# COMPLIANCE TODAY

Volume Nine
Number Twelve
December 2007
Published Monthly

## Earn CEU credit

SEE INSERT

Meet

## Michael R. Clarke Esq.

Vice President - Chief Ethics & Compliance Officer, University of Medicine & Dentistry of New Jersey

PAGE 14

## Mandatory rules for reporting medical errors, adverse events, near misses, and device failures

PAGE 4

Also:

## How to effectively negotiate a Certificate of Compliance with the Office of the Inspector General

PAGE 44

Feature Focus:

## Quality of care and corporate compliance– Perfect together!

PAGE 32

# Mandatory rules for reporting medical errors, adverse events, near misses, and device failures

**By Michael A. Morse, Esq.**

*Editor's note: Michael A. Morse is a former Philadelphia prosecutor and current shareholder at the Philadelphia law firm of Miller, Alfano & Raspanti, PC. Beginning January 1, 2008, Michael will become a partner in the new national health care and litigation firm of Pietragallo, Gordon, Alfano, Bosick & Raspanti, LLP. Michael concentrates his practice in the areas of health care compliance, white collar criminal defense, and whistleblower litigation. He may be reached by telephone at 215/972-6400 and by e-mail at mmorse@mar-law.com.*

News stories recounting errors that occur during surgical or other medical procedures are nothing new. Recent reports of the failures in outpatient care at the Walter Reed Army Medical Center are just one example. For decades, the conventional wisdom was that these medical errors were the result of isolated, individual failures by unqualified physicians or other health care professionals. The public and health care professionals alike did not conceive that these errors were symptomatic of larger, systemic problems in our nation's health care network.

In 1999, the conventional wisdom received a sudden and significant jolt when the National Academy of Sciences, Institute of Medicine (IOM) published the result of a landmark analysis entitled "To Err is Human: Building a Safer Health System." This report revealed that medical errors were a nationwide epidemic, affecting the treatment and outcomes of hundreds of thousands of patients. In particular, IOM, building on earlier studies performed by a number of states in the late 1990s, concluded that as many as 98,000 Americans died each year from medical errors, and that approximately 1 million experienced significant adverse events resulting in as much as $29 billion in annual financial costs.

IOM recommended a comprehensive set of measures to address the systemic problem of medical errors, including a nationwide mandatory reporting system for medical errors.[1] The goals of such a reporting system were to ensure a response to specific reports of serious injury, to hold organizations and providers accountable for guaranteeing patient safety, to respond to the public's right to be informed about unsafe conditions, and to provide incentives to health care organizations to implement internal safety systems that would reduce the errors that cause these events.

Far from a uniform nationwide reporting system, what emerged following the 1999 IOM report has been a patchwork of disjointed and divergent federal and state mandatory reporting statutes, regulations and regimes. A number of states also have voluntary reporting regimes and "apology" laws. In addition, in 2007, the Centers for Medicare and Medicaid Services (CMS) began its Physician Quality Reporting Initiative (PQRI), which provides financial incentives to physicians and other practitioners who voluntarily report 74 specified quality measures.

Hospitals and health care providers and the attorneys that counsel them, often have little or no idea that these mandatory reporting requirements exist, let alone have systems in place to ensure their compliance. As a result, medical errors continue to be significantly under reported. Such under reporting continues to hamper meaningful efforts to reduce the systemic causes of medical errors and exposes hospitals and health care providers to a growing compliance risk.

### Federal reporting requirements

In 2005, the United States Congress enacted the Patient Safety and Quality Improvement Act of 2005 (PSQIA), an attempt to establish some degree of nationwide uniformity in the reporting of medical errors and adverse events. PSQIA creates a database to which health care providers can voluntarily submit patient safety information, which is then analyzed to determine the causes of and, eventually, prevent medical errors. PSQIA contains a number of noteworthy provisions, such as those providing for confidentiality of adverse event reports and broad-ranging "whistleblower" protections. Although PSQIA was enacted in July 2005, it is still awaiting a number of regulations to be written by the Department of Health and Human Services (HHS) before it can properly take effect.

A number of highly specialized, mandatory, federal reporting regimes predate the PSQIA. These regimes are focused not on medical errors in general, but on regulating and monitoring specific aspects of health care services. The finely circumscribed nature of these regimes can make compliance difficult without a proper understanding of what these regimes regulate.

**Medical device reporting.**

Congressional regulations require that medical device "manufacturers"[2] and "device user facilities"[3] report deaths or serious injuries[4] that result from the use of medical devices.[5] Device user facilities are required to report these adverse events within 10 business days to the Food and Drug Administration (FDA) Center for Devices and Radiological Health and, if the manufacturer's identity is known, to the manufacturer as well. The manufacturer must, in turn, investigate the event and provide additional information to the FDA within 30 calendar days.[6] Because of the broad definition of "manufacturer" in this context, it is important for any device user, including hospitals and other medical facilities, to carefully determine whether it might also be deemed a device manufacturer for reporting purposes.

**Vaccine Adverse Event Reporting System.**

Manufacturers and health care providers are required to report any adverse events through the Vaccine Adverse Event Reporting System (VAERS) and the system also accepts reports from the public regarding adverse events associated with U.S.-licensed vaccines. VAERS is administered jointly by the FDA and the Centers for Disease Control (CDC), and both entities receive reports via VAERS. Sanctions for failure to report are generally limited to license revocation or similar disciplinary action.[7]

**Current good tissue practice regulations.**

Human cells and tissue, other than blood, intended to be transferred in any way into a human being are regulated by the FDA as a human cell, tissue, and cellular and tissue-based product (HCT/P). A HCT/P "establishment" (which recovers, processes, stores, labels, packages, manufactures, or distributes HCT/P) is required to investigate adverse reactions involving any communicable disease associated with HCT/P it distributed and to report any such reactions that are fatal, life-threatening, result in permanent impairment or harm, or require medical or surgical intervention.[8] Health care providers that do not qualify as HCT/P establishments are encouraged to voluntarily report adverse reactions to the FDA and to the HCT/P establishment from which the HCT/P was acquired.[9]

**Blood and blood product manufacturing errors.**

Manufacturers of blood and blood products[10] are required to report any event related to the manufacture (including testing, processing, packing, labeling, or storage) or the holding or distribution of blood or blood products which represents a deviation from good manufacturing practice or standards or represents an unexpected event that may affect the safety, purity, or potency of the product.[11] These reports must be made to the Center for Biologics Evaluation and Research (CBER), Office of Compliance and Biologics Quality (OCBQ) no more than 45 calendar days from the date of discovery of information that reasonably suggests a reportable event has occurred.

**Patient deaths related to restraint or seclusion.**

As part of the Medicare Conditions of Participation, CMS requires hospitals to report any patient death that occurs while the patient is restrained or in seclusion, within 24 hours after the patient has been removed from restraint or seclusion, or within one week after restraint or seclusion, where it is reasonable to assume that the patient's death resulted in part from restraint or seclusion.[12] "Reasonable to assume" includes, but is not limited to: deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing, or asphyxiation. The report to CMS is to be done via telephone by the close of business on the business day on which the hospital learned of the patient's death.

## State legislation requiring mandatory reporting

Most mandatory reporting obligations come from various state laws and regulations, as opposed to the narrowly tailored federal reporting regimes. Although a small number of states have had reporting requirements for some time, most have just recently adopted reporting requirements. As of July 2006, at least 33 states had some form of mandatory or voluntary requirement for reporting medical errors. At least 24 states had some type of mandatory reporting requirement and a number of states are currently considering adopting them. Moreover, given the increasing public attention paid to medical errors, the number of states with reporting requirements is likely to continue to grow.

These state reporting requirements have little uniformity, and they are subject to statutory and regulatory changes, as well as updates to interpretive guidelines, Web sites, and forms. In a number of key aspects, the state reporting requirements differ quite dramatically, including:

- the definition of an "adverse event,"
- what type of information needs to be reported,
- when the reporting must be made,
- the consequences, if any, for failing to report, and
- what the state does with the adverse event information it receives from health care facilities.

Although the differences in the state mandatory reporting statutes far outweigh the similarities, one common element is that nearly all provide some degree of confidentiality concerning adverse event reports. In general, these confidentiality provisions prevent adverse event reports from being used in subsequent civil lawsuits. A few states go even further by prohibiting the use of adverse event reports in criminal and administrative

*Continued on page 7*

proceedings. The scope and strength of these confidentiality measures should be carefully analyzed by all health care facilities that are subject to mandatory reporting rules.

**Definition of "Adverse Events".** One of the key ways in which state adverse event reporting statutes differ is in the definition of those events that must be reported. The state adverse event reporting statutes generally fall within three categories:
(1) States with specific lists of adverse events,
(2) States with broadly defined adverse events, and
(3) States with narrowly defined adverse events.

Understanding the precise adverse events that trigger a mandatory reporting obligation is a critical component of an effective compliance program for all hospitals and health care providers.

**1. States with specific lists of adverse events**
A number of states, currently require mandatory reporting of a specific list of adverse events, defined either in the reporting statute itself or in related regulations. For example, Connecticut, Illinois, and Minnesota generally require the reporting of a broad list of 27 "Serious Reportable Events," created by the National Quality Forum (NQF), which includes:

- Surgery on the wrong body part
- Surgery on the wrong patient or wrong surgical procedure performed
- Retained foreign object within a patient after a procedure
- Intraoperative or immediate post-operative death in an American Society of Anesthesiologists' (ASA) Class I patient (healthy, no medical problems)
- Patient death or serious disability caused by the use of contaminated drugs or devices provided by the facility
- Patient death or disability caused by misuse of a device
- Patient death or serious disability caused by an intravascular air embolism while cared for in a facility
- Infant discharged to the wrong person
- Patient death or disability associated with patient elopement
- Patient suicide or attempted suicide (resulting in serious disability)
- Patient death or serious disability caused by medication error
- Hemolytic reaction caused by an incompatible blood
- Maternal death or serious disability during a low-risk pregnancy
- Patient death or serious disability caused by hypoglycemia
- Death or serious disability caused by a failure to identify and treat hyperbilirubinemia in neonates
- Stage 3 or 4 pressure ulcers acquired after admission to the facility
- Patient death or serious disability due to spinal manipulative therapy
- Artificial insemination with the wrong donor sperm or egg
- Patient death or serious disability caused by electric shock while in the facility
- Incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances
- Patient death or serious disability caused by a burn incurred while in the facility's care
- Patient death or serious disability associated with a fall while in the facility
- Patient death or serious disability associated with the use of restraints or bedrails
- Any instance of care ordered or provided by someone impersonating a health care provider
- Abduction of a patient
- Sexual assault on a patient
- Death or significant injury of a patient or staff member resulting from a physical assault on the facility's property.

A number of other states have defined lists of specific adverse events that must be reported, although not identical to the NQF's list of Serious Reportable Events. These states include: Colorado, Florida, Georgia, Kansas, Maine, Massachusetts, New York, Rhode Island, South Carolina, South Dakota, Texas, Utah, and Washington. The lists of adverse events that must be reported in these states vary significantly from state to state.

**2. States with broadly defined adverse events**
A number of states, including California, New Jersey, Pennsylvania, and Tennessee, have more broadly worded, less precise rules as to what must be reported. In these states, the task for hospitals and health care providers is often more challenging, because they are forced to make their own judgment as to whether an event must be reported, as opposed to consulting a narrowly defined list of adverse events.

Pennsylvania, for example, requires that all licensed hospitals, ambulatory surgical facilities, birthing centers, and certain abortion facilities report what are defined as "serious events" and "incidents."[13] A "serious event" is defined as an event, occurrence, or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional health care services to the patient. An "incident" is defined as an event, occurrence, or situation involving the clinical care of a patient in a medical facility which *could* have injured the patient but did not either cause an unanticipated injury or require the delivery of additional health care services. By requiring the reporting of both adverse events and near misses, Pennsylvania's mandatory reporting statute is arguably one of the most expansive in the U.S. Hospitals and medical facilities subject to this expansive statute face the potential for far greater reporting obligations than those in states that follow a more narrowly defined list of reportable adverse events.

*Continued on page 8*

**3. States with narrowly defined adverse events**

The last group of states with mandatory reporting rules includes those that limit the reporting obligations to either a specific type of facility and/or adverse event. For example, Ohio requires freestanding Radiation Therapy Centers (RTCs) to identify, document, and report to the Ohio Department of Health, Bureau of Radiation Protection, incidents in which equipment malfunction contributed or may have contributed to patient injury or death.[14] In addition, Ohio RTCs are required to report all instances of treatment of the wrong subject, wrong treatment site, or wrong modality of treatment.

While such statutes are clearly more limited in scope, they nonetheless present unique compliance risks for those health care facilities that are required to follow these more narrowly defined reporting obligations. One obvious concern is that health care facilities may be unaware of their reporting obligations because the reporting statute is narrowly tailored and applies to relatively few facilities. Because these more narrowly tailored reporting statutes can often "fly under the radar," health care facilities must continue to pay attention to whether their state has adopted, or is even considering, any type of medical error reporting.

### Lack of uniformity in reporting requirements

Although the 1999 "Too Err is Human" report called for the standardized reporting of adverse events, efforts to achieve uniformity in the type of information that must be reported have, to date, been largely unsuccessful. Instead, the rules vary widely from state to state, often making it difficult for providers to know precisely what information they need to collect and report. Additionally, the lack of uniformity has hampered the ability to use adverse events reports to draw broad, definitive conclusions about the quality of health care in America, and to develop strategies to prevent future adverse medical events.[15]

Many of the states with mandatory reporting statutes require an immediate notification of the adverse event, followed later on by a more detailed root-cause analysis and corrective action plan. Maryland, for example, requires hospitals to report adverse events to the Maryland Department of Health and Mental Hygiene within five days of the hospital's knowledge of the event.[16] Hospitals also must conduct a root-cause analysis for certain events, and file an action plan with the Department within 60 days of the event.

A few states, by contrast, require that substantially less information be disclosed about adverse events. Texas, for example, requires hospitals to submit an annual report to the state listing the numbers of specific adverse events that have occurred.[17] Texas facilities are obligated to create a root-cause analysis and corrective action plan, but those reports need not be submitted to the state. Instead, the root-cause analysis documents must be maintained at the facility and must be made available to the state upon request.

These differences highlight the importance for all health care providers to determine precisely what adverse events trigger their reporting obligations, as well as the need to determine the type of information they will be required to report. Unfortunately, at the present time, only a handful of states have Web sites and/or handbooks that provide answers to these and other important questions regarding mandatory reporting obligations.[18] We hope, as the focus on medical errors and quality of care continues to increase, more states will devote resources to helping providers understand and fulfill their reporting obligations.

### Consequences for failing to report medical errors

Complying with mandatory reporting requirements is not simply an academic exercise. Failing to report adverse events, as required by federal and state statutes and regulations, can have far reaching consequences for health care providers and facilities. Moreover, systemic failures to report can potentially serve as a catalyst for whistleblower suits and investigations by various government agencies.

The most immediate, direct consequence for failing to comply with mandatory reporting requirements is that licensed health care providers (and in some cases, even unlicensed staff) and facilities can potentially face criminal, civil, administrative, and licensing sanctions. In the majority of states with mandatory reporting statutes, the failure to report adverse events as required is punishable by a combination of civil penalties and potential disciplinary action against the facility's operating license.[19] In two states, California and Utah, the potential sanctions for failing to report adverse events can result in criminal prosecution.[20] Therefore, the stakes are high for health care facilities that, either intentionally or through oversight, fail to fulfill their federal and state mandatory requirements for reporting adverse events.

The failure to report adverse events can also trigger a number of significant collateral consequences. First, such failures can raise larger questions about a facility's overall quality of care and compliance that can provoke investigations by federal and state regulatory agencies. A number of regulatory agencies are beginning to use more creative means to monitor compliance with reporting requirements, including matching death certificates with reports of adverse events.

Second, failing to report adverse events can encourage whistleblower litigation by employees who are concerned that the facility is not adequately addressing potential failures in quality of care. This risk continues to grow as more and more states pass their own false claims statutes in

response to incentives provided in the federal Deficit Reduction Act of 2005.

Third, systemic failures to report adverse events can serve as compelling evidence in so-called "quality-of-care" false claims cases, which seek recovery based upon the violation of Medicare and Medicaid regulations that require, as a condition for payment, that hospitals and physicians provide patients with quality medical care.

These potentially devastating direct and indirect consequences demonstrate the essential need for health care facilities to comply with federal and state mandatory requirements for reporting medical errors. Although there are many personal, emotional, and institutional barriers that can inhibit efforts to report such errors, the consequences that can result from failing to report far outweigh these barriers.

The obligation to make reports of adverse events has implications for virtually everyone with hospital responsibilities for patient care, governance, finance, legal compliance, and risk management. Every hospital needs to ensure that it has systems in place to capture and report adverse events. Every hospital board, CEO, and medical staff leader needs to identify a responsible individual with both the power and the information to determine whether required reporting is occurring. Without such measures in place, hospitals and other health care facilities face a significant, and potentially far-reaching compliance risk. ■

1 For a more complete description of the IOM Report and its recommended approach, see James G. Sheehan and Michael A. Morse, "Mandatory External Reporting of Adverse Events Near Misses and Unanticipated Consequences," in Health Law Handbook, Alice G. Gosfield, ed, 2007, pp. 197,207-209
2 "Manufacturer" defined as "any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedure." 21 CFR § 803.3(o)
3 "Device user facility" defined as "a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility". 21 CFR § 803.3(2)(f)
4 "Serious injury" defined as any injury or illness that is life-threatening, results in permanent impairment to body function or permanent damage to body structure, or requires medical or surgical intervention to prevent such impairment or damage. 21 CFR § 803.3(bb)(1)
5 65 Fed. Reg. 4112-4121.
6 For a more detailed explanation of this process and additional information about medical device reporting requirements, see Reference #1
7 For a more extensive look at reporting procedures, vaccines subject to these procedures, and disciplinary actions see Reference #1 at pp 209-210
8 21 CFR 1271.350(a)
9 For further information on reporting requirements regarding HCT/P, see Reference #1 at pp 211-12.
10 A "manufacturer" includes any organization involved in the testing, processing, packing, labeling, storage, or distribution of blood or any blood product.
11 21 CFR § 606.171
12 71 Fed. Reg. 71378 (December 8, 2006)
13 40 Pa. Cons. Stat. Ann. § 1303.313 (West, 2006)
14 Ohio Admin. Code 3701:83-47 (2006).
15 There also is no uniformity as to the distribution of adverse event information. Some states publish periodic bulletins summarizing trends in the reported adverse events. Other states, however, do not publish any information about the adverse events that are reported by health care facilities.
16 Maryland Code Regs. 10.07.06.09 (2006).
17 Texas Health & Safety Code Ann. § 241.202 (Vernon 2006).
18 A number of private resources may assist health care providers in identifying and understanding their potential reporting obligations. For example, a number of Web sites maintain lists of various reporting statutes, such as National Academy of State Health Policy (NASHP). In addition, for a detailed discussion of federal and state reporting statutes see Reference #1
19 In Florida, for example, the failure to report adverse events, or file any required corrective action plan, may result in civil penalties and fines of up to $5,000 for nonwillful violations, and $250,000 for intentional and willful violations. Fla. Stat. Ann. § 395.0197 (12).
20 California Code Regs. Title 22, Section 70737, 2006: Failure to report as required is punishable as a misdemeanor offense under California's Criminal Code; Utah Admin. Code R380-200, 2006: An entity that violates any provision of Utah reporting rules may be assessed a civil money penalty not to exceed the sum of $5,000 or be punished for violation of a class B misdemeanor for the first violation and for any subsequent similar violation within two years for violation of a class A misdemeanor.

# CHC CERTIFIED IN HEALTHCARE COMPLIANCE

## The Compliance Professional's Certification

**The Healthcare Compliance Certification Board (HCCB) compliance certification examination is available in all 50 states. Join your peers and become Certified in Healthcare Compliance (CHC).**

**CHC certification benefits:**

- Enhances the credibility of the compliance practitioner
- Enhances the credibility of the compliance programs staffed by these certified professionals
- Assures that each certified compliance practitioner has the broad knowledge base necessary to perform the compliance function
- Establishes professional standards and status for compliance professionals
- Facilitates compliance work for compliance practitioners in dealing with other professionals in the industry, such as physicians and attorneys
- Demonstrates the hard work and dedication necessary to perform the compliance task

Congratulations on achieving CHC status! The Health Care Compliance Certification Board announces that the following individuals have recently successfully completed the Certified in Healthcare Compliance (CHC) examination, earning CHC designation:

***Robert S. Brown***

***Laurel Anne Eakes***

***William James Greenwood***

***Paul Meyer***

***Timothy Scott Peterson***

***Barbara J. Piascik***

***Hemansuroy Sasenaraine***

***Staci Schatzman Solomon***

***Gary Lynn Thomas***

Since June 26, 2000, when CHC certification became available, hundreds of your colleagues have become Certified in Healthcare Compliance. Linda Wolverton, CHC, says she sought CHC certification because "many knowledgeable people work in compliance and I wanted my peers to recognize me as one of their own."

For more information about CHC certification, please call 888/580-8373, e-mail hccb@hcca-info.org or click on the HCCB Certification button on the HCCA Web site at *www.hcca-info.org*. ■