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New EMTALA rules: What you don't know can hurt you

Feds get tough on patient dumping

Now may be a good time to launch a new series of inservices to educate your staff and physicians about changes in case law and federal regulations, according to speakers at the recent annual meeting of the American Society for Healthcare Risk Management (ASHRM) in New Orleans. There are plenty of new risks looming that should scare the dickens out of even the most blasé health care providers, they say.

Some of the most important lessons concern the Emergency Medical Treatment and Active Labor Act (EMTALA), the federal rule that prohibits patient dumping and requires facilities to stabilize patients before transferring them to another facility. EMTALA has long been a minefield for risk managers, but **Mark Kadzielski**, JD, says traversing that minefield is going to be even trickier from now on. Kadzielski is head of the West Coast health practice for the law firm of Akin Gump in Chicago. He says risk managers must study changes in the EMTALA rule that went into effect in October.

"The heat is building on EMTALA," Kadzielski says. "I expect to see more violations and penalties in the near future. They're looking for it."

Another ASHRM speaker agreed with Kadzielski that the coming months may include some tough challenges for risk managers. Recent changes in case law have upped the ante on some risks, according to **John West**, JD, MHA, DFASHRM, senior health care consultant with AIG Consultants in Atlanta.

"You may want to have an inservice to educate your staff and physicians about some of these

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COMING IN FUTURE ISSUES

- Liability for inadequate pain relief
- Preventing sex harassment claims
- Criminal charges from medical wrongs
- Multiple personality disorder now risky diagnosis
- OIG focuses more on civil monetary penalties

developments," he says. "Some of these things can be very effective in scaring people to death so you get their attention."

Definitions clearer, but scope broadened

Much of the increased risk from EMTALA stems from changes and clarifications in the rule that went into effect on Oct. 10, 2000. Originally proposed in 1998, the Final Outpatient PPS Rule for hospitals, 64 *Fed Reg* 18434 (April 7, 2000), answered some questions that health care providers had asked about how to comply with the rule. Unfortunately, some of the answers aren't what anyone was hoping for.

For instance, the EMTALA rule now applies to any person up to 250 yards away from the hospital. Kadzielski says this clarification was made in response to a recent case that gained widespread media attention, in which employees and staff of a major hospital refused to aid a gunshot victim who was lying just beyond the hospital property. Now the federal government has made clear that all the requirements of EMTALA apply not just in the emergency room or just in the hospital building itself.

"No one knows exactly where you're supposed to measure that 250 yards from, but it's safe to say that you should measure from the edge of your campus, not the front door," he says. "The idea is that they want you to be responsible for anyone who is, in their opinion, close enough to be considered your responsibility even if they're not on your property."

That interpretation could be particularly troublesome for smaller hospitals in rural areas, Kadzielski says.

"In some towns, 250 yards might cover 90% of the town," he says. "That raises interesting questions about your obligations when someone passes out at the liquor store."

Beware of transfers

The EMTALA clarification also makes clear that the rule is limited to those areas of the hospital that are determined to be departments of the hospital by the Health Care Financing Administration (HCFA). That means transferring a patient to that department, even within the same hospital building, could constitute an EMTALA violation.

Similarly, HCFA now says that freestanding facilities are not considered part of the hospital for the purposes of EMTALA. If a patient shows

up at a health system's urgent care facility or clinic, transferring that patient to the main hospital could violate EMTALA.

"You can now dump a patient by sending them to your own ER," he says. "Don't let your business people declare all of your related off-site property as part of the hospital. They usually want to do that and call every little office a satellite hospital with all the signage and logos, but that basically gives the government permission to hit you with an EMTALA violation."

HCFA also has addressed the current trend of hospitals to open clinics and urgent care centers within a competing hospital's traditional operating area. Hospitals have found such facilities to be an effective way to encroach on the other hospital's turf and try to steal away patients, Kadzielski says. But as far as EMTALA is concerned, HCFA says those offices must be willing to send patients to the competing hospital if the parent hospital is too far away.

Not only must the off-site facility transfer the patient to the nearby competitor when a trip to the parent hospital would take too long, but HCFA says the off-site facility must have a transfer agreement in place in advance. It is not sufficient to decide the patient must go to the competitor and then figure out how to get him or her there.

"This is the first time that HCFA has specifically required transfer agreements be in place prior to an accident," Kadzielski says. "Apparently it requires preplanning so that a simple phone call to one prearranged phone number would be sufficient to confirm transfer in a matter of a *very* short time. Your business people won't like you sending patients to the competition, but EMTALA requires it."

West also explains that recent case law has clarified that a family history of a medical condition is not sufficient to trigger the requirements of EMTALA. The patient must actually have symptoms at the time the facility treats him or her in order for there to be an obligation. In the past, plaintiffs have alleged that a facility could be held liable if they discharged or transferred a patient with knowledge that a family history made the patient susceptible to a problem, which then manifested after the discharge or transfer. **(See p. 136 for more EMTALA clarifications.)**

West updated ASHRM attendees on recent changes in case law that can affect health care providers, and says there are a number of developments that should prompt risk managers to take action. In one case, *Colbert v. Rolls*, a Florida appeals court ruled that a doctor's unusual religious beliefs were relevant to a malpractice case and discoverable. The patient had consulted the doctor for epigastric pain, but the doctor did not order an EKG. It turned out the man was having a heart attack.

The patient later testified that the doctor told him he did not order an EKG because a "spirit" had not told him to. He further discussed his beliefs in spiritual healing and his admiration for a televangelist known for "healing" the sick. The doctor denied that was the reason he did not order an EKG, but the appeals court eventually ruled that his religious beliefs were discoverable.

"The lesson is to figure out if your doctors have odd beliefs, and if so, you may want to consider counseling them on those practices," West says. "In professional liability actions, those beliefs could be a real problem."

Who's to judge?

It is not acceptable to simply quiz each physician about his religion upon hiring or granting privileges, because that could lead to discrimination charges. But West says risk managers should be alert for any signs that the doctor's treatment is unorthodox. The key is to judge the doctor on his or her actions, or lack thereof, not just on his or her religious beliefs.

"If you determine that a physician is basing his or medical judgments on spiritual inspiration, observations made during astral projections, voices within their heads, tea leaves, Tarot cards, or such other less than commonly accepted medical practices or sources of information, you certainly would be within your rights to investigate further and take such action as necessary to ensure the quality of patient care," he says.

In another recent case, *Dunkley v. Shoemate*, the North Carolina Supreme Court determined that a health care provider cannot mount a defense for a third party without that party's consent. The case involved a woman who was admitted to a residency program at a major hospital and subsequently sued, along with the hospital, for malpractice. The patient alleged that a "doctor" forced her to have sex with him and threatened to commit her to an institution if she refused. When the case arose, it was revealed that the doctor was not actually a doctor at all and apparently had no verifiable medical training. The man fled as soon as the suit was filed and has not been heard from since.

The hospital's insurer wanted to mount a defense for the man to avoid a default judgment, since the court had refused the argument that his deception meant he was not really an employee of the hospital. The Supreme Court of North Carolina decided that the hospital's insurer could not defend the man without his consent.

"This is a pretty scary case, and I don't know how to get around it," West says. "I don't know if you could get residents to agree to a defense before a suit is filed against them, or if that would hold up later. The lessons are that you should keep track of residents as much as you can after they leave your facility, and always check the credentials. Always."

West also drew attention to a recent Virginia case involving the alteration of medical records. In *Stevenson v. Virginia*, a physician was seeking preauthorization from an insurance company so that a patient could be placed on a list of patients requiring a kidney transplant. The insurance company required proof that the patient had passed a cardiac evaluation recently, but the doctor had not performed one recently. He altered the date on one from earlier in the patient's treatment.

The doctor eventually was convicted of forgery but the penalty was a fine of only $1. Nevertheless, the doctor appealed the conviction because the felony was reportable to regulatory bodies, and it was generally unappealing for a doctor to have such a record. The forgery conviction was upheld and then taken to the Virginia Supreme Court. The Supreme Court noted that Virginia law requires a forgery to prejudice, or have the potential to prejudice, the rights of another. In other words, simply creating a false document is not enough; someone has to be hurt by it.

Testimony revealed that the falsified date was not crucial to the insurer's decision. Since the insurer's approval process was such that it would have approved the procedure even without the fraud, the court ruled that the company's rights

Crucial EMTALA phrases clarified

Here are more of the clarifications of the EMTALA rule that providers must now follow to avoid patient-dumping charges. The interpretations of the revised EMTALA rules are provided by **Mark Kadzielski**, JD, head of the West Coast health practice for the law firm of Akin Gump in Chicago.

• "Comes to the emergency department" means that the individual is on hospital property, which means the entire main hospital campus including the parking lot, sidewalk, and driveway, as well as any facility that is located off the main hospital but has been determined to be a department of the hospital.

• "Property" also includes ambulances owned and operated by the hospital even if the ambulance is not on hospital grounds. An individual in a nonhospital-owned ambulance on hospital property is considered to have "come to the hospital's emergency department." An individual in a nonhospital-owned ambulance off hospital property is not considered to have come to the hospital's emergency department even if a member of the ambulance staff contacts the hospital by phone or telemetry and informs the hospital that the patient will be delivered for treatment.

• The capability of the hospital includes that of the hospital as a whole, not just the capability of the off-campus department. With a few exceptions, the obligation of a hospital must be discharged within the hospital as a whole. However, the hospital is not required to locate additional personnel or staff for off-campus departments to be on standby for possible emergencies.

• The hospital must establish protocols for handling potential emergency conditions at off-campus departments. These protocols must provide for direct contact between personnel at the main hospital campus and may provide for dispatch of practitioners, when appropriate, from the main hospital campus to the off-campus department to provide screening or stabilization services.

• If an off-campus department is an urgent care center, primary care center or other facility routinely staffed by physicians, RNs, or LPNs, they must be trained and given appropriate protocols for handling emergency cases. At least one person on duty during regular hours of operation must be designated as a qualified medical person. If that person is not a physician, Kadzielski says you should be especially careful to meet the requirements for nonphysician screening. ■

were not compromised. On that basis, the court overturned the conviction.

West says the doctor "barely wiggled out of this conviction," and did not know at the time of his forgery that the date was not so important. If he had not overcome the conviction, he would have been left with a criminal record that could hamper his licensure and his ability to participate in managed care programs appropriately," West says. "How many inservices do you have on documentation and it never sinks in? This is one case that I think everyone should incorporate into their inservices on documentation, to scare them into complying or at least not committing outright forgery."

West notes that had the doctor done the same thing with a Medicare document instead of a private insurer, the doctor would be guilty of filing a false claim.

A case in Maryland also should get the attention of wayward physicians. In *Board of Physician Quality Assurance v. Banks*, a physician was accused of sexually harassing several female co-workers and took a leave of absence from the hospital. When he reapplied for privileges, he was refused. When the medical licensing board received notice of the denial of privileges, it investigated and brought charges against him under state law that prohibits "immoral or unprofessional conduct in the practice of medicine." The doctor's defense was that he was not practicing medicine at the time of the alleged incidents. They all took place during his down time between seeing patients, much of it during the long periods when he was on call at the hospital but not actively working.

"The court ruled that if you're employed as a physician, working as a physician in a health care facility, you're practicing medicine no matter what you're doing at the moment. If you're just waiting to make copies or getting coffee, you're still practicing medicine," West says. "This is a good one to include in sex harassment inservices to scare people, especially if you can get the attention of your physicians."

Not all of the case law developments were detrimental to health care providers. In one recent case, *Pegram v. Herdrich*, the U.S. Supreme Court determined that managed care organizations do *not* have a fiduciary responsibility to their subscribers. This was an important decision, West says, because a fiduciary responsibility essentially trumps any other responsibility. The plaintiff in the case had sued because she thought her managed care provider had put cost-cutting efforts ahead of her own best welfare, arguing that the company had a fiduciary responsibility to provide the best care possible no matter what it meant to the company's bottom line. The woman's appendicitis was misdiagnosed, an error she blamed on the managed care group's cost-cutting protocols.

"The Supreme Court said it's not possible for a managed care organization to act in the best interest of each individual participant without going bankrupt, especially involving utilization decisions," West says. "The ruling could mean that providers won't automatically be held liable if they admit they were trying to save money and that inadvertently led to a problem with a patient." ■

Feds say beware of the scorned, banished provider

Federal regulators are on the lookout for health care institutions that continue to employ or otherwise work with individuals given the Medicare kiss of death, says a prominent attorney. He cautions that health care organizations risk a great deal by continuing to work with such people.

The Office of the Inspector General has made it clear that it is looking for such allegiances and will punish them severely, says **Mark Kadzielski,** JD, head of the West Coast health practice for the law firm of Akin Gump in Chicago. When the federal government "debars" or "excludes" individuals from participation in federal programs such as Medicare because of fraud or other misdeeds, no organization participating in Medicare or other programs may employ that person in any position with direct responsibility for or involvement with business operations related to the federal program. Furthermore, the person may not be employed in such a way that his or her salary or other compensation are derived, even indirectly, from any federal funds.

As a practical matter for most facilities, that means the person cannot be employed or a physician may not have privileges at a facility receiving federal funds. But Kadzielski says many such people still are affiliated with hospitals and other facilities. To determine whether a person is

debarred or excluded, providers can check the OIG's database on the Internet at www.hhs.gov/oig/cumsan/index.htm.

"You should consider automatic termination after you go on that Web site and find them there," he says. "The argument is always that the doctor is a wonderful clinician, and you don't want to fire him for missing a student loan payment or checking the wrong box on a Medicare form. Wrong answer! Debarred or excluded providers are a major danger, and you must sever ties with them immediately."

Kadzielski says federal inspectors will be looking for any such people when they visit a facility, and it is easy for them to make the connection since they only have to check their database against the facility's records.

"They will be looking for them at every opportunity, and it's an easy way for them to slap you with a penalty," he says. ■

Hospice stay unlikely to bring charges of fraud

A recent letter from the former administrator of the Health Care Financing Administration (HCFA) appears to dispel fears that hospice referrals could inadvertently lead to charges of health care fraud.

Nancy-Ann DeParle recently issued a letter to hospices explaining that the government will not consider a stay of longer than six months reason to suspect health care fraud. The letter was issued in response to concerns in the health care community that a physician could refer a patient to a hospice, thinking that the patient would not live longer than six months, and then be charged with fraud if the patient lived substantially longer.

The concern partly arose because the federal government's continuing crackdown on fraud in health care has included an emphasis on hospice care. In the Office of Inspector General's "Compliance Program Guidance for Hospices," regulators make it clear that there are many ways in which hospice programs can result in fraud charges, but the guidance documents specifies one risk area as "admitting patients to hospice care who are not terminally ill." (The compliance guide can be found on the Internet at www.hhs.gov/progorg/oig/modcomp/hospic99.htm.)

The key is that a hospice patient may receive reimbursement for hospice services under Medicare only if he or she is "terminally ill." That term has generally been interpreted as meaning the patient will die within six months. But even the most experienced physician can find it difficult to pinpoint the time remaining.

The compliance guide says "it is important to make a distinction between admitting a patient to a hospice program and certifying a patient for the Medicare Hospice Benefit. Based on an individual hospice's admission criteria, some patients may be admitted to hospice care prior to an estimated six months before death, as long as the hospice is paid fair-market value for its services. Regardless, patients can be certified for the Medicare Hospice Benefit *only* when it is reasonable to conclude that a patient's life expectancy is six months or less if the illness runs its normal course. In other cases, alternative modes of reimbursement, often provided through community support, should be sought outside the Medicare Hospice Benefit."

Congress critical of short hospice stays

Partly as a result of the way health care professionals interpret those rules, patients are entering hospices only at the end of their lives, according to a new report from the General Accounting Office (GAO), the investigative arm of Congress. The GAO report says that 28% of all Medicare beneficiaries in the hospice program received hospice care for one week or less.

The director of health care studies for the GAO, **William Scanlon**, says the health care community has been dissuaded from referring patients to hospice early enough for them to truly benefit. The average Medicare patient in the hospice program received 59 days of hospice care in 1998, down 20% from an average of 74 days in 1992, Scanlon reports.

"Although more Medicare beneficiaries are receiving hospice services, they are, on average, receiving fewer days of care than did beneficiaries in the past," he says.

Part of the problem may involve the changes in the overall hospice population, Scanlon says. Hospices used to care primarily for cancer patients, which accounted for 75% of all Medicare hospice patients in 1992, according to the GAO report. But now cancer patients account for only about half of Medicare hospice care, with 43% of the patients dying from heart and lung disease, stroke, and other ailments.

Some of the conditions now commonly found in hospice programs pose more of a challenge to physicians attempting to estimate the patient's life expectancy, Scanlon says.

There is no six-month time limit

In her letter to hospices, DeParle acknowledged that the health care community has been spooked by the possibility of such fraud charges and clarifies that there is little to fear.

"Under the law, Medicare beneficiaries are eligible for hospice care when they decide to choose palliative and other care from a hospice, and a physician and the hospice medical director certify that they have a medical prognosis of six or fewer months to live if their illness runs its normal course," DeParle wrote. "The Balanced Budget Act of 1997 made important changes to the law to ensure that patients whose prognosis improves or who choose to resume curative care can leave hospice and return at a later date.

"However, I am concerned that some individuals who want and could benefit from hospice care may not be receiving it or may be receiving it late in the course of their illness because the difficulty in making end-of-life prognoses may affect their access to hospice care. There also is a disturbing misperception that hospices and beneficiaries will be penalized if a patient lives longer than six months. Nothing could be further from the truth.

"There have been a handful of cases in which beneficiaries who were not carefully diagnosed in the first place were inappropriately enrolled in hospice. Nevertheless, that is very different from situations in which a terminally ill patient has had the good fortune to live longer than predicted by a well-intentioned physician.

"Let me be clear:

" In no way are hospice beneficiaries restricted to six months of coverage.

" There is no limit on how long an individual beneficiary can receive hospice services, as long as they meet the eligibility criteria.

"As long as a physician continues to properly and conscientiously recertify the six-month prognosis, a beneficiary can continue to receive the hospice benefit."

DeParle pointed out in the letter that about 10% of Medicare hospice beneficiaries stay longer than six months. She also announced that HCFA may develop a voluntary program in which physicians and hospice directors can seek confirmation from Medicare contractors before enrolling beneficiaries in a hospice.

"A preauthorization program would help beneficiaries and providers, in cases where prognosis is difficult, by pre-empting concerns about denial of claims and thereby promoting earlier enrollment for more beneficiaries who want and are eligible for hospice care." ■

Study shows safety violations at homes

About 70% of nursing homes in Texas have "serious deficiencies" that threaten the safety of patients, according to a new study released by federal investigators. Similar problems were found in about 40% of nursing homes on Long Island, NY, and in New Jersey, and at more than half the homes in Chicago, Los Angeles, and San Francisco.

The investigation was requested by members of Congress and carried out by the Democratic staff of the House Committee on Government Reform. They used federal data to study nursing home compliance with federal regulations, examining a sample of annual inspection reports. The report delivered to members of Congress states that there were widespread problems in the nursing homes surveyed, including "violations that caused actual harm to residents, or had the potential to cause death or serious injury." Those problems were found at 26% of nursing homes in Texas, 17% on Long Island, 18% in central New Jersey, 15% in Chicago, 19% in Los Angeles, and 41% in San Francisco.

What they found

The investigators did not name specific nursing homes in the report. Some of the allegations in the report involved gross neglect. The report says the investigators found an 83-year-old patient in a San Francisco nursing home with ants crawling on her face and in her mouth; and in a Los Angeles nursing home, they witnessed a nurse assistant bathing a resident in her bed with a cloth soiled with feces.

The inspectors were in a Chicago nursing home when they heard a resident calling out for help, and they watched as nearby staff did not respond.

The inspectors finally went to the patient's room themselves and found her trapped, wedged between a bed rail and a mattress.

Ciro Rodriguez (D-TX) was one of the representatives who requested the investigation. Upon receiving the report, Rodriguez responded by saying the high rate of deficiencies was unacceptable and that he blamed the problem largely on a shortage of staff. The shortage is caused by the low level of reimbursements paid by the state under the Medicaid program. ■

New report confirms medication stats

A new report says medication errors are the most common type of medical errors at health care facilities in the United States, seeming to confirm confirm the findings of a controversial 1999 Institute of Medicine (IOM) report.

This is a case you can use to scare people into documenting the findings of a controversial 1999 Institute of Medicine (IOM) report.

HCPro, a health care consulting company in Marblehead, MA, announced the results of the survey, which it conducted in an effort to determine the nature and frequency of medical errors in health care facilities. The survey was launched in response to the IOM report that concluded that medical errors in U.S. hospitals may be responsible for up to 98,000 deaths per year. HCPro surveyed about 300 risk- and quality-assurance managers, senior administrators and nonphysician clinical staff members from 380 hospitals participated.

Ninety-four percent of those surveyed reported that medication errors had occurred at their facilities during the past year. Sixty-four percent also said that medication errors were the most frequent medical error, followed by patient falls and delay of treatment.

In addition, 13 respondents said the medication errors had led to deaths. Out of 95 deaths in the past year at the hospitals surveyed, 29 were caused by medication errors.

"While there has been considerable debate over the validity of the IOM findings, our survey clearly indicates that medical errors are a legitimate and critical concern for health care professionals," says **Bob Croce**, executive editor at HCPro. He notes that the results of the HCPro survey are almost identical to the IOM survey, with medication errors ranking at the number one in both surveys.

In a related effort, VHA Inc. has launched three new medication error reduction initiatives, engaging clinical teams from more than 50 facilities in six states in a collaborative program to quickly reduce the likelihood of medication errors in their hospitals. This brings the total number of hospitals participating in VHA's Clinical Advantage medication error-reduction initiative to more than 100 nationwide. VHA is a national alliance of more than 2,000 community-based health care organizations.

The three new programs include hospitals from VHA's East Coast, Empire States, Pennsylvania, Northeast, and West Coast regions. The medication error initiative focuses on problematic drug labeling, inadequate practitioner and patient education, unrestricted drug access, ambiguous order communication, and error-prone device design. Other areas of concentration include the safe use of insulin, concentrated electrolytes, chemotherapy and drugs such as heparin and warfarin; and the use of automatic dispensing and medication delivery devices.

When errors occur

"The large number of facilities participating in this initiative underscores the importance VHA hospitals place on this issue," says **Stuart Baker**, MD, VHA's executive vice president of clinical affairs. "We believe that through efforts such as this, VHA members can lead the way in developing methodologies to avoid unnecessary, costly, and often tragic medication errors."

VHA staff members facilitate the program, together with leadership from the nationally recognized Institute for Safe Medication Practices (ISMP). **Michael Cohen**, ISMP president, is VHA's national chairman for the initiative.

"VHA has a long history of working with its hospitals, business partners, and the ISMP on guidelines and recommendations to improve patient care — from strict labeling standards to innovative information technology solutions," said Cohen. "These hospitals are taking active, significant steps to improve patient care, and we look forward to sharing information with associations and governmental agencies to fix the problems found in an increasingly complex health system."

According to the ISMP, medication errors occur

in 5.3% of hospitalized patients, costing health care organizations from $2,500 to $4,500 per episode. More than 40% of these errors are significant or life-threatening, and 1% result in a patient death.

Participants in the medication error initiative also have access to the MedMARx software product from U.S. Pharmacopeia, an Internet-accessible database that confidentially and anonymously documents and tracks medication errors.

The medication error initiative is part of VHA's Clinical Advantage program, through which interdisciplinary teams at hospitals across the nation apply evidence-based methodologies, measurement tools, and clinical information to improve patient care. The program is organized around specific medical conditions and a framework of resources to accelerate implementation, produce results, and overcome barriers to change. Currently more than 525 organizations and thousands of clinicians are participating in other Clinical Advantage initiatives to improve the treatment of stroke, heart attacks, medication error reduction, breast cancer, congestive heart failure, and patient safety. New initiatives will soon begin for pain management and spreading and sustaining improvements. ■

CA tells pharmacies to reduce errors

California's governor, Gray Davis, recently signed a bill sponsored by the California Board of Pharmacy to reduce the number of people injured by medication errors.

The new law requires all pharmacies to establish quality assurance programs that evaluate medication errors and identify changes that can prevent those errors from recurring, according to Board president **Bob Elsner**.

"Patients in California will receive better, safer pharmaceutical care because Governor Davis has signed this important consumer protection bill," he says. "California is leading the way by being the first state in the country to require such a patient safety program in all pharmacies."

Quality assurance processes have a record of success in other areas of health care, and applying quality assurance processes to the dispensing of prescription drugs should substantially reduce the number of medication errors. In fact, last year's report issued by the Institute of Medicine recommended that state regulators should require health care organizations to implement meaningful patient safety programs.

Elsner says the new law will do just that for California pharmacies. He notes that hospital patients account for a fraction of all prescriptions filled each year. One study found that 4.2% of outpatient prescriptions result in adverse drug reactions. Pharmacies dispense over 2.5 billion prescriptions each year. The California Board of Pharmacy is a consumer protection agency charged with ensuring public safety through licensure and education of practitioners and enforcement of the laws governing the distribution of prescription drugs. Over 70,000 licensees are regulated by the board in twelve major license categories. ■

Awards show efforts to reduce medical errors

The National Patient Safety Foundation (NPSF) has announced the winners of the first-ever Patient Safety Awards, which recognize practical solutions that reduce medical errors and improve patient safety. Award recipients presented their winning solutions during the "Patient Safety Initiative 2000: Spotlighting Strategies, Sharing Solutions" conference held recently in Chicago.

To address the problem of medical errors, the NPSF has been working with the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to identify and disseminate proven, practical solutions that reduce medical errors and improve patient safety. In May of this year, the NPSF and JCAHO issued a nationwide call for abstracts outlining real world health care strategies shown to achieve these goals. As a result, 30 solutions were chosen to be presented at the conference, which was co-hosted by NPSF and JCAHO.

In addition to hosting the conference, NPSF has established Patient Safety Awards to be presented to three individuals or institutions that have demonstrated superior foresight and innovation in their approach to patient safety. Each award winner will receive $10,000.

"These three outstanding award winners exemplify the five criteria that we were looking for in our call," said **Joanne Turnbull**, PhD, executive

director of the NPSF. "The solutions have been tested, implemented, and proven to reduce errors, are scientifically based, are practical to implement and administer, are creative and innovative and are transferable across organizations and settings. Each of the three winners has provided excellent examples of real-world, practical solutions that have helped to reduce medical errors and improve patient safety in their respective situations; and in addition, these cases offer insight into larger-scale progress in patient safety and medical error reduction."

The winner of the Janssen Patient Safety Award for Elder Care, sponsored by Janssen Pharmaceutica, was a solution presented by Christopher Koepke, PhD, social science research analyst at the Health Care Financing Administration (HCFA). His team's research, titled, "Which Messages on Patient Safety Should the Federal Government Promote? HCFA Research with Medicare Beneficiaries," looked at whether widespread popular interest in medical errors can be transformed into an active public role in preventing those errors by Medicare beneficiaries. Koepke's team found that consumer messages on reducing medical error work best if the messages: advocate a collaborative doctor-patient relationship in which patients work with, rather than challenge, health professionals; specify action to be taken, i.e., directive messages that are readily understood by patients; and clearly indicate the mode of implementation, i.e., patients need directions on how they should act on these messages.

Steven Meisel, PharmD, assistant director of pharmacy at Fairview Southdale Hospital in Edina, MN, was awarded the Patient Safety Award for Innovative Clinical Solutions, sponsored by 3M, for his team's work, "An Interdisciplinary Model for Reducing Intravenous Heparin Errors." The error reduction program of heparin, a drug used in the treatment of a variety of thromboembolic conditions, was designed to reduce intravenous heparin errors in cardiac care units. Once implemented, the program helped reduce heparin errors by 66% in four months in these units, and as a result, was expanded to the other units of his institution.

The recipient of the Patient Safety Award for Patient Provider Communication Solutions, sponsored by *The St. Paul*, is Children's Hospitals and Clinics in Minneapolis. Julie Morath, RN, MS, chief operating officer, presented the winning solution, "Partnering with Families: Disclosure and Trust," which focused on the manner in which an organization responds to a medical error as the way to advance a culture of safety, particularly for pediatric patients. This patient safety agenda includes: encouraging families to participate in patient care and to ask questions; complete, prompt, and truthful disclosure of information and counseling to families when a medical accident has occurred; full analysis of each accident to prevent such an event from happening again; protecting staff who promptly and appropriately report accidents to a patient's immediate caregiver, manager, or safety office; and continuing patient safety education through the development of targeted learning packets for leadership and clinical staff, as well as information packets for patients and families. ■

Joint Commission brings more info to the public

The Joint Commission on Accreditation of Healthcare Organizations, the nation's leading quality of care evaluator in health care organizations, has launched a series of public accountability initiatives to ensure the availability of information about the quality of care provided in accredited health care organizations to consumers.

"The Joint Commission has long been attuned to its public accountability," Dennis O'Leary, president of the Joint Commission, said in announcing the initiatives. "This accountability is demonstrated in every aspect of our organization — from policy-setting by our Board of Commissioners; to the establishment of consensus-based, state-of-the-art standards; to rendering objective accreditation decisions based on actual organization performance; to providing to the public important information about the quality of care in Joint Commission-accredited health care organizations."

Check the Web site

The Joint Commission evaluates and accredits nearly 19,000 health care organizations and programs in the United States, including almost 11,000 hospitals and home care organizations, and more than 8,000 other health care organizations that provide long-term care, behavioral

health care, laboratory, and ambulatory care services.

One of the initiatives, "Quality Check — A Comprehensive Guide to Learning About the Quality of Health Care Organizations," is on the Joint Commission's Web site.

Quality Check provides information about each Joint Commission-accredited health care organization and program. This information includes the organization's name, address, telephone number, accreditation decision at the time of its last full survey, date of accreditation, and current accreditation status. Quality Check also provides access to organization-specific performance reports for most accredited organizations. Performance reports detail the organization's overall performance level; its performance level in key areas; areas identified as needing improvement, if any; and for most organizations, a display of how the individual organization compares to other organizations nationally in each performance area.

"This is the first time I've seen information that has some teeth in it. . . . Quality Check really evaluates the care at particular hospitals," said **Jean Campbell**, PhD, of the Missouri Institute of Mental Health. "The information presented on Quality Check is leading the movement to consumer health informatics, empowering consumers around issues of choice."

Additional significant information that the Joint Commission makes available to the public includes the following:

• Listing of scheduled surveys — The Joint Commission posts the dates of upcoming full surveys on Quality Check. Interested parties can search for organizations due for survey within the next month or those that were surveyed within the previous two months.

• Consumer brochures — The Joint Commission publishes a series of consumer brochures to help individuals choose a hospital, home care provider, nursing home, assisted living community, outpatient surgery center, behavioral health care facility, or laboratory service. These free brochures are designed to help the public identify quality health care services. A special feature is a list of questions to help the user engage in discussion with the health care provider organizations. For a free copy of any of the brochures, call the Joint Commission's Customer Service Center at (630) 792-5800, between 8 a.m. and 5 p.m. CST, on weekdays. The Helping You Choose brochures also are available on the Joint Commission's Web site. ■

Insurer recommends device to avoid claims

The Physician's Insurance Company (PIC) of Wisconsin is recommending the use of active electrode monitoring technology to reduce risks in laparoscopic surgery, saying the machine could reduce malpractice claims.

With the announcement, PIC joins malpractice carriers in Arizona and Colorado in recommending Encision's AEM Laparoscopic Instruments. The device helps to eliminate unintended electrosurgical burns during minimally invasive surgery, according to **Jan Haedt**, risk management consultant to PIC Wisconsin.

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Editorial Questions

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"Various studies have shown that the risks of laparoscopic surgery have proven to be fertile ground for plaintiff attorneys," she says. "Knowing these risks and the factors contributing to potential liability, what can health care organizations do to help mitigate these risks? They can begin by utilizing appropriate safety equipment to prevent thermal injuries from stray energy released during the procedure."

Rise in malpractice claims linked to procedure

Haedt says that while laparoscopic techniques have led to important advances in minimally invasive surgery, they also have been brought with them an increase in malpractice claims related to thermal injuries.

American Physicians Insurance, Mutual Insurance Co. of Arizona, and Colorado Physician's Insurance Co. also have recommended their surgeons consider the use of active electrode monitoring technology to improve patient safety in laparoscopic surgery. More recently, the Association of Operating Room Nurses (AORN) recognized active electrode monitoring technology as an "AORN Recommended Practice" for minimally invasive surgery.

Active electrode monitoring technology helps to minimize stray electrosurgical burns during laparoscopic surgery by preventing the stray energy from contacting tissue. ■

HCFA developing standards for treating deaf patients

The Health Care Financing Administration (HCFA) is developing standards of care for providing health care services to the deaf and hard of hearing, according to a presentation at the annual conference of the American Public Health Association in March.

David Boan, MD, and colleagues at Delmarva Foundation for Medical Care in Easton, MD, have been working with Gallaudet University in Washington, DC, to draft a set of standards, guidelines, and recommendations.

The standards will state that the provider and/or health care organization should be responsible for ensuring that communication does not create a barrier to the equal access to services, he says. Also, providers should be familiar with interpreters and how to acquire and assess their services, as well as assistive technologies.

Boan also says providers should develop programs for educating deaf and hard-of-hearing consumers should include such topics as how to provide a clear medical history, appropriate use of emergency services and medications, and clear expression of needs.

Hospitals also should have interpreting services available on short notice, as well as accommodations that would include closed-caption TV and clear labeling of patient needs on the patient's chart, he says.

HCFA's entire proposal is available on the Internet at http://deafness.dfmc.org/resources/proposedguidelines.htm. ■

Healthcare Risk Management's
Legal Review & Commentary™
A Monthly Supplement

Equipment failure ends in brain injury: $500,000 settlement

By **Mark K. Delegal**, Esq., and **Jan Gorrie**, Esq.
Pennington, Moore, Wilkinson, Bell and Dunbar, PA
Tallahassee, FL

News: A man was admitted to the hospital for hip replacement surgery. While being anesthetized, the expiratory valve on the anesthesia circuit was stuck in the closed position. The anesthesiology resident was unable to ventilate the patient, who suffered from the loss of oxygen. The medical malpractice claim resulted in a $500,000 settlement.

Background: The 53-year-old man was admitted to a Veterans Affairs (VA) hospital for replacement of his left hip. Before surgery, he was assessed as a low-risk patient by nursing and anesthesia staff. The next morning he was taken to the operating room. At 12:45 p.m., he was given an epidural and general induction began. Fifteen minutes later, the anesthesiology resident noted the patient was breathing well with mask ventilation. At 1:05 p.m., after being intubated, the doctor observed that the patient was unable to breathe through the endotracheal tube. At 1:20 p.m., after several attempts were made to manually intubate him and re-establish respiration, mask ventilation was resumed.

While the patient was without effective oxygen for several minutes and suffered bradycardia and complete cardiopulmonary arrest. At 1:18 p.m., his arterial blood gases were taken and the results indicated that he was in a state of respiratory acidosis. The patient gradually awoke, but several days passed before he could talk or communicate.

Records indicate that the ventilation equipment had been inspected at 7 a.m. the day of surgery and appeared to be functioning properly. The patient's medical records indicate that the machine was again examined following the incident and the expiratory valve on the anesthesia circuit was stuck in the closed position. When the valve is closed, no oxygen can be delivered to the patient. An assessment performed by the VA medical staff showed that the patient sustained ischemic brain damage as a result of oxygen deprivation.

The plaintiff claimed injuries that included ischemic brain damage, suicidal depression, difficulty in doing simple math, mnemonic difficulty, inability to follow directions, inability to help around the house, and general irritability. Since the incident, he calimed he was noncommunicative and unable to handle stress. In his claim against the VA and its medical and nursing staff, the plaintiff contended that the defendants failed to properly inspect the anesthesia equipment immediately before it was connected to his respiratory system. The patient claimed that even if the equipment did not perform correctly, he could have and should have been manually ventilated, and his injuries would have been minimized. Given that medical residents were seemingly responsible for the administration of his anesthesia, the patient claimed that the residents were not experienced enough to check the

machinery prior to use in surgery, not skilled enough in airway management to have properly intubated him, and not sufficiently trained to have managed his care under crisis. Despite the assessment by VA medical personnel to the contrary, the defendant claimed that the patient suffered no significant brain damage and, absent injury, there is no viable claim.

What this means to you: Anesthesiology historically has been risky business. The inherent risk is intensified when coupled with training and educating future health care practitioners.

"The first thing that came to mind after reading this case is the responsibility of all health care facilities, regardless of size or staff mix, to ensure that all persons who perform patient care are properly trained and qualified to do so, with documented competency assessments on file," notes **Susan Keaton**, RN, BSN, director of PI & RM at Summersville (WV) Memorial Hospital.

"Teaching facilities have a more complex system to deal with because of the need to balance a meaningful clinical experience for inexperienced students and trainees with the delivery of good-quality patient care, but the responsibility is the same."

"Teaching facilities have a more complex system to deal with because of the need to balance a meaningful clinical experience for inexperienced students and trainees with the delivery of good quality patient care, but the responsibility is the same. Effective and appropriate supervision of trainees goes hand-in-hand with credentialing and privileging, and such oversight may have been lacking in this particular case. Novices should have direct supervision by a designated proctor who is experienced and proficient in their field. As the newcomer gains experience and shows progress in clinical ability and judgment, more independence may gradually be granted, but the need for them to have a seasoned professional immediately available in case of an unexpected event is constant.

"It is not uncommon for unexpected occurrences, especially life-threatening emergencies, to cause an adrenaline rush and at least momentary panic and confusion for even the most experienced veteran, let alone newcomers to health care. This may account for the resident repeatedly trying to reintubate the patient without remembering to provide adequate ventilation in between attempts. Skilled airway management is an essential requirement for anesthesia providers and proficiency in it must be proven before independent practice is permitted. Completion of courses such as Advanced Cardiac Life Support also may be beneficial as a prerequisite to certain clinical practicums; basic medicine is still good medicine," adds Keaton.

"It is conceivable that the resident in this case was not fully knowledgeable about the machinery he was using or the protocols they should follow. Checking any equipment immediately prior to use is prudent practice. When that piece of equipment is crucial to patient safety, such as an anesthesia machine, that final check must be made a gold standard. This is why training and competency assessments must include demonstration of hands-on proficiency, not just verbal understanding. Such teaching and training should include not just how the machine works but also how to troubleshoot problems and what to do in the event of a malfunction during use. In addition to initial training, periodic drills using emergency scenarios may help maintain adherence to proper protocols when a real emergency occurs and may minimize the sense of panic that can cost precious seconds or even minutes when someone's life is in the balance," advises Keaton.

Staff training and education aside, a well-run biomedical program entails a system of checks and balances. Just as preventive medicine should be practiced; the same applies to maintenance of critical machinery.

"This case points out the need for a proactive preventive maintenance program that encompasses periodic equipment checks and calibrations by qualified biomedical engineers. A good biomedical program should include scheduled routine maintenance checks which include a general inspection, assessment of the integrity of electrical circuits and grounding, calibrations as appropriate and checking and, as needed, replacement of parts as recommended by manufacturers. Preventive maintenance functions must be well-documented in an organized and retrievable manner, and records should contain the equipment's history, including past problems [real or suspected] and all maintenance conducted on the piece. Further, preventive maintenance varies by equipment, with the obvious note to check critical, life-preserving monitors more frequently," states Keaton.

If something does go wrong, staff should know how to respond.

"Facility policies and staff education for all employees should include how to manage any malfunctioning equipment. Any real or suspected malfunction should result in the equipment being immediately removed from service, labeled with a highly visible 'Do Not Use' sign, and taken to a designated location away from patient care areas to be forwarded to the biomedical department or shipped to the manufacturer if required by service contracts. Finally, under operation of the Safe Medical Device Act of 1990 [and subsequent revisions], health care facilities are required to report all occurrences in which a medical device is believed to have caused or contributed to the serious injury of death of a patient, including injuries due to user error that are attributable to devise design and/or labeling. This would not include dropping an instrument, but might include poor placement of the valve making it difficult to read, which might have been a factor in this case. Such information must be reported to the Food and Drug Administration using uniform MedWatch forms within 10 working days of the time staff becomes aware of the event.

Reporting under the Act is often handled by the facility's purchasing agent or biomedical program personnel. However, the risk manager should be keep in the loop of anything that is reported and contact with the risk manager should be incorporated into the facility's Safe Medical Device Act policies and procedures," concludes Keaton.

Marco A. Velasquez and Dora Velasquez v. U.S.A., San Diego Superior Court, Case No. 970045 H (LSP). ■

Inadequate security: $3.4 million TX award

News: After completing her hosptial shift, a nurse walked by herself to the parking garage where she was raped. The nurse's total award was $3.4 million. The hospital's security contractors were held liable for one-third of the amount.

Background: On most nights, the 55-year-old nurse finished her 3 p.m to 11 p.m. shift on time. But on the evening of March 7, 1997, she did not clock out until 1:41 a.m. She usually left with others from the shift, passing a security guard on the first level of the hospital's parking garage, and then to the employee parking area on the fourth floor. On this particular evening, she did not use the hospital's escort service and she did not see the security guard. Instead she encountered a man who cut her with a box-cutting knife, beat her, then raped her.

Despite her screams for help, none of the security personnel were close enough to hear. After the assault, the nurse got into her car and drove through the garage to the hospital's emergency room.

The nurse sustained multiple facial lacerations, which eventually necessitated reconstructive surgery. She was permanently disfigured by scarring. In addition, seven tendons were severed in her dominant right wrist and, despite being surgically reattached, she permanently lost full use of her right wrist. Her treating physician indicated at trial that she will require long-term treatment for depression and post-traumatic stress disorder.

Because the nurse had received worker's compensation benefits from the hospital, she was statutorily barred from seeking additional damages from the hospital in accordance with the laws of the jurisdiction. The hospital's security services, however, were provided under contract with a company managed and owned by another company. The plaintiffs pressed their claim against them, saying the security staff had stopped covering that part of the garage at 1:50 a.m, when staff were supposed to patrol until at least 2 a.m.

The contractors unsuccessfully argued that the guard was on duty in another part of the garage. The defendants argued that the nurse did not use the escort service, electing to go to her car alone.

The security contractors filed a third-party action against the rapist, contending the rape and assault incident were solely his responsibility. The rapist is serving a sentence for his criminal conduct in this case.

Prior to trial, the security company offered the plaintiffs $200,000, which was rejected.

The jury divided negligence into these parts: contractor 26%, company that owned contractor 8%, the rapist 51%, and the nurse 15%. The gross award of $3.4 million was apportioned as $1.25 million for past pain and suffering, disfigurement, and physical impairment; $1.1 million for future pain and suffering, distress due disfigurement, and physical impairment; $120,000 for lost wages; $175,000 for future lost wages; $270,000

for past disfigurement; and $50,000 for past and future direct medical expenses.

In addition, her husband was awarded loss of consortium damages of $425,000.

What this means to you: This case illustrates how risk management interacts with other hospital departments, such as security and human resources. The International Association for Healthcare Security and Safety reports an average of 47 sexual assaults every nine years in the United States.

"Undoubtedly, a situation such as this is a security director's worst nightmare . . . a violent sex crime on your premises, an employee, and contract providers. Unfortunately, sexual assaults do happen at health care facilities and must be considered when security management plans are developed," states **Paul Ford**, director of safety, security, and transportation at Tampa (FL) General HealthCare.

"First and foremost, whether security services are contracted out or handled internally, the goal of any hospital security department should be the assurance to staff, patients, and visitors that the hospital is a safe environment. The irony of violent crimes occurring at health care facilities is unfortunately not lost on those with criminal intent, and it is security's responsibility to maintain vigilance against such persons. And, since most hospitals are open for business 24 hours a day, seven days a week, every day of the year, that need for vigilance is ever present and extends from internal hot spots like the emergency room to external sites such as the parking garage," notes Ford.

"When key services are contracted out, it is generally still the institution's responsibility to make sure that those services are operated with the facility's goals and objectives in mind, whether it is with agency nurses, food services, cleaning or security. In this particular instance, the hospital could not be a named party due to workers' compensation statutes. But the hospital still had to deal with the impact the incident had upon the employee, her co-workers, medical staff, and everyone else in the community who used the hospital. Contracting of services has become a cost-savings mechanism for many health institutions. However, the contract must specify what is expected from the contractor. It is critical for hospital personnel to provide oversight and auditing of any contracted service. For instance, local crime rates, current law enforcement warnings, and staff perception must be monitored to adjust manpower and assignments. If security is contracted out, the flexibility to adjust for these factors should be included in the contract. Further, when dealing with contracts that have potential risk management repercussions, risk management should be involved in reviewing the contract to minimize exposure," adds Ford.

"Employees, patients, physicians, and visitors expect the premises to be safe. To ensure continued safety, security directors should review their facility's security management plan on an annual basis. That review should include the involvement of other departments to the extent that they are affected by any of the provisions of the plan. Specifically, parking garages produce their own vulnerabilities. Patrols, closed-circuit television cameras, emergency phones, and lighting can be used to reduce security problems.

"The particular needs of each garage should be assessed after review of past incidents, staff perceptions, the neighborhood, hours of operation, and budget constraints. A 24-hour operation requires 24 hours of security, though some hours are busier than others. Many hospitals have instituted buddy systems and/or escort services for late-shift personnel. While escorts may be a security function, their use should be encouraged by both human resources and risk management. Escorts, like most security activities, are preventive and much more cost effective than dealing with the consequences," concludes Ford.

Susan Elizabeth Lucas and Billy Lee Lucas v. Silver Star Security Inc., f.k.a. Top Gun Security Inc. and Unique Services Inc. v. Charlie Harbert III (Third-Party Defendant), Tarrant County (TX) District Court, Case No. 17-175955-98. ■

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