Dear Colleague:

Patients have a right to accept or refuse the medical treatment that you propose. The following article looks at the issues that arise when patients refuse treatment and focuses on the "informed" part of informed refusal.

This newsletter also contains an update on the HIPAA regulations (see Fall/Winter 2001 Doctors RX) which you should find useful as you work your way towards compliance.

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Chair of the Board
MEDICAL MUTUAL Liability Insurance Society of Maryland

INFORMED REFUSAL

The refusal of consent to treatment is an area of medicine and the law which raises a host of legal, ethical and moral issues. The following case study illustrates just one of these issues but is representative of the broader picture of patient refusal.

Case Summary: A 57-year-old female was seriously injured in a car accident and taken to the hospital unconscious. A nurse discovered in the woman’s handbag a card signed by the woman identifying her as a Jehovah’s Witness and requesting that no blood transfusions be given to her under any circumstances; that she fully realized the implications of that position, but did not object to the use of non-blood alternatives. The treating physician was informed about the contents of the card, but ordered the administration of blood transfusions to the woman based on his belief that they were necessary to replace her lost blood and preserve her life and health.

The woman made "a very good recovery from her injuries." She was discharged from the hospital after six weeks and sued the treating physician for negligence and assault and battery. The trial judge dismissed all but the battery charge, concluding that the card validly restricted the physician’s right to give the patient blood transfusions and that there was no rational basis for ignoring that restriction. He awarded her $20,000 in damages. The Court of Appeals affirmed the judge’s decision.

In this new era of patient rights legislation, patients and their families are taking greater control over the course of their care. Additionally, with the broad accessibility of the Internet, patients and their families have a great deal of information at their disposal and are increasingly well educated about their rights.

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Few issues relating to the care and treatment of patients can be as difficult to manage as when patients or families refuse treatment because of religious beliefs, which, to the physician, seem unrelated to actual medical circumstances. Consequently, health care providers are being held to their responsibilities to heed patients’ wishes regarding, among other things, the refusal of treatment, especially when that refusal is based on a religious belief. Along with that responsibility, physicians must still ensure that the refusal is an informed one and that this refusal is documented in the record. Merely assuming that a patient knows the consequences of his/her decision is not enough.

Such cases raise ethical as well as legal issues and create dilemmas for health care providers. When a competent adult refuses treatment on religious grounds, the courts cannot be dictated by its view of what would be in the best interests of the patient, but rather must look to the validity of the refusal based in terms of the capacity of the patient to make that determination. In the same way, physicians cannot substitute their decision for the validly made decision of the patient. Therefore, in the case mentioned above, the trial court held that there was no rational basis (in the form of contradictory evidence) for the physician to doubt that the card was anything but a true expression of the patient’s wishes.

A patient’s decision-making capacity is commonly referred to as “competency.” It is not necessarily cut and dry. Patients may have the capacity to make some decisions, but not others.

The components of competency are as follows:

• The ability to understand the options
• The ability to understand the consequences of choosing each of the options
• The ability to comprehend the risks and benefits of each of the consequences

If a patient is deemed “incompetent,” family members, court-appointed guardians or others (as determined by state law) may act as “surrogate” decision-makers and make decisions for the patient.

Just because a patient is deemed competent does not mean that he/she will always make “good” decisions, or decisions that the physician agrees with. Likewise, making a “bad” decision does not mean that the patient is incompetent.

Competency simply means that the patient can understand and explain the options, their consequences and give a rational reason as to why they chose a particular option.

Where treatment involves an incompetent patient, it may not always be clear what the patient’s wishes are. Family members may not know or may offer conflicting accounts of what they think the patient wants. These types of situations need to be looked at more carefully. The physician or hospital staff should check for evidence of the patient’s wishes, such as an advanced directive or, in the case of a Jehovah’s Witness, a wallet card.

Competent patients who refuse medical treatment because it conflicts with their religious beliefs pose difficult issues for physicians. Despite the not unrealistic fears as to whether or not the patient had changed their religious beliefs before the incident occurred, the Courts have tended to favor the patient’s right to refuse in the absence of evidence to the contrary. In light of these rulings, physicians must respect the patient’s right to refuse, regardless of whether the physicians agree with the religious reasons or not. Regardless of whether you agree with the patient’s religious reasons for refusal of certain treatments, you must respect their right to make an informed choice of treatment alternative. What is the general rule if a patient refuses the treatment you have determined is necessary?

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• The ability to understand the consequences of choosing each of the options
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Because a competent adult can legally refuse treatment, this kind of documentation is critical. Good documentation is the most valuable tool in preventing and minimizing liability exposure. We offer the following risk management suggestions for your consideration:

• It is the physician’s duty and responsibility to obtain consent personally; it is not to be delegated to non-physicians.
• Accept the patient’s right to refuse the treatment you have proposed.
• Do not try to force the patient to consent.
• Document the patient’s refusal in the medical record.
• Have the patient sign an informed refusal form or your method for handling informed consent and informed refusal and can lessen your exposure to the risks associated with the process.

HIPAA UPDATE

The Department of Health & Human Services recently published changes to the current HIPAA privacy regulations in a notice of proposed rulemaking (NPRM). The Department’s reason for the NPRM was to address problems in the privacy regulations that could have hindered patient access to quality health care.

Some important changes:

• “Health care providers with direct treatment relationships with individuals would no longer be required to obtain an individual’s consent prior to using and disclosing information about him or her for treatment, payment and health care operations.”

A provider may still obtain consent for treatment, payment and health care operations, but would not be required to do so.

Providers would still have to provide patients with a notice of privacy practices and would still have to make a good faith effort to get a patient’s written acknowledgement that the patient got the privacy notice. If the provider doesn’t get this acknowledgement, it would have to document its efforts and the reason acknowledgement was not obtained.

• The NPRM made no major changes to the business associate requirement, however the date for compliance would be affected. The changes would allow a health care organization to continue to operate under its existing contracts with its business associates for up to one year past the April 14, 2003 compliance date. So, you would not need to amend your contracts with your business associates to comply with the HIPAA requirements until whichever of the following dates comes first: 1) the date the contract is renewed or modified after April 14, 2003, or 2) April 14, 2004.

The NPRM also includes an appendix with model provisions that you can incorporate into your business associate contracts.

The NPRM was published on March 27, 2002 and is open to a 30-day comment period which ends on April 26, 2002. The Department will then consider the public comments and publish the final version that may include additional changes in the Federal Register.

To review these and all other changes to the privacy regulations, see www.hhs.gov/ocr/hipaa.

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Compliance Deadline Extended for National Standards for Health Care Transactions and Code Sets

The Department of Health & Human Services, through its Centers for Medicare and Medicaid Services also established national standards for electronic health care transactions and code sets. October 16, 2002 was the original deadline for covered entities to be in compliance. However, in December 2001, the Administrative Simplification Compliance Act (ASA) extended the deadline for compliance one year – to October 16, 2003 – for all covered entities other than small health plans.

In order to qualify for this extension, covered entities must submit a compliance plan on or before October 15, 2002. Completion and timely submission of this model compliance plan will satisfy the federal requirement.

Completing this model compliance plan takes about 15-20 minutes. Simply answer a few questions about compliance concerns you may have and let CMS know where you are in the implementation process. This can be done on-line or by using a paper form. For those filing electronically, your electronic confirmation number will serve as your only approval notice.

If you are a covered entity and do not submit a compliance plan, you must be compliant with the HIPAA Electronic Health Care Transactions and Code Set Standards by October 16, 2002. The Extension Form/Model Compliance Form can be accessed by visiting the CMS HIPAA website at: http://cms.hhs.gov/hipaa/hipaa2/TCSForminstructions.asp
**Part I. Educational Value:**

I learned something new that was important.  
I verified some important information.  
I plan to seek more information on this topic.  
This information is likely to have an impact on my practice.

**Part 2. Commitment to Change:**

What change(s) (if any) do you plan to make in your practice as a result of reading this newsletter?

**Part 3. Statement of Completion:**

I attest to having completed the CME activity.

Signature: ___________________________ Date: ___________________________

**Part 4. Identifying Information:**

Please PRINT legibly or type the following:

Name: ___________________________ Telephone Number: ___________________________

Address: ___________________________