Special Report

MIEC Claims Alert

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California version

Disclosure of unanticipated outcomes

July 2001, the Joint Commission for Accreditation of Healthcare Organizations (JCAHO) Patient Safety Standards went into effect. One of these standards has caused concern among physicians. It says

> "Patients, and when appropriate, their families are informed about the outcomes of care, including unanticipated outcomes." [*Standard RI.1.2.2*]

Physicians, hospital administrators, medical staff officers, and others have expressed apprehension about the Standard, but its intent is not significantly different from the advice MIEC has been giving policyholders for over twenty-five years.

Intent of Standard R1.1.2.2: "The responsible licensed independent practitioner or his or her designee clearly explains the outcome of any treatments or procedures to the patient, and when appropriate, the family, whenever those outcomes differ significantly from the anticipated outcomes."

The Standard conforms to the philosophy that patients have a right to their health care information, including the results of diagnostic tests, medical treatment, and surgical or procedural intervention.

The American Society for Healthcare Risk Management (ASHRM), defines an unanticipated outcome as "a result that differs significantly from what was anticipated to be the result of a treatment or procedure." The Joint Commission does not define the phrase, but medical-legal experts have linked it to reviewable or sentinel events, or to outcomes significant to a patient's well-being. Contrary to physicians' fears, it is possible to comply with the JCAHO standard without admitting guilt or inevitably increasing one's liability risks.

Is Standard RI. 1.2.2 a law?

No. It is a Joint Commission standard.

A policy is required

The JCAHO requires that hospitals develop a policy regarding the disclosure of unanticipated outcomes. A written policy is not required, but the Joint Commission will evaluate hospitals on the degree to which appropriate staff uniformly understand and implement the stated policy. Physicians should participate in the development of hospital policy to make it reasonable, workable, understandable, protective, and

respectful of all involved. Physicians who influence hospital policy should consider the following questions when participating in the formulation of a policy:

What events will be disclosed?
Each facility must determine what types of events must be disclosed, but medical-legal experts encourage policymakers to draft broad policy rather than to define each and every potentially disclosable event. The Standard requires that unanticipated outcomes are to be disclosed, not medical errors, per se. While some unanticipated outcomes are the result of medical error, not all medical errors result in an unanticipated outcome and therefore needn't be reported to patients or family members.

When should disclosure take place?
Most authorities believe that disclosure of unanticipated outcomes should take place as soon as reasonably possible. Avoiding a necessary disclosure could prompt a patient or family members to conclude that the physician lacks concern, or worse, is attempting to conceal or deny the event. In some instances, a physician may wish to first seek advice from a risk manager, malpractice carrier, or an attorney. It's always a good idea for the physician to think through what to disclose and how he/she wants to convey the information before meeting with the patient or family; and in that circumstance a slight delay is understandable. However, discussion of an unanticipated outcome must occur without much delay.

Who will conduct the disclosure discussion?
JCAHO suggests that disclosure be the responsibility of the treating physician. Depending on the circumstances, the physician may want other supportive and appropriate participants such as the risk manager, a nurse with whom the patient and/or family has a rapport, a member of the clergy, a social worker, or others to participate in the initial discussion.

Who must develop a compliance policy?

It is a hospital's responsibility to develop the policy.

What should we say and how do we say it?
Physicians and other staff who are likely to participate in disclosure discussions should be trained about what to say and the most **effective** way to say it. Physicians must clearly understand the difference between sympathetic disclosure and admission of liability. When disclosing outcomes to patients, the physician should objectively articulate what occurred, based on facts known at that time – without conjecture, innuendo, speculation, or blame. Prior to speaking with patients and/or their families about unanticipated outcomes, physicians should also consider the patient's culture, disability (if any), cognitive skills, language, race, religion, and other factors that might influence the style and content of the discussion. Wise physicians will seek assistance.

Communication experts in a hospital training program can teach physicians and staff to convey "bad news" in effective ways without unnecessarily increasing liability risks. To increase the likelihood of a successful meeting, communication experts suggest planning what to say ahead of the actual meeting, and carefully choosing a private setting for the discussion.

As a follow-up to physician and staff training, hospitals may also wish to implement a program to provide emotional support to doctors and others who advise patients about unanticipated adverse outcomes, as the psychological toll varies with clinicians and specific events.

Should we offer assistance to the patient or family?
Not all unanticipated outcomes are adverse events, but it is for negative outcomes

that the JCAHO Standard exists. If an outcome negatively impacts a patient or family, it may be helpful to offer practical assistance (such as referrals to resources, follow-up medical care at hospital expense, etc.) in circumstances in which it is possible and advisable to do so.

Is a written policy required?

No, but the policy is to be understood and implemented by the medical staff.

What should we say about what is being done?
In most instances, an untoward event or unanticipated outcome will be subject to an internal review that involves time and several layers of investigation (such as equipment examination, interviews with staff, bioethics committee analysis, clinical review, systems review, etc.). In the interim, the patient and family should be informed of the follow-up processes related to the event, and assured that they will be informed of the ultimate result, including accountability and personal responsibility, if and when appropriate. (Example: "Based on the information we have today, this is what we believe may have happened, but as we investigate the situation, it is possible we will find that our initial assessment was inaccurate. We will keep you informed.") In some instances, patients should be informed of policy changes subsequent to the event that will protect future patients from a similar outcome.

Should we document discussions about unanticipated outcomes? Defense attorneys agree that accurate, objective documentation of events is almost always beneficial in the event of later conflict about the substance of the conversation. The key words to effective documentation are "accurate" and "objective."

Although the Joint Commission does not require a written policy about the disclosure of unanticipated outcomes, hospital administrators are encouraged to put their policy in writing for clarity and uniform staff access and compliance. Hospitals should have the final version reviewed by legal counsel before implementation.

Must all medical errors by disclosed?

No. The Standard applies only to unanticipated outcomes, not medical errors, per se.

When you must disclose an unanticipated outcome

Ultimately it is up to the physician to "do the right thing," and to do what good physicians have been doing for years. Those physicians focus on the patient's experience, instead of trying to withhold significant information for self-protection. Disclosure is not intended to be adversarial, but a part of the therapeutic process. The "right thing" begins the day the patient sets foot in the doctor's office and presents with a medical problem. Good communication and trust are the foundation of a successful doctor-patient relationship. Physicians who establish good rapport and solid communication with their patients from the beginning of the doctor-patient relationship realistically inform patients about the risks of a recommended treatment and lay the groundwork for future discussions, including those that may be difficult. Effective communication includes informed consent discussions before prescribing medication or performing an invasive procedure or surgery; quality care includes careful documentation of such discussions. (See MIEC's Loss Prevention Claims Alert No. 17 on informed consent.)

Attorney Joe Gharrity, of the Hassard Bonnington law firm in San Francisco, has this

to say about physicians' fear of liability:

> "Most cases that end up in medical malpractice litigation involve untoward or unexpected results. Ideally a physician has discussed risks, complications and the potential for less than desirable outcomes ahead of time, documenting the discussion. Many physicians have used analogies such as air travel in disclosing remote risks such as death or serious disability. A subtle reference to those prior discussions at the time the unanticipated outcome is discussed may remind the recipient that the misfortune was not incomprehensible, and the patient who has accepted the risk of death or serious disability may understand a lesser risk even if not previously mentioned. When the unexpected result was not the subject of prior discussion, an objective explanation of how the outcome occurred should be offered. Patients and/or their families who sense they are being addressed candidly and respectfully are less likely to become angry at a time when they otherwise are frustrated."

Doing the "right thing" in a discussion of unanticipated outcomes requires empathy and honesty, but does not necessarily require admitting guilt, finding fault or placing blame. Unexpected outcomes are not always the result of error or medical negligence. If it appears that a physician or hospital staff member may be held accountable and personally responsible for an error that led to patient injury, the physician should consult the risk manager or his/her malpractice carrier before proceeding with the disclosure discussion. MIEC policyholders who are concerned that an untoward event and subsequent honest discussions of the outcome will lead to litigation, should call MIEC's Claims Department for advice and support.

If I say I'm sorry, is that an admission of guilt?

Not necessarily, but you must be judicious in your expression of sympathy.

In California, Section 1160 was added to the Evidence Code in 2000. This statute protects a physician's expression of sympathy from being used in a civil action as an admission of liability. However, if a physician pointedly accepts liability, the confession of fault is admissible. (Examples: "I'm so sorry this happened," is not admissible, but "I'm so sorry that I injured you, or ... I severed your artery, or ... I prescribed the wrong medication," all might be admissible.) Physicians in other states are well-advised to follow California's example. MIEC's Claims staff is prepared to assist policyholders to comply with disclosure policies without unnecessarily increasing their liability.

Summary

JCAHO Standard RI.1.2.2 went into effect in July 2001. It mandates that patients be informed of unanticipated outcomes to their treatment. It underscores patients' rights to information about their medical health, and physicians' obligations to be honest and forthcoming about patient care and outcome. Consistent with the Joint Commission's other Patient Safety Standards, its primary concern is for patient well-being. If hospital policy and its implementation are properly accomplished, physicians needn't fear increased liability.

Policyholders are invited to call MIEC's **Claims Department** to discuss patient-specific situations in which the disclosure standard should be invoked. Call the **Loss Prevention Department** if you would like to discuss general aspects of the JCAHO Standard.

How to reach MIEC

REQUEST A PUBLICATION

Home Office Claims

Oakland, CA
510/428-9411 (Bay Area)
Outside 510: 800/227-4527
Fax: 510/654-4634

Hawaii Claims Office

Honolulu, HI
Phone: 808/545-7231
Fax: 808/531-5224

Idaho Claims Office

Boise, ID
Phone: 208/344-6378
Fax: 208/344-7192

Loss Prevention Department

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