RISK MANAGEMENT RESOURCES

SAMPLE FORM

Refusal of Treatment Form

Patient _____

Date _____ Time_____ Place_____

I understand that Doctor _____ recommends I undergo the following test, treatment, operation or procedure:

_____
_____
_____
_____
_____
_____

The risks and benefits of (as well as alternatives to) this recommendation, and the reasons for the recommendation, have been explained to me (or I have refused to have them explained to me).

I refuse the recommended test, treatment, operation or procedure even though my failure to follow the advice I have received may seriously impair my health and my doctor's ability to determine the nature of my condition and treat me.

Specific, significant and likely risks of refusing my doctor's recommendation include:

_____
_____
_____
_____
_____
_____

I assume the risks and consequences involved in my refusal.

_____
Patient's Signature

_____
Physician's Signature

Revised: December 08

RISK MANAGEMENT

RESOURCES

Informed Consent: California

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*:

- 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.

Healthcare providers should also be aware that certain procedures (such as sterilization and HIV testing) and certain groups of patients (such as minors or patients participating in medical trials) require specific informed consent information and documents. For detailed discussion regarding informed consent, please see the California Medical Association (CMA) On-Call Document #0415: "Informed Consent."

Additionally, the Centers for Medicare and Medicaid Services (CMS) issued interpretative guidelines as part of the conditions for participation in the Medicare/Medicaid programs. 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.*

Medical Professional Liability Risks

- 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:
    1. An examination or treatment for which there was *no* express or implied consent.
    2. 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 would allege that the physician failed to disclose information that the patient should have had in order to make an informed decision about the treatment.

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**
   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.

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 about certain medical realities.

3. **Documentation**
   Documenting the informed consent discussion is crucial to reducing risk and minimizing liability.

4. **The Consent Form**
   The use of an informed consent form should supplement or enhance the discussion between the physician and patient. Most attorneys do not consider a witness necessary; however, some physicians prefer to have a witness's signature.

Barriers to the Informed Consent Process

A patient's limited health literacy skills, fear, sensory issues, level of intimidation, modesty, optimism regarding a specific outcome, or inability to truly accept the risks of the procedure are all issues that can diminish the patient's ability to comprehend the consent process.

In May 2003, the National Quality Forum (NQF) published "Safe Practices for Better Healthcare." These practices, when used universally, are designed to reduce the risk of unfavorable outcomes in healthcare. "Safe Practice 10" requires the provider to "ask each patient or legal surrogate to recount what he or she has been told during the informed consent discussion." (This strategy is frequently referred to as the "teach back" method.). For a detailed discussion regarding informed consent for inpatient procedures, please see "Informed Consent Guide" on the National Quality Forum website. Available at:
http://www.qualityforum.org/publications/reports/informed_consent.asp

Informed Refusal

Of note, along with the right of patients to be fully informed of risks, benefits and alternatives before consenting to a treatment or procedure, patients with decision-making capacity also have the right to refuse treatment. Physicians have the corresponding duty to inform patients of the risks and benefits of, as well as the alternatives to, foregoing treatment. The CMA notes that the physician's duty is broader than the informed consent requirement, as it applies to all medical tests and procedures. The patient's refusal should be documented in the medical record, and the patient should be asked to sign a refusal of treatment form (see NORCAL's sample "Refusal of Treatment Form"). An adult does not, however, have the right to deny life-sustaining treatment to his or her child. For a more detailed discussion of informed refusal, please see CMA On-Call Document #0415: *Informed Consent*.

Content of the Consent Form

Develop consent forms for procedures that require informed consent. The consent form should include the same elements as the consent discussion and should be written in language that the patient can understand. The elements on the form include the following:

- 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:
  - Complications (e.g., bleeding, possibility of additional procedures)
  - Severity (e.g., death, paralysis and loss of function)
  - Incidence of risks (e.g., 1 in 1000 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
- A statement that there are no guarantees that the procedure will be 100% successful
- Information about potential outcomes if treatment is refused
- Encouragement of the patient to ask questions
- Acknowledgment that the patient can withdraw consent
- The offer of a second opinion

Informed Consent Exceptions

There are four exceptions to informed consent standards:

1. **Emergency situations.** In an emergency situation, if the patient does not have the cognitive capacity to make decisions and there is no legally designated decision maker or representative, and all reasonable efforts were made to contact the legal representative, then a patient will be presumed to have consented to necessary medical treatment. The emergency exception does not apply if the patient has already refused similar treatments in the past in writing (i.e., through an Advanced Directive, Durable Power of Attorney and a Declaration under the Natural Death Act).

2. **The patient requests not to be informed.**

3. **Therapeutic privilege.** A very rare exception that arises when a physician **can prove** that "the disclosure would so seriously upset the patient that the patient would not have been able dispassionately to weigh the risks of refusing to undergo the recommended treatment." (*Cobbs v. Grant* 8 Cal. 3d 229, 104 Cal. Rptr. 505 (1972)).

4. **The testing of blood or patient samples to determine exposure to HIV or other communicable diseases.**

For a detailed discussion regarding informed consent exceptions, please see the California Medical Association (CMA) On-Call Document #0417: "Informed Consent Exceptions: Emergencies, Therapeutic Privilege and Patient Requests not to be Informed."

Risk Management Recommendations

- Be aware that a patient's informed consent is necessary when a reasonable patient could or would not be aware of the consequences of a given treatment or procedure without first obtaining specific information about that treatment or procedure.
- Recognize that **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.**
- Develop a policy and procedure for the informed consent process that ensures that patients' rights are honored (see accompanying "Informed Consent: Sample Policy and Procedure"). The process should focus on the four key elements: 1) informed consent discussion; 2) education; 3) documentation; and 4) consent form.

1. Discussion

- Recognize that 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.
- Recognize that the office setting is the best place for the discussion to occur, and that the physician must 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

2. Education

- Utilize educational pamphlets, written handouts, and preoperative and postoperative instructions to help patients make informed decisions and remember possible complications involved in procedures. Document in the

patient's record that the patient received these materials, as educational materials provided could be called into question at a later date.

3. **Documentation**
   - Document the informed consent discussion in the medical record. 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 (A patient's refusal of any treatment should be documented in the medical record, and the patient should be asked to sign a refusal of treatment form; see NORCAL's sample "Refusal of Treatment" form.)
     - A notation regarding what items specific to that patient were discussed and any items that received special emphasis
     - A notation or copy of any written material given to the patient
     - The signed and dated consent form, if applicable
     - The originals of educational handouts or information sheets given to the patient
     - Notation that the patient received any videotape, visual aids, etc.
     - Notation of the patient's language if not English, and the name and relationship of the translator.

4. **The Consent Form**
   - Develop consent forms for procedures that require informed consent.
   - Never replace the informed consent discussion with the consent form, which is simply a **record** of the discussion.
   - Do not delegate obtaining the patient's signature on an informed consent form to a staff assistant.
   - Give the patient a copy of the signed and dated consent form, and keep one copy in the chart.

Additional Resources

- NORCAL Mutual Insurance Company. Informed consent. [Continuing medical education (CME) course.] Available at: www.norcalmutual.com/cme or (800) 652-1051, ext. 2244.
- California Medical Association (CMA) Legal Counsel. CMA On-Call Document #0415: Informed consent. 2009. Available at: www.cmanet.org.
- California Medical Association (CMA) Legal Counsel. CMA On-Call Document #0420: Format for informed consent forms. 2009. Available at: www.cmanet.org.
- California Medical Association (CMA) Legal Counsel. CMA On-Call Document #0430: Informed consent: inpatient procedures. 2009. Available at: www.cmanet.org.
- California Medical Association (CMA) Legal Counsel. CMA On-Call Document #0417: Informed consent exceptions: emergencies, therapeutic privilege and patient requests not to be informed. 2009. Available at: www.cmanet.org.

RISK MANAGEMENT
RESOURCES

- NORCAL Mutual Insurance Company. When a patient refuses medical treatment. Claims Rx. February 2006. Available at: (800) 652-1051, ext. 2244.
- NORCAL Mutual Insurance Company. Health literacy: a prescription to reduce claims. Claims Rx. July 2006. Available at: (800) 652-1051, ext. 2244.
- NORCAL Mutual Insurance Company. Informed consent update. Claims Rx. March 2007. Available at: (800) 652-1051, ext. 2244.
- National Quality Forum (NQF). Informed consent guide. Available at: http://www.qualityforum.org/publications/reports/informed_consent.asp.

NORCAL Mutual Insurance Company

CLAIMS Rx

February 2006

When a Patient Refuses Medical Treatment
The Risk Management Perspective

A 50-year-old male patient presented to his internist with complaints of chest pain and reflux symptoms. The patient was treated with antacids and his symptoms improved. On examination, the patient's stool was positive for occult blood. The internist recommended follow-up hemoccults as well as additional studies to rule out polyps or colon cancer, but the patient initially refused. The patient finally did hemoccult tests 14 months later, which were negative, and he subsequently presented to the internist on two additional occasions for routine physical examinations and some ankle problems, which were unremarkable. Two and one-half years after the initial visit, the patient came in for an office visit complaining of feeling run down and fatigued. A complete workup was done at this time, which showed elevated calcium levels and liver enzymes. The patient was further evaluated and diagnosed with carcinoma of the sigmoid colon with metastasis to the liver. He underwent a resection of his sigmoid colon and liver metastasis and received chemotherapy, but died within a year of diagnosis. The family of the patient brought suit against the internist, alleging failure to diagnose colon cancer, resulting in metastasis to the liver and death.

At deposition, the internist stated that he was more concerned about the patient's chest pain than his GI symptoms. The internist's impression at the time of the initial visit was that the blood in stool was most likely due to superficial esophageal irritation from acid reflux. Although the records did not indicate that the internist recommended a barium enema or sigmoidoscopy, he was quite confident that he had numerous conversations with the patient about the importance of such studies, as it was his normal practice to do so in a patient of this age with positive occult blood in the stool. According to the internist, the patient repeatedly refused to undergo additional evaluation.

While experts made a strong argument that the internist in this case met the standard of care in his evaluation and treatment of the patient, his poor record keeping and mishandling of the patient's refusal made this case a difficult one. A jury ultimately decided that the internist was not negligent, but not until a great deal of money and effort were spent in his defense.

This *Claims Rx* examines patient refusal of treatment vis-à-vis the informed consent obligation. Communication, documentation and follow-up practices are reviewed from a risk management perspective.

Consent, Refusal 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 medical treatment or procedure, even if, from the point of view of the medical provider, that decision may not be in the patient's best interest.

The concept of informed consent to medical treatment is based on the following premises, 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.

(continued on page 2...)

- 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.

An informed-consent-based negligence claim by a patient would include allegations that the physician failed to disclose information that the patient should have had in order to make an informed decision about the treatment.

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 that:

> "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."[2]

Thus, informed refusal is an integral part of patient consent and patients' rights. The doctrine of informed refusal also instills in the patient the right to be informed of what is likely to happen if the patient declines treatment or does not follow up for additional treatment or diagnostic tests. Informed refusal rights apply equally to all tests and procedures that the physician believes are medically indicated, including a physician's recommendation that patient see a specialist. In that case, the patient would have a right to know the consequences that could occur if the patient does not obtain consultation with a specialist.

Consequently, a prudent physician will strive to ensure that a patient who refuses treatment understands the seriousness of his or her condition and, if appropriate, that the risks associated with the refusal may include death. Patient refusal of medical treatment or procedures, if not properly managed, could result in a negligence claim against the physician or physicians involved in the patient's care (e.g., the failure to diagnose colon cancer case presented at the beginning of this article).

Communicating the Risks of Foregoing Treatment

Physician-patient communication is at the heart of informed medical decision-making. It has been noted in many publications that patient consent should be thought of as a *process*, not merely a form. When a patient refuses medical treatment or procedures (including recommendation to see a specialist), physicians are encouraged to examine whether any breach in communication has taken place between themselves and the patient, and to take steps to ameliorate that communication breakdown.

Of course, patient refusal is not always a result of a communication problem, nor does it always reflect negligence on the part of the physician. Regardless, the failure to inform can result in significant patient harm as well as a serious liability exposure. It is thus worthwhile to investigate the physician-patient interaction for any gaps in communication.

A review of the four key elements of informed consent can help guide physicians as they approach patient refusal of treatment:

- **Discussion.** Discussion is the most important aspect of informed refusal, and is the cornerstone of this process (as opposed to the signing of any particular consent or refusal form). A face-to-face discussion with the patient allows the physician to observe body language and tone of voice, as well as listen to the patient's remarks. It can be helpful to elicit the reason the patient is refusing to undergo a specific treatment or procedure, and to empathize with patient fears. Verbally acknowledging the patient's right to make his or her own medical decisions, while at the same time educating the patient on any misinformation he or she may have, can help build rapport and increase compliance in patients who are "on the fence."
- **Education.** The physician bears the burden of helping patients to comprehend the risks and benefits of a proposed course of treatment

(continued on page 3...)

or procedure, and the full range of possible consequences if the patient does not adhere to the recommendations. Educational pamphlets and written handouts can help the patient make an informed decision, but do not replace direct physician-patient education that addresses specific patient concerns and apprehensions, especially when a patient is refusing care.

- **Documentation.** Documenting refusal (and noncompliance) is critical. This documentation is the physician's most effective proof that the refusal was an *informed* refusal. Thorough documentation in the patient's medical record includes the following points:
  - ✓ A notation about the 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.
  - ✓ A notation that the patient was advised of the risks and consequences (including loss of life or limb) of failing to undergo the treatment or see a specialist.
  - ✓ A notation about the patient's refusal of treatment plan or advice and/or the patient's signature on a refusal of treatment form. Use of the form is optional but helpful.
  - ✓ A notation about the physician's referral of the 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).
  - ✓ Notations about any attempts to contact the patient after referral to a specialist (if applicable).
- **Refusal of Treatment Form.** The refusal of treatment form is a *record* of the discussion and does not *replace* the discussion. A refusal of treatment form is helpful to ensure that none of the disclosure items is inadvertently missed. The use of a refusal of treatment form supplements the conversation between physician and patient, thus, obtaining the patient's signature is the duty of the physician, not the staff assistant. The laws do not require, and most attorneys do not consider a

(continued on page 4...)

Withdrawal of Consent

Patients may withdraw 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. Informed consent is a process that continues through the patient's treatment. In order to ensure that the patient is not coerced into proceeding against his or her will, the physician may need to reassess the originally discussed risks and benefits of treatment or refusal of treatment. For example, 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[1] shows 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. 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. ■

Notes

1 West JC. Case law update [Schreiber v. Physicians Insurance Company of Wisconsin, 588 N.W. 2d 26 (Wis. 1999). Journal of Healthcare Risk Management 1999:19(3):69.

witness necessary; however, some physicians prefer to have a witness signature.

Providing a patient with a copy of the signed and dated consent or refusal form allows for the patient to review the risks and benefits of the treatment or refusal on his or her own time and in the company of family. Additionally, should the informed consent process come under question, the fact that the patient was given a copy will tend to weaken a lack of informed consent allegation. Keeping the original in the chart provides further proof that the patient was informed.

Proper Follow-Up Minimizes Professional Liability Risk

Patient refusal of treatment is not always as straightforward as an individual sitting in a medical office declining to undergo a recommended test or procedure. At times, refusal might be *implied* by a patient's noncompliance with a recommendation or referral, or his or her failure to show up for office visits. As a preparation for this scenario, in addition to implementing the four elements of informed consent, it is useful to scrutinize follow-up systems and take steps to ensure that patients such as these do not slip through the cracks.

When a patient fails to keep a scheduled appointment or leaves the office without being seen, a review of the patient's record will provide the physician with clinical findings documented in the medical record that will indicate the urgency with which the patient needs to be seen. If the matter is not urgent, a staff member's call to the patient to reschedule the appointment can be enough to get the patient back on track. If, on the other hand, the matter is urgent, the physician will want to make the call to insure that the patient understands the risks associated with his or her behavior.

Documenting calls in the record validates the practice's attempts to reach the patient and have him or her return for necessary follow-up. If a practice employee or the physician is unable to contact the patient by phone, sending a reminder by certified mail will serve a similar purpose. Chart stamps indicating missed appointments can supplement medical record documentation regarding the missed appointment and the physician's attempt to contact the patient. Keep in mind, however, that the appearance of chart stamps alone in the record does not constitute complete documentation.

Keep in mind that failing to follow up can result in making a claim much more difficult to defend, despite evidence of patient noncompliance with recommendations.

The Role of Policies and Procedures

Policies and procedures exist to augment patient care and streamline practice operations. Policies and procedures can also help or hinder the defense of a medical malpractice claim. Informed consent (including informed refusal) and patient follow-up (e.g., patient scheduling and telephone contact documentation) have been identified by NORCAL as high-priority areas for policy and procedure development.[3]

Physicians are encouraged to develop a policy and procedure for the informed consent process that ensures that patients' rights are honored. A process that focuses on the four key elements of informed consent—1) discussion; 2) education; 3) documentation; and 4) form—is most effective. As an aspect of informed consent, patient refusal of treatment would be specifically addressed in this policy and procedure.

In keeping with the goal of ensuring that patients should be well informed regarding their treatments, physicians are encouraged to develop policies and procedures to address several key components of patient follow-up, including management and documentation of missed appointments, telephone contact and other aspects of patient compliance or noncompliance.

CONCLUSION

A patient's right to refuse medical care and treatment is protected by law. While improper handling of patient refusal is unlikely to give rise to a claim by itself, consent and refusal issues can

(continued on page 5...)

complicate the defense of malpractice allegations when they do arise. The informed refusal obligation requires physicians to take a great deal of responsibility in communicating with patients about the need for specific treatment or tests, the risks involved, and the consequences of noncompliance. Proving that this communication has taken place, and that a patient's refusal is an "informed" one, hinges greatly on proper follow-up and documentation practices. Policy and procedure development can assist with establishing solid follow-up and documentation systems, but physician diligence and commitment to good record keeping is requisite for such systems to work. ☰

Notes

1 Cobbs v Grant 8 Cal. 3d 229, 104 Cal. Rptr. 505 (172)

2 Truman v. Thomas 611 P. 2d 902, 27 Cal. 3d 285 (1980).

3 NORCAL Mutual Insurance Company. *Claims Rx*. Key areas for policy and procedure development. San Francisco (CA): NORCAL, October 2004.

Refusal of Treatment Form

Patient_____ Date_____ Time_____ Place_____

I understand that Doctor _____ recommends I undergo the following test, treatment, operation or procedure:

_____

_____

_____

The risks and benefits of (as well as alternatives to) this recommendation, and the reasons for the recommendation, have been explained to me (or I have refused to have them explained to me). I refuse the recommended test, treatment, operation or procedure even though my failure to follow the advice I have received may seriously impair my health and my doctor's ability to determine the nature of my condition and treat me.

Specific, significant and likely risks of refusing my doctor's recommendation include:

_____

_____

_____

I assume the risks and consequences involved in my refusal.

_____ _____

Patient's signature *Doctor's signature*

This form is intended solely for the use of NORCAL policyholders. Keep in mind that this form is intended as a sample only and should be customized to the individual practice.

This form does not constitute legal advice, but is intended to supplement risk management advice provided in our CME courses. In addition, you may want to have this form reviewed by your Forms Committee or legal counsel to determine if it is appropriate for use in your practice or institution. Legal inquiries about the topic(s) addressed in this form should be directed to your attorney.

6/7/2004

NORCAL *Claims Rx* Editorial Board

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