risks, benefits and complications of a test, treatment or procedure
 - Whether the consent is verbal, written or both
 - Whether the physician must use standardized written summaries to convey information to the patient
 - The need for documentation in the medical record
 - Applicable time frames from the date consent is obtained to the date of the procedure
 - Confidentiality provisions

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Informed Consent

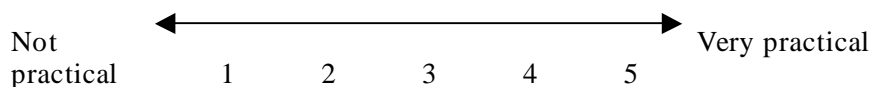
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Educational Outcomes

Informed consent is an essential part of the physician-patient relationship. While it may not always be possible for physicians to meet all patient expectations, they must comply with certain requirements regarding a patient's participation in his or her own medical treatment, according to both good medical practice and the law. As treatment options have become more technical, the consequences of various treatment choices have become more difficult for a layperson to understand. Therefore, it is part of the physician's duty to help the patient understand the options so that the patient can make the choice appropriate for him or herself. Physicians' inconsistency in obtaining informed consent and informed refusal has surfaced as an important issue in malpractice allegations. This course addresses the gaps in physician competence and performance related to the informed consent process in order to reduce malpractice claims and improve patient care.

1. Overall, degree to which the material presented is applicable in your practice setting:



2. Application of Risk Management Strategies

After participating in this CME activity and with the understanding that this course material is designed to affect your ability to deliver and execute safe care practices, review and select the risk management strategies you plan to implement in your practice:

Educational Objectives	YES	NO
Consistently apply the four elements of proper consent (e.g., discussion, education, documentation and form).		
Utilize plain language in oral and written communication to facilitate consent with patients whose health literacy is limited.		
Differentiate needs and circumstances of patients and adapt the consent process based on patient legal status (as in the case of minors), severity of treatment, and capacity of consent giver.		

3. Other Strategies to Minimize Risk

Informed consent is a process, not a form. This process incorporates educating the patient through discussion, documenting the discussion in the medical record and using a form to record the discussion. There are additional resources available to you to guide you through the informed consent process. The resource documents include risk management recommendations to mitigate your medical professional liability risks associated with informed consent and include additional reference material such as sample policies and procedures and refusal of treatment forms. **Would you be interested in the additional informed consent resources available?**

YES

NO

Commercial Support and Disclosure

	True	False	Comments
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