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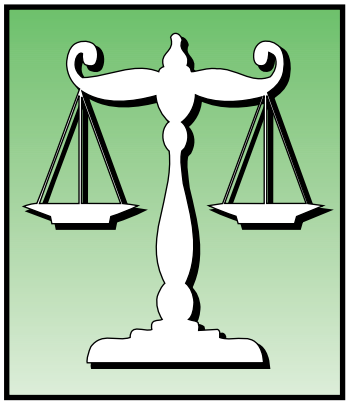

Healthcare Risk Management™

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Salesman in OR leads to state fine, lawsuits after patient death

Investigators claim salesman actually performed part of procedure

A New York hospital is facing major malpractice lawsuits, a state-imposed fine, and a public relations disaster after an incident in which a woman died during what should have been a routine procedure. Investigators claim the woman died because two surgeons made gross medical errors. They also claim that an equipment salesman actually performed part of the procedure.

The incident should be a warning about the risks of allowing salespeople in the operating room without adequate constraints, some observers say. Even though the salesman's alleged participation in the procedure apparently was not the cause of the woman's death, it greatly complicates the defense of the malpractice cases and creates extremely bad publicity for the facility, Beth Israel Medical Center in New York City.

The immediate fallout from the incident was a $30,000 fine imposed on Beth Israel by New York state health officials. The officials concluded that a salesman of hysteroscopy equipment participated in the procedure, actually manipulating the new electrosurgery system because the doctors and nurses did not know how to operate it.

But that is only the beginning of the hospital's troubles. The woman's husband has filed suit against the hospital, both surgeons, the anesthesiologist, and Ethicon, the company whose salesman allegedly participated in the procedure. Ethicon is a division of Johnson & Johnson.

Observers also expect the incident will be considered a sentinel event by the Joint Commission on Accreditation of Healthcare Organizations, obligating the hospital to conduct a thorough analysis of how it happened and how it can be prevented in the future. Sentinel event status is likely because the incident was widely reported in the general media, one of the Joint Commission's main sources for identifying sentinel events, and because it so obviously signals a major problem at the hospital.

The extreme nature of the problem is mind-boggling, says **Sam Bishop**, ARM, vice president of compliance and insurance services for Wellstar Health System in Marietta, GA. Though it is not the first time

he has heard of such an incident, Bishop says hands-on participation by salespeople is obviously wrong.

"This is just a nightmare, a failure of the system that is supposed to protect the patient," he says. "There's no way to make an excuse for this, to make this sound like anything better than what it is. You'd think these things just couldn't happen, but then they seem to pop up every once in a while."

The incident shows that staff may need to be educated and reminded about issues that seem obvious to risk managers and other managers, Bishop says. It may be time to remind surgical staff about proper conduct of visitors in the operating room. **(See p. 5 for more on how such incidents can be avoided.)**

Procedure should have been routine

The incident began in October 1997, according to a report from the New York state health department. Ethicon salesman David Myers reportedly met with Allan Jacobs, MD, chairman of the hospital's OB-GYN department, to introduce an Ethicon product used for hysteroscopies, a minimally invasive procedure. The product, the Versapoint Bipolar Hysteroscopy Electrosurgery System, allows the surgeon to cut and ablate with electrosurgery probes.

Jacobs made no commitment to purchase the product but did not dissuade Myers from seeking the support of surgeons and other administrators, according to the report. Myers arranged to have the product used in surgery about a month later with OB-GYN partners Marc Sklar, MD, and Robert Klinger, MD. The patient, Lisa Smart, 30, was a healthy accountant and financial analyst undergoing hysteroscopy for the removal of a benign fibroid tumor — a routine procedure with relatively little risk.

State health investigators say the OR nurses told the surgeons they were not familiar with the new electrosurgery system, but that the surgeons dismissed the nurses' concerns and said Myers would operate it. The salesman was scrubbed and did operate the electrosurgery system during the procedure, according to the health department report.

However, the report does not claim the salesman's actions led to the woman's death. As a normal part of the procedure, the patient's uterus was filled with saline, and nurses monitored the fluid output closely to make sure the patient was not overloaded with fluids. The salesman reportedly was operating the electrosurgery equipment and had no involvement in the fluid administration. The state report says that a nurse told the doctors several times during the surgery that the fluid output was too low, but her concerns were dismissed.

If the incident happened as state health officials say, the nurses should have reported the surgeons' intent to their supervisors and not proceeded.

But immediately after the surgery, the patient appeared bloated from excess fluid. According to the state report, one of the OR nurses claims Klinger admitted to shutting off the fluid outflow so he could get a better view of the uterus, an action that could lead to fluid overload if not corrected quickly. Klinger denied shutting off the flow or making the statement afterward, according to the report.

As a result of the fluid overload, the woman went into cardiac arrest soon after surgery and died in the emergency department. The autopsy determined she had died of "excessive infusion and absorption of normal saline."

Healthcare Risk Management contacted Sklar's and Klinger's offices to request comments, as well as the attorneys representing both doctors, but the calls were not returned. Beth Israel released a statement saying, "those who acted inappropriately violated Medical Center rules and procedures and have been severely disciplined."

Salespeople in the OR are nothing new, and risk managers have expressed concern about them in the past. **(For details, see *HRM*, "Who**

COMING IN FUTURE MONTHS

- Keeping peer review confidential
- Increase in criminal charges
- Reviewing contracts for exposures
- Reducing drug errors
- How to handle an angry patient

More than 12 violations cited; Ethicon denies claims

One surgeon was already on probation

State health investigators concluded that more than a dozen medical standards were violated in a hysteroscopy at Beth Israel Medical Center in New York City, including the use of equipment not authorized by the hospital and allowing an unlicensed person to operate medical devices.

The report also revealed that one of the doctors, Marc Sklar, MD, already was on a five-year probation from the state office of professional conduct. He was placed on probation in 1997 after 20 charges of misconduct involving the delivery of babies, with the requirement that he be supervised by another physician during the delivery of babies but not during other procedures.

According to the hospital, Sklar resigned his privileges after the fatal hysteroscopy. The other surgeon, Robert Klinger, MD, was suspended for two weeks and now is allowed to resume surgery. He was prohibited from performing other hysteroscopies until after completing further training, the hospital reported.

Healthcare Risk Management contacted Sklar's and Klinger's offices for comments, as well as the attorneys representing both doctors, but the calls were not returned. Beth Israel released a statement saying, "those who acted inappropriately violated Medical Center rules and procedures and have been severely disciplined." The statement also noted that it "from the outset has accepted its responsibility in this case. It immediately notified the New York State Department of Health of the incident, and launched an extensive investigation."

Beth Israel also noted its "plan of correction to the New York State Department of Health details actions — most of which were implemented soon after the incident occurred one year ago — that will prevent such an occurrence from happening again." Because of the impending litigation, Beth Israel officials would not allow their risk manager to comment.

Ethicon spokeswoman **Susan Odenthal** denies the conclusions in the state health department report and says Myers did not participate in the surgery. Ethicon policy forbids salespeople from participating in surgery, and "our information is that the Ethicon representative present during the procedure at Beth Israel Medical Center adhered to that policy, which prohibits him from contact with the patient or medical instrumentation during the surgical procedures." ■

is that performing surgery in the OR? A doctor or a sales rep?" February 1997, pp. 13-15.) The Beth Israel incident raises troubling questions nonetheless. If the state health report is accurate, the nurses knew before the procedure was under way that the salesman would be operating the electrosurgery system, which means there was, presumably, time to try to stop the procedure. The implications of that scenario would differ significantly from those resulting from an infraction occurring after a procedure begins; in that case, the damage may be done before the staff can protest.

A failure to refuse improper orders?

If the incident happened as state health officials say, the nurses should have reported the surgeons' intent to their supervisors and not proceeded with the surgery, says **Margaret Douglass,** MPH, RN, director of risk management at FPIC, a physicians' insurance company based in Jacksonville, FL. Such an incident would serve as a clear example of a situation in which nurses must refuse improper orders and report the problem through the chain of command, she says.

"Absolutely, the nurses should know just from being a nurse that it's not right for a salesperson to perform patient care," she says. "They should have questioned the doctor's orders on the spot and then should have run right out and grabbed their OR supervisor. This certainly was out of the ordinary, and they should have acted to protect the patient."

If the nurses did not refuse unusual instructions, it would raise questions about their nursing education and Beth Israel's risk management program, according to both Douglass and Bishop. If *they* were risk managers at a hospital where such an incident happened, both say they would question their risk management efforts and wonder how nurses and physicians could feel comfortable with allowing it to happen.

"It would signal some major problems within the facility that I, as a risk manager, would feel somewhat responsible for," Douglass says. "I would want to see the policies in place at the time, the chain of command policies, and shoot the charts through peer review to see if any education is needed for the physicians involved. In addition to the chain of command questions, I'd want to know whether there had been any education on fluid overload."

Bishop and Douglass question why the nurses might not have followed the chain of command, both surmising that nurses *must* realize a salesperson's participation in a procedure is wrong. That question remains unanswered, but Bishop and Douglass speculate that young nurses might be intimidated, or, conversely, more experienced nurses might be so comfortable with the doctors that they trust them even after such unusual instructions.

Who was protecting the patient?

Bishop acknowledges it might be very stressful for a nurse to challenge a surgeon's instructions, and if the surgeon persisted with the plan, to invoke the chain of command. Nevertheless, he says this action must be expected of nurses and any other staff who have knowledge of improper care. He suggests the circulating nurse may have to take the initiative if the surgery is under way.

"The circulating nurse should have slipped out of that room and invoked the chain of command," he says. "Nobody wants to encourage staff to ignore physicians' orders when they're legitimate, but the nurse has to do what is necessary to protect the patient."

Bishop tells *HRM* it is rare for nurses to have to go that far to protect the patient, but he has seen it happen. He once had a nurse invoke the chain of command during a surgical procedure because she felt the doctor was exhibiting psychotic behavior and was not capable of operating.

"She called it to his attention, but he continued with the procedure," he says. "She was very concerned, so she slipped out and called the chief of service, who removed the doctor during the procedure. That's the way it's supposed to work." ■

For More Information

- **Margaret Douglass**, Director of Risk Management, FPIC, 1000 Riverside Ave., No. 800, Jacksonville, FL 32204. Telephone: (904) 354-5910.
- **Sam Bishop**, Vice President of Compliance and Insurance Services, Wellstar Health System, 805 Sandy Plains Road, Marietta, GA 30066.

Visitor's involvement fundamental to lawsuit

A malpractice case against Beth Israel Medical Center in New York City and the doctors involved will be greatly complicated by a New York state health department report that says a salesman participated in the surgery, say risk managers who have reviewed the allegations.

Even though the report from the state health department does not conclude that the salesman's actions led to the patient's death, the allegation that he performed part of the procedure will be a fundamental element in the lawsuit, says **Sam Bishop**, ARM, vice president of compliance and insurance services for Wellstar Health System in Marietta, GA. "It doesn't matter that he didn't cause the fluid overload," he says. "There's no way you can support having a nonlicensed person performing a licensed function. [If he did what the report said], he was practicing medicine, and there's no way you can defend that."

Tort litigation requires the plaintiff prove damages, so the patient may have had a hard time bringing a malpractice case against the hospital if all had gone well in the procedure. In fact, if the salesman did participate, and the outcome was good, it may never have been discovered. If a salesman's participation in a successful surgery were discovered, however, Bishop says the patient still could report the improper conduct to state health authorities.

Because the patient died from the procedure, the malpractice suit is inextricably linked with the salesman's actions. The plaintiff's attorney could argue that his alleged participation somehow contributed to the death, or his alleged participation could be introduced as evidence of sloppy practices at the hospital. Either way, the jury would be presented with a very disturbing image of a salesman operating on a woman.

"It will be very much an issue if a lay jury hears this case," Bishop says. "A lay jury probably will escalate this to a punitive level because they just will not accept this scenario or any explanation for it. A jury won't care that the salesman's actions weren't directly responsible for the death."

Observers expect the hospital and the physicians to settle for a large sum to keep the case away from a jury.

Another legal consideration is noted by **Margaret Douglass,** MPH, RN, director of risk

management at FPIC, a physicians' insurance company in Jacksonville, FL. She says a salesman performing any part of a procedure could be charged with battery. And if so, it is possible that the hospital, physicians, and staff could be roped into criminal charges for allowing him or her to commit battery with a patient under their care.

In this case, the dead woman's husband, a police officer, has asked that criminal charges be filed against the two surgeons and the salesman. The New York state education department, which licenses doctors, reports there is evidence Myers practiced medicine without a license. The department recommended that local authorities prosecute Myers on criminal charges.

To help avoid such a fiasco in your own facilities, Douglass and Bishop advise you to establish two policies on OR visitors, if you have not already done so, and formally remind staff about the policies, even if you have reminded them before. The first policy should require that physicians obtain informed consent from the patient for any unlicensed visitor to the OR, including salespeople. The second policy should state that the visitor must never touch the patient or operate medical equipment in any way.

That second policy may seem painfully obvious, but Bishop and Douglass say it is necessary to remind staff and visitors. ■

Most hospitals allow salespeople in the OR

Although you hope they aren't poking around in the patient, salespeople are a common sight in almost any hospital's operating rooms. That is the conclusion of a recent report from ECRI, the independent health care research organization in Plymouth Meeting, PA. Researchers there recently conducted a survey of 180 hospitals and found it is common to find salespeople and other types of visitors in hospital operating rooms. A firm 95% reported they allow salespeople and others to be present during surgery.[1]

Ostensibly, the salespeople are there only to give pointers on how to use a surgical item and to schmooze with decision makers who are trying out the new items. But sources tell *Healthcare Risk Management* it is not exactly a rarity for a salesperson to step over that line and actually use the instrument on the patient, especially during high-tech procedures in which the salesperson might be much more familiar with the device than the surgeon.

A New York case in 1979 is one of the few instances in which such an incident was documented. The patient did not die, but a malpractice case resulted in a $1 million settlement. **(See *HRM*, February 1980, p. 157.)** The case involved a total hip arthroplasty. The patient claimed the two orthopedic surgeons allowed a salesman to perform most of the procedure, making the existing hip problem worse. The surgeons said the salesman did not participate, and the case was settled without establishing the facts. The hospital agreed to pay $275,000, and the surgeons paid the remaining $725,000.

Tips for developing OR policy

Although nearly all of the hospitals surveyed by ECRI allow salespeople in the OR, there were many different policies regarding their presence, and some facilities had no policy specifically addressing them. ECRI advises having a policy that outlines exactly what is and is not acceptable. The group makes these suggestions:

- **Obtain a legal release and require prior approval.** The company represented by the visitor should provide a document releasing the hospital from any liability related to the sales representative's presence. Any visitors, including sales representatives, should be required to make appointments to visit the OR. Even with an invitation from the surgeon, the visitor should notify the OR manager and obtain permission.
- **Make sure the visitor knows proper OR conduct.** Any non-OR personnel must be educated, either with written materials or an informal verbal discussion, on topics such as OR apparel, traffic patterns, avoiding the sterile field, universal precautions, fire safety, electrical safety, and radiation safety. The education does not have to be repeated for each procedure if the visitor has been in the OR before, but ECRI advises at least an informal reminder if this is his or her first time in your facility's OR.

Document any noncompliance with proper OR conduct, including accidental violations. Report the incidents to the OR manager, who should have the authority to ban the visitor from the OR for causing serious disruptions.

- **Do not take any guff from the salesperson.** The salesperson or other visitor is always a guest in your OR and should act accordingly. If you

determine that the OR is too crowded to allow the visitor even though there was prior approval, for instance, your determination is final. Do not let the salesperson argue about it.

The visitor also must comply with any instructions in the OR, and if the visitor interferes with the procedure in any way or upsets any member of the OR team, he or she should be told to leave immediately.

• **Prohibit wandering.** If the visitor is allowed to observe surgery, he or she should be escorted to and from the OR area. Clearance to observe the surgery should not be construed as clearance to wander the OR area and chat with anyone in sight. The visitor should not be allowed in the doctors' lounges unless invited there by a doctor.

Reference

1. ECRI. Managing the risk of sales representatives in the operating room: an HRC survey. *The Risk Management Reporter* 1996; 15:1-7.

2. Salesman-surgeon case settled for $1 million. *Hospital Risk Management* 1980; 2:157. ■

Ethics can coexist with corporate compliance

Integrity approach can be more cost-effective

Now that most health care institutions have accepted the idea of having a corporate compliance officer, some are discovering that a good approach is to place corporate compliance under the larger rubric of "corporate ethics." While the two concerns are not necessarily the same, they can work well together, says **Mary Ann Bowman Beil**, MS, corporate ethics and compliance officer at Memorial Health in Savannah, GA.

Beil spoke on the issue at a recent meeting of the American Society for Healthcare Risk Management in San Diego, telling attendees that many providers set up their corporate compliance programs under the heading of corporate ethics, business conduct, or business practice. That can work if you follow a strategy based on integrity and not simply a strict legal compliance, she says. "Legal compliance and corporate ethics are not the same, but they can coexist. Understanding the difference between having a legal compliance program only and having a compliance program implemented in the context of a broader commitment to corporate ethics are two entirely different approaches to implementing compliance."

An integrity-based program is more likely to create an "authentic compliance posture" rather than just putting on a good face based on the most recent recommendations or enforcement patterns, Beil says. That approach also assumes upper management will integrate compliance in day-to-day business conduct, instead of a strictly legal approach that sets up the compliance officer as the corporate watchdog. "The corporate watchdog may get things done right now, but that is a far less-effective compliance strategy in the long term," she says. (Beil also offered a few compliance tips from her experience as the ethics and compliance officer at her institution. **See box, p. 11, for some of her advice**.)

Integrity can save money

Beil says an integrity-based approach can be even more cost-effective for the institution. If compliance is completely integrated within upper management, there is no need to create a new cost center with additional staff. Placing corporate compliance within the ethics heading also meets the federal recommendations that the corporate compliance officer not be part of the office of legal counsel. Placing the corporate compliance officer within the ethics division instead of the legal department draws a clear distinction, but it also creates some problems.

"The relationship between the compliance officer and legal counsel is a complicated one," Beil says. "The very nature of performing the most remedial tasks of compliance in the current health care environment is of concern to counsel. The requisite levels of education and the discussions of this complex regulatory environment with employees increase the amount of conversation and speculation of what may or may not be fraudulent in the institution. This conversation and speculation in and of itself is cause for concern."

Legal counsel also might find written communications from employees to the compliance officer are a serious danger, she says; the communications will be filled with allegations, all discoverable.

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Consider these tips from ethics, compliance officer

These tips on corporate compliance are from **Mary Ann Bowman Beil**, MS, corporate ethics and compliance officer with Memorial Health in Savannah, GA:

• **Pull shift reports and exit interviews for review.** "They can be the best source of the *real* problems at your facility," she says. "These are the problems that people know are threatening patients, but they are frustrated by what to do about it." A good example would be staffing shortages that threaten patient safety. Beil reported feeling a chill when she read a shift report in which a frustrated nurse complained of short staffing and added, "Don't say I didn't tell you Rome was burning."

• **Tell physicians not to fear the hotline.** Physicians often fear that the compliance hotline will be used to report allegations of malpractice and other problems involving them, but Beil says that has not been the case at her institution. In the first year of the hotline's availability, physicians used it to report problems themselves seven times more often than they were reported on the hotline by others.

• **Appoint a medical director of compliance.** This should be a physician who is in charge of compliance issues involving physicians. He or she will act as a liaison to the medical staff, in addition to dealing directly with some medical issues involving compliance. "A medical director of compliance greatly facilitates taking issues to the medical staff, who otherwise can see you as unqualified to talk to them about compliance issues," she says. ■

(Continued from page 6)

"The truth of the matter is that while counsel is dedicated to protecting the institution from any and all risks, the compliance officer introduces a function that is largely antithetical to the basic premise of the legal counsel."

Such problems can't be dismissed lightly, she says, but an integrity-based approach to corporate compliance still is a better approach than one that emphasizes short-term technical compliance with laws and recommendations from the government. "Long after the fraud and abuse investigations have died down, an integrity-based compliance program will enhance the quality, the patient satisfaction, and the management of the institutions in which the programs were implemented." ■

Joint Commission addresses confidentiality

Contractual methods may protect your records

Confidentiality concerns regarding sentinel events can be addressed in part by making the Joint Commission on the Accreditation of Healthcare Organizations a kind of partner in your health care organization, according to newly released advice from the group.

The Joint Commission released the advice as part of a "Dear Colleague Letter" dated October 23, 1998. Such letters are the Joint Commission's official way of communicating new developments and recommendations to providers. The most recent letter outlines some of the latest changes to the controversial sentinel event policy. **(For a report on those changes, see *Healthcare Risk Management*, December 1998, pp. 145-149.)**

New ways to protect information

But in addition to the policy changes, the Joint Commission offers contractual methods that might improve your protection of confidential information in the sentinel event system. The options were developed with the assistance of the sentinel event legal issues task force, which includes representatives from the American Society for Healthcare Risk Management. These are the suggestions:

• Identify, through written agreement, the Joint Commission as a participating entity in the organization's peer review or quality improvement activities.

• Appoint the Joint Commission to the organization's peer review or quality improvement committee.

Using one or both of those options should clarify that "the Joint Commission is not an external third party in the limited context of an intensive assessment of a sentinel event and, therefore, no waiver of confidentiality protections has occurred by sharing sentinel event-related information with the Joint Commission," the letter states. The Joint Commission says these options, especially the first one, should help you comply with the sentinel event policy without giving up confidentiality.

The Joint Commission also used the letter to offer clarifications of some issues that have caused confusion recently regarding sentinel events. Here are some of the clarifications:

Joint Commission, NCQA call for more privacy protections

Patients may withhold crucial information

Saying patients may withhold important information because they fear losing their privacy, the Joint Commission on the Accreditation of Healthcare Organizations and the National Committee for Quality Assurance (NCQA) are calling for measures that will improve protections on patient privacy.

Patients' reluctance to divulge information could result in an increased risk of misdiagnosis and improper care, according to a report released jointly by the two groups. They say they will consider additional accreditation requirements to encourage managed care groups and other providers to improve the ways they protect patients' privacy.

Their recommendations include establishing periodic audits that ensure compliance with confidentiality policies, improved informed consent procedures for patients to release confidential health information, and more education of consumers about how medical information is used.

The Joint Commission and the NCQA noted that research activities need more attention and urged managed care organizations to look at how patient confidentiality might be better protected in research studies. ■

• An on-site visit to discuss the root cause analysis or otherwise hear of the provider's analysis will cost $2,300. But a "for cause" survey, conducted when the Joint Commission thinks there is an ongoing threat to patient safety or a significant noncompliance with standards, will cost $3,500.

• Only 60% of initial root cause analysis submissions have met the established "thorough and credible" criteria. The Joint Commission urges providers to seek help from the commission before starting the review process. "We will respond to generic or 'what if' questions," the letter states.

• The Joint Commission says it has no intention of disclosing information about sentinel events during the review process. If someone asks the Joint Commission about the accreditation status of an organization that has experienced a reviewable sentinel event, the organization's accreditation status will be reported in the usual manner without making reference to the sentinel event, the letter states.

"If the inquirer specifically references the sentinel event, the Joint Commission will acknowledge that it is aware of the event and is working with the organization through the sentinel event review process," the letter says.

(*Healthcare Risk Management*'s experience with the Joint Commission supports that position. When *HRM* asks about known sentinel events, the Joint Commission representative acknowledges that he or she knows of the event but says little beyond that.)

The letter goes on to stress that the Joint Commission "scrupulously maintains the confidentiality of organization-specific sentinel event-related information in its possession. Sensitive documents are eventually returned to the organization or destroyed."

However, information about or resulting from a "for cause" survey will be disclosed to the public on request. ■

Major changes likely from feds next year

Look for erosion of ERISA protections for MCOs

Regulatory pressures continue to mount in the nation's capital and will result in significant, far-reaching changes in the next year, warns **Mark Kadzielski**, JD, a partner-in-charge with Epstein Becker & Green in Los Angeles. He told attendees of the recent meeting of the American Society of Healthcare Risk Management in San Diego that state and federal legislators have done a lot of posturing so far about important issues and probably will take action soon.

David Manoogian, JD, a senior partner with the Washington, DC, office of Epstein Becker & Green, reiterated that message. He stresses that one of the biggest threats to health care providers comes from the potential changes to the Employee Retirement Income Security Act of 1974 (ERISA). Managed care plans currently enjoy a number of legal protections under ERISA, but threatened changes in ERISA may erode many of the firewalls that protect managed care plans from action in state courts. ERISA survived the most recent legislative session unscathed, but he says that probably will not be the case next year.

The most likely change will be to abolish employers' tax advantages for providing employee health care benefits, he says. "The word on the street is that the Republicans will try to abolish all employer-sponsored health care. The rumor is they are going to do it through the tax code. In exchange, they're going to try to get the employer to give the income directly to the employees, who will use it to buy their own health insurance."

But he says that would be a disaster for health care providers because it is unlikely that most employees would use that money to buy health insurance. Those people are still going to get sick and come to your hospital, though, and that means health care providers could face a staggering increase in unpaid medical bills.

"This would be an absolute catastrophe," he says. "On a scale of one to 10, for us in this room it would be a 10 catastrophe."

If Congress follows the same pattern it established in the past session, there will be several different threats to ERISA in the next year, he says. The biggest threat could be HR 4250, the Patient Protection Act of 1998, which was introduced by the House Republican leadership. The bill passed the House of Representatives in the 1998 session in only seven weeks, an enthusiastic response he calls "stunning."

More bills that erode ERISA

That bill was not as detrimental to ERISA as some other proposed changes, but Manoogian says its quick acceptance signals an attitude in Congress that should be troubling for health care providers. Another troubling bill was the Patient Access to Responsible Care Act of 1997 (PARCA), introduced in the House as HR 1415 and in the Senate as S 644. He says he expects PARCA to be introduced again next year. It also would erode the ERISA protections.

Kadzielski also warned risk managers that more trouble from the Health Care Financing Administration is coming in the next year. Congressional leaders are putting a lot of pressure on HCFA to crack down on providers, so he says there will be a stiffening of the requirements providers must meet to participate in Medicare and Medicaid. The "conditions of participation" will modified in the next four to six months, he predicts. The likely changes include efforts to ensure patient rights and improve patient admissions, assessment, plans of care, actual care, and quality assessment.

"Be on the alert for some of these changes because they are going to create some real liability issues," he says. He adds that those in the know expect the government to put more effort in enforcing the Emergency Medical Treatment and Active Labor Act. ■

For More Information

❑ **Mark Kadzielski** and **David Manoogian**, Epstein Becker & Green, 1227 25th St. NW, Washington, DC 20037-1156. Telephone: (202) 861-0900. Fax: (202) 296-2882.

Outpatient clinics may hold hidden exposures

The acquisition and merger game continues unabated in health care, and that puts a burden on risk managers to spot hidden liability exposures when their organizations take on new clinics, says **Debra McBride**, JD, assistant vice president for risk management at Midwest Medical Insurance Company in Minneapolis.

Acquiring or merging with another clinic can bring a host of problems because you are taking on whatever risks previously existed in that clinic, McBride says. Even though you had nothing to do with creating or tolerating those problems, they're yours now. She warned members at the recent meeting of the American Society for Healthcare Risk Management in San Diego that they should go over each merger or acquisition carefully to spot the hazards.

Many of the hazards are the result of a less formal operation than demanded by most larger health care providers with a solid risk management program. These are some of the potential hazards she noted:

1. **Inadequate record keeping.**

Many small clinics are run with a more casual approach than you would tolerate in your own facility. That can include record keeping, which may need to be improved. For instance, McBride notes that clinic physicians may be in the habit of giving away free samples of medication without

noting them in the patient charts. That can become a liability issue if the patient's future treatment suffers because there was no record of the previously issued medications.

2. **Improper patient transfers.**

Clinic staff may be comfortable with occasionally using their private vehicles to transfer patients, but that habit carries a number of liability risks for both employee and employer. It should be stopped.

3. **Inadequate staffing.**

Small clinics often are working on a shoestring budget, and that means they sometimes have nonmedical staff providing some care, such as giving injections.

That sort of thing is overlooked in the small clinic, but you can't let it continue because it is a significant liability risk.

4. **Extended clinic hours.**

If the clinic is open late, or even 24 hours because it is an urgent care facility, those extra hours can cause concerns you might not have to deal with in your other off-site facilities.

Such late hours can increase the chance of violence against patients and staff, particularly if there are narcotics on site that could attract thieves.

5. **Credentialing.**

The clinic staff may have to meet credentialing standards within your organization they did not have to meet previously. It would be risky to allow the clinic staff to meet a lower credentialing standard than that found elsewhere in your organization.

A plaintiff's attorney would ask why you thought it was OK for clinic patients to be treated by a less-qualified provider than patients at your other facilities. ■

For More Information

- **Debra McBride**, Assistant Vice President for Risk Management, MMIC, 6600 France Ave. S, Suite 245, Minneapolis, MN 55435. Telephone: (612) 922-5445. Fax: (612) 922-7323. E-mail: Debra.mcbride@mmic.com.

New baby tags help thwart kidnappings, switching

The effort to prevent baby kidnapping and switched identities is focusing more and more on high-tech solutions. The latest is an umbilical cord clamp with an ID number that can be part of an elaborate security system within the hospital.

About 200 hospitals across the country have adopted the Prosec Infant Identification System, manufactured by Prosec Protection Systems in Lakewood, NJ. The system is different from many identification systems in use now because it depends on a tag attached to the baby's umbilical cord instead of just the wrists and feet. That offers several advantages, according to **Michael Lutz**, CPA, president of Prosec.

First, the umbilical cord tag is hidden from view so that a potential kidnapper would not be tempted to tamper with it and or try to remove it. Secondly, the tag is clamped on the cord in such a way that it can be removed only with a special tool, unlike some wrist and ankle bands that could be cut off or forced off the appendage. The umbilical clamps also avoid the occasional problem of wristbands slipping off the babies when they lose weight after birth.

Once burned, twice shy

Many identification systems and alarms are available, but the Prosec system has been getting a lot of attention lately. One of the newest users is the University of Virginia Medical Center in Charlottesville, which was the site of a widely publicized identity mix-up that resulted in two babies being sent home with the wrong mothers three years ago. The mix-up was not discovered until July 1998, after one child lost her parents in an automobile accident.

A recently released report from the Charlottesville police says the mix-up apparently happened when one or more of the babies' wrist and ankle bands slipped off in the nursery. Police concluded there was no evidence of intentional switching, and the identities were exchanged while the babies were in the nursery together.

That incident prompted the medical center to investigate ways to improve its baby identification, and it is now trying the Prosec system, says spokeswoman **Marguerite Beck**. The hospital is phasing in various security improvements and

expects the Prosec system to be adopted fully after more testing. In addition to the new clamps, the hospital has installed 24-hour surveillance cameras in labor and delivery, added unique identification badges for staff allowed to handle babies, and installed delayed egress doors in some areas.

Beck says hospital officials were attracted to the Prosec system because the umbilical cord clamps seemed to offer an extra measure of security beyond the typical wrist and ankle bands. Like many facilities, UVA formerly used a system of three identification bands — one for the baby's wrist, one for the baby's ankle, and one for the mother's wrist. Now they are using two ankle bands for the baby (any type of band is less likely to slip off the foot than the wrist), the Prosec umbilical cord clamp, and a wristband for the mother.

UVA may add more protections

The umbilical clamps are used only as an extra layer of identification at UVA right now, but Beck says hospital officials expect to add electronic security measures that Prosec offers in conjunction with the clamps. The clamps can come with a transponder that is monitored by panels hidden in ceilings, making it possible to sound audible alarms, notify the nurses' station, and lock doors and elevators when a baby is moved beyond acceptable areas.

The system can be integrated with surveillance cameras and fire alarm systems. The cost of the Prosec system varies depending on which elements are purchased, but a monitoring system for one door costs $3,995. An elevator package costs $4,950, and a bypass keypad, which shuts off the alarm to allow staff or parents to take the baby off the floor, costs $375.

Prosec reprocesses the clamps, sterilizing them and applying new identification numbers. The cost varies from $7.50 to $12 each, depending on what the hospital wants included in the kit. ■

For More Information

❑ **Michael Lutz**, President, Prosec Protection Systems, 19255 Swarthmore Ave., Suite 3, Lakewood, NJ 08701. Telephone: (800) 776-7328. Fax: (732) 886-1486. World Wide Web site: http:\\www.prosec.net.

Telemedicine increasing liability exposures

Ready or not, telemedicine appears to be taking a more prominent role in health care delivery, and that could mean a significant increase in liability exposure if you do not take the proper steps to ensure this technology meets the same standards of care you demand of more traditional health care scenarios. Some words of advice on lowering the telemedicine risk were offered recently at a meeting of the American Society of Healthcare Risk Management in San Diego by **Judith Klein**, PA, a senior risk management specialist with OHIC Insurance Company in Grantville, OH, and **Patricia Meador**, MSN, MPH, JD, an attorney with Woble Carlyle Sandridge & Rice in Durham, NC.

Klein told attendees that telemedicine is gaining prominence in radiology, pathology, dermatology, ophthalmology, psychiatry, home health care, correctional medicine, and the transmission of

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Editor: **Greg Freeman**, (404) 320-6361.
Publisher: **Brenda Mooney**, (404) 262-5403, (brenda.mooney@medec.com).
Executive Editor: **Susan Hasty**, (404) 262-5456, (susan.hasty@medec.com).
Production Editor: **Terri McIntosh**.

Editorial Questions

For questions or comments, call **Greg Freeman** (404) 320-6361.

electroencephalograms and electrocardiograms. From a technology standpoint, those are wonderful innovations, she says. But from a risk manager's viewpoint, telemedicine comes with a host of serious questions about standards of care, licensure, credentialing, informed consent, management of records, confidentiality, and other issues.

"For instance, at what point does the MD-patient relationship exist?" she asks. "Does the type of telemedicine technology being used make a difference? More and more questions come up every time you look at this issue."

There are more questions than solid answers at this point, but Klein and Meador offer these suggestions that cover the areas in which the right path is clear:

• **Do not allow your staff and physicians to practice telemedicine without constraints.** The most apparent problem is the issue of privileges. If your staff use telemedicine to consult with a remote physician, for instance, that remote physician should have privileges at your facility if he or she is providing direct patient care or interpretation that will be entered into the patient's record. If the remote physician is providing only consultation, with no patient care or interpretation in the medical record, privileges are not necessary.

• **Enact a policy that requires all your facilities to adhere to telemedicine rules.** A system-wide policy should require all your facilities to follow the same rules regarding telemedicine, with particular attention to the requirement that only providers credentialed at the facility are to use the facility's telemedicine apparatus. It is unacceptable for others to "borrow" the telemedicine technology if they are not credentialed to practice at the facility.

• **Use the same informed consent guidelines that you would use for other care.** Treatment consent forms should include authorization to photograph, videotape, and otherwise record the patient's likeness and medical information.

• **Remember that telemedicine must meet all standards of care that would be applicable in less high-tech situations.** In other words, it is never acceptable to lower your standards to accommodate the telemedicine technology or the limitations of your telemedicine system. If the doctor can not see the patient clearly enough to render a diagnosis or opinion, the physician should say so and decline. If the patient needs a test before the physician renders an opinion, it should not matter that the test will disrupt a telemedicine session for which 100 people have gathered to watch in different sites.

• **Keep detailed records of telemedicine use.** In addition to all the typical medical records, your providers should record information about the telemedicine use. The telemedicine records should include the patient name and identification number, date of service, referring physician, provider facility, type of evaluation performed, informed consent, evaluation results, diagnosis or impression, and recommendations for further treatment.

• **Investigate how your professional liability policies cover telemedicine.** Insurers cover telemedicine in different ways, with some providing much more coverage than others and some leaving the question essentially unanswered. Ideally, your policy should state the limitations on coverage related to telemedicine or state that telemedicine is covered as any other service as long as standards of care are met. ■