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Wrong-site surgery: Officials now recommending zero tolerance

They say there's no reason for one more wrong-site error

Voicing ever stronger concerns that the health care community still is not doing enough to prevent wrong-site surgery, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) recently called on all providers to adopt a no-nonsense, zero-tolerance policy toward that grave error. There is no excuse for performing a procedure on the wrong body part, wrong person, or the wrong procedure on the right patient, say leaders from the Joint Commission and virtually every specialty medical organization.

The nearly universal endorsement of steps to prevent wrong-site surgery creates a de facto standard of care for which your organization will be held accountable, they say. But spot checks show that more than a third of providers are not following the required steps, JCAHO reports.

More than 40 organizations now have endorsed a new Universal Protocol to standardize pre-surgery procedures for verifying the correct patient, the correct procedure, and the correct surgical site. The protocol focuses attention on marking the surgical site, involving the patient in the marking process, and taking a final timeout in the operating room to double check information among all members of the surgical team. **(For more details on what the Universal Protocol requires, see www. jcaho.org and *Healthcare Risk Management*, September 2003, pp. 97-100.)**

In announcing the widespread endorsement of the Universal Protocol, JCAHO president **Dennis S. O'Leary**, MD, emphasized that wrong-site surgery still is a problem despite years of intense focus by JCAHO and other organizations such as the American College of Surgeons (ACS) in Chicago. Despite issuing *Sentinel Event Alerts* about wrong-site surgery in 1998, and again in 2001, JCAHO continues to receive five to eight new reports of wrong-site surgery every month, O'Leary reports. The Joint Commission's new National Patient Safety Goals, which became effective Jan. 1, 2003, include a goal to eliminate wrong-site surgery.

"Despite the know-how that we have to prevent these occurrences,

wrong-site, wrong-procedure, and wrong-person surgery remains a significant national problem today," O'Leary says. "We have been addressing wrong-site surgery for five years, but the problem persists. The Joint Commission received over 60 wrong-site surgery reports in 2002, and already we have received over 50 in 2003. And these are only the cases where organizations have voluntarily decided to share the information with us or we have learned about them from the media."

Universal Protocol promises to reduce errors

The answer to the ongoing problem is strict adherence to the Universal Protocol, O'Leary says, and many health care leaders agree. The Universal Protocol grew out of a May 2003 summit convened by JCAHO, in collaboration with the American Medical Association, the American Hospital Association, the American College of Physicians, the ACS, the American Dental Association, and the American Academy of Orthopaedic Surgeons. More than 30 organizations were represented at the summit. Summit participants quickly reached consensus that a Universal Protocol would help to prevent the occurrence of wrong-site, wrong-procedure, and wrong-person surgery, O'Leary says. The participants also agreed that the protocol should be specific, both to eliminate confusion about surgical site marking and to facilitate communication among surgical team members, and that it should provide the flexibility needed for unique surgical situations.

"With physicians, nurses, and other practitioners — as well as health care organizations themselves — standing behind this Universal Protocol, we have a real opportunity to reach our collective goal to eliminate this problem," O'Leary says.

The Universal Protocol officially becomes effective July 1, 2004, for all JCAHO-accredited hospitals, ambulatory care surgery centers, and office-based surgery sites. Compliance may require substantial changes in policy and procedure at some hospitals, he says. Though much of the protocol already has been in place as part of the Patient Safety Goals, O'Leary says recent unannounced JCAHO site visits have revealed that 36% of accredited organizations are not marking the operative site.

Diligence can eliminate errors

The ACS is a major proponent of the protocol, and executive director **Thomas R. Russell**, MD, FACS, says risk managers should require strict adherence. The protocol is more than just a good idea, he says — it's an absolute necessity.

"Wrong-site, wrong-person, wrong-wrong procedure errors should no longer exist in our hospitals or our ambulatory care centers throughout the United States," he says. "Though this is not a particularly frequent event, we had 60 reported [in 2003], and clearly there were more than that. This protocol should eliminate that problem."

Russell says one of the most important parts of the Universal Protocol is the concept of a time out during which all members of the team, not just the surgeon, pause to discuss whether any concerns or questions remain.

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Editor: **Greg Freeman**, (770) 998-8455.
Vice President/Group Publisher: **Brenda Mooney**, (404) 262-5403, (brenda.mooney@thomson.com).
Editorial Group Head: **Lee Landenberger**, (404) 262-5483, (lee.landenberger@thomson.com).
Production Editor: **Nancy McCreary**.

Editorial Questions

For questions or comments, call **Greg Freeman**, (770) 998-8455.

"This is an important time when all members of the team can come to an understanding about this procedure and this patient before the anesthetic is administered," he says. "We are most enthusiastic about this. We believe that if hospitals and health care providers adopt this Universal Protocol, we can eliminate this problem."

That prediction is supported by **James H. Herndon**, MD, president of the Rosemont, IL-based American Academy of Orthopaedic Surgeons, which first promoted the idea that surgeons should sign their names or otherwise mark directly on the correct operative site to avoid wrong-site errors. That practice now is included as part of the Universal Protocol. Herndon says that, unlike some medical errors, wrong-site surgery is 100% preventable.

"One more incident of wrong-site surgery is one too many," he says. "If all health care providers commit to following this protocol, wrong-site, wrong-procedure, wrong-person surgery can become obsolete."

Some room for judgment calls

Though the proponents call for strict adherence to the protocol, they also acknowledge that there is some question as to exactly what procedures require use of the protocol at all. Obviously, is it necessary for surgical procedures in a hospital operating room, but what about a procedure performed on an outpatient basis in a physician's office with no assistants?

JCAHO's O'Leary says some judgment will be necessary in those situations. But even if the entire Universal Protocol is not necessary for such situations, the practitioner still should follow the intent of the protocol by taking the time to verify the procedure details before proceeding.

"Things like marking the site can be appropriate even for simple procedures, and taking the time out to verify that everything is correct can be a useful thing to do," he says. "My experience is that even with an office procedure you usually have some nursing support and being able to use that to play back and verify is helpful, at least in procedures involving some risk."

Russell agrees that "judgment will be necessary because obviously the Universal Protocol will not be appropriate in some procedures performed in a doctor's office." But he also encourages practitioners to use at least some components of the protocol that might be appropriate.

"We'd like to see the protocol used outside the hospital, and even in the hospital it isn't just for the operating room," he says. "I think the protocol would be appropriate in cath labs and GI labs in hospitals."

Should lower malpractice risk

Proponents of the Universal Protocol say it should lower a hospital's malpractice risk. Russell says a hospital can cut its wrong-site malpractice risk to zero by following the protocol religiously.

"This is malpractice," he says. "It's hard to defend one of these cases. That's why they're generally settled out of court."

O'Leary notes that a provider could *increase* its malpractice risk by not complying with the Universal Protocol now that it is so universally accepted as the standard of care an effective means for preventing the error.

"If a specific injury can be linked to a national requirement and you can make a persuasive case for it, that exposure exists today," he says. "I guess you could say that the Universal Protocol amplifies that risk."

One surgeon who performed wrong-site surgery says the Universal Protocol could have prevented his mistake. **Arnold A. Zeal**, MD, FACS, chief of neurosurgery at Baptist Health

System in Jacksonville, FL, was performing a lumbar disc operation and intended to approach the disk from the right to look for a bone fragment. But instead he approached the disk from the left and could not find the fragment.

"I could never understand how this could happen until I had the unfortunate experience of performing wrong-site surgery myself," he says. "Fortunately, there was no real injury to the patient, but the procedure was truly devastating not only to the patient but also to myself. When I started investigating, I found that it was much more common than I ever imagined. I became acutely aware of the need for a protocol to prevent this from happening again, and also how the operative team needs to be involved to prevent these instances."

In his case, Zeal says he never realized he was on the wrong side until the procedure was complete. When he couldn't find the bone fragment he was looking for, he kept searching and taking X-rays, but the X-rays were side views that don't indicate which side of the patient they depict. After realizing the problem, Zeal operated on the patient an hour later and removed the fragment from the correct side.

"I think the protocol would have totally prevented this. If we had a mark on the appropriate side, if we had a time out, if we had a checklist, I think all of that would have prevented it," he says. "It was not my usual operating room and not my usual operating staff, and nobody raised the issue of which side of the patient I was standing on. That would have been corrected if we had a protocol and the marking." ■

Surgeon or nurse should mark the operative site

At a recent press conference concerning the Universal Protocol to prevent wrong-site surgery, proponents answered some of the most frequent questions about how to follow the protocol:

Question: Is it necessary for the surgeon to mark the operative site or would it be acceptable for the patient to write the word "yes" on the operative site? How about having a nurse do it?

Answer: James H. Herndon, MD, president of the Rosemont, IL-based American Academy of Orthopaedic Surgeons, says research shows that patients cannot be trusted to mark the site themselves. "They often are incorrect, forgot or got confused about which foot was going to be operated on," he says. "Therefore, I don't think you can trust patients to do the signing for you. It has to be a joint process between the patient and the treating physician. Our academy feels the surgeons themselves should sign the operative site, but others don't feel that strongly. But it has to be a joint effort between the patient and whoever is authorized to sign the site."

Thomas R. Russell, MD, FACS, executive director of the American College of Surgeons in Chicago, says surgeons should sign the site themselves.

Dennis S. O'Leary, MD, president of the Joint Commission on Accreditation of Healthcare Organizations in Oakbrook Terrace, IL, says his organization expects the patient to be involved but not actually signing the site. "Involvement of the patient means the patient should actually be interacting, but it does not mean the patient is actually marking the surgical site. The expectation is that to every extent possible, the surgeon should be the one marking the site; but failing that, it should be someone who is going to be in the operating theater as part of the surgical team."

Question: Are you supposed to mark the actual incision site or just more generally on the correct limb?

Answer: O'Leary says the marking should be "as close to the site as possible. If the question implies whether there is any infection risk, that has never been documented."

Herndon notes that the proximity to the actual incision site can make a difference. He cites a case in Florida in which a patient was to have surgery on one heel, and the surgeon correctly signed that foot to indicate the operative site. But the patient was turned over on his stomach for the surgery, placing the other heel on that side of the operating table. The surgeon's signature was covered with drapes, so no one noticed the error, and the procedure was performed on the wrong foot.

"So if the initials were nearer the site of the surgery, that could have been prevented," he says.

Question: Is it necessary to mark the operative site for midline procedures and orifices, since you can't really confuse right and left?

Answer: JCAHO takes a conservative approach and encourages marking of all sites unless there is obviously no room for confusion,

O'Leary says. But he cautions that even midline procedures can result in wrong-site errors, such as approaching a spinal operation from the wrong side.

Russell notes that the Universal Protocol does not require marking midline procedures because many surgeons resisted the idea and the ACS wanted to encourage participation.

• **Question:** What about high-volume situations in which the surgeon is doing the same procedure over and over? Is it still necessary to mark the site and follow the rest of the protocol?

Answer: Yes. Russell says high volume is no excuse to not mark the site.

"High-volume surgeons are at risk. You may be high volume one day; and if you do a wrong-site surgery, you may not be high volume the next day," he says. "Our protocol at ACS calls for surgeons to do it, and being too busy with a high volume of surgeries doesn't change that." ■

Kaiser hospital vows to enforce Universal Protocol

A San Francisco hospital is taking the Universal Protocol so seriously that it has threatened to suspend entire operative teams — the surgeon, anesthesiologist, nurses, and anyone else in the room — if the procedures to prevent wrong-site surgery are not followed.

The warning was recently issued at Kaiser Foundation Hospital, where **Linda Groah**, RN, is chief nurse executive and director of hospital operations. She also is past president of the Association of periOperative Registered Nurses.

"My medical center has taken a very firm stand on this. We believe this is a team effort," she says. "It starts with the anesthesiologist, the person we have delegated the responsibility for declaring a timeout, and then the rest of the team is to join in."

If the anesthesiologist does not take the lead for some reason, the circulating nurse or the surgeon must call the timeout, Groah says. Ultimately, every person in the operating room is expected to speak up if the procedure is about to begin and no one has called a timeout. And once a timeout is called, it is mandatory that each person participate.

"If all of the team members do not take part in this timeout or they do not implement the time out, the privileges for the surgeon are suspended and the entire team is suspended, the nurses and the anesthesiologist also. That's how strongly we believe in this Universal Protocol."

That may sound like a tough stance, but Groah says it is supposed to. She says the hospital has shifted from a "no-blame culture" to what it calls a "just culture" that requires accountability and responsibility for following policies and procedures that protect the patient.

"If anyone sees anything happening that is not as it should be, they have a responsibility to put a stop to it until the issue is resolved. We feel there is no room for not following this protocol," Groah says. "We haven't had to implement the suspension yet because once we announced it, all the nonbelievers suddenly became believers." ■

Case of the killer nurse reveals new-hire obstacles

A nurse who admitted to authorities that he killed 30-40 severely ill patients is putting the spotlight on the difficulty of investigating the backgrounds of those applying for patient care positions in health care, says the CEO of the hospital where many of the deaths are thought to have occurred.

The president and CEO of Somerset Medical Center in Somerville, NJ, is campaigning now for more openness in background checks. **Dennis Miller**, FACHE, says his hospital did everything possible to check the background of the man who admits killing patients, but that previous employers did not reveal the man had a history of leaving hospitals under questionable circumstances.

Hospital spokeswoman **Vicki Allen** tells *Healthcare Risk Management* that Somerset performed a customary background check before hiring the nurse, including verifying his credentials and checking with previous employers.

"But we really didn't get any information other than the dates of his employment. That's one of the things our CEO wants to change," she says. "Had we gotten more information about investigations that took place at other hospitals, we might have taken precautions in hiring him."

Somerset County Prosecutor **Wayne Forrest**, JD, reports that Charles Cullen, 43, told investigators he killed between 30 and 40 severely ill patients at several hospitals and nursing homes in Pennsylvania and New Jersey, starting in 1987. All of the

victims were killed with drug injections, Forrest reports.

If Cullen's admissions prove true, he would be one of the most prolific "angel of death" killers in the country's history. Somerset County authorities charged him with one count each of murder and attempted murder, but are considering more charges as they investigate his employment history at 10 health care facilities. The current charges stem from the deaths of a Roman Catholic clergyman and a 40-year-old woman, both at Somerset Medical Center. Both had elevated levels of digoxin, a heart medication, in their bodies.

During a recent court appearance, Cullen told the judge he was going to plead guilty and did not want a lawyer, according to local media reports. He was held on $1 million bail.

Somerset Medical Center apparently was only the latest in a string of hospitals where Cullen is thought to have killed patients, but it is under fire for hiring him after he left other facilities under questionable circumstances. Somerset claims that it checked Cullen's background as well as it could under restrictions that made full disclosure of his past impossible, and Allen says the hospital aggressively investigated the suspicious deaths at its own hospital.

Suspicious deaths prompt concern

Between June and August 2003, Somerset Medical Center documented six abnormal results in routine laboratory tests, he says. No patient deaths were related to these abnormal lab results in five of the six cases. In the sixth case, a death occurred, but the cause of death was inconclusive.

"In June, after the first three abnormal lab values came to light, we launched an internal investigation," according to a statement released by the hospital. "After ruling out a range of possible explanations — faulty equipment, human error, other medical conditions in the patients — we then moved quickly to ask the New Jersey Department of Health to conduct its own investigation. The Department of Health spent several days reviewing patient medical records and our policies and procedures."

When these Department of Health investigations identified no fault with the hospital's internal systems, the hospital expanded its internal investigation to include external investigative experts. That investigation was ongoing when a decision was made to contact the Somerset County Prosecutor's Office, the hospital reports.

"We contacted the Prosecutor's Office and have worked closely with them over the past two months in their investigation," the statement says. "As a result of this investigation, we identified a nurse who we suspected was involved with the abnormal laboratory test results and terminated this individual on Oct. 31, [2003]. We terminated the nurse in question and reported him to the appropriate state authorities."

Other investigations come to light

Allen says it was only after firing Cullen that Somerset became aware that he had previously worked at three other hospitals in New Jersey and two hospitals in Pennsylvania where similar investigations may have been conducted. Information about potential investigations apparently was never reported to either state or criminal authorities, she says.

"We are outraged that some hospitals who have hired this nurse and who may have conducted an investigation did not share the information with us or the appropriate authorities," the hospital statement says. "These incidents have illustrated that Somerset Medical Center is committed to patient safety. To our knowledge, we were the only hospital to report this nurse to the New Jersey Board of Nursing. We were contacted by another New Jersey hospital that was considering hiring this nurse. At this point, we contacted the Board of Nursing to prevent any future concern of patient safety in another hospital."

Allen says Somerset Medical Center is cooperating fully with the investigation of Cullen and is happy to do so. The hospital has turned over a total of eight patient medical files to the Somerset County Prosecutor's Office.

Legislators address problem

New Jersey assemblyman Jerry Green (D-Plainfield) announced recently that he will introduce a bill that would close loopholes in New Jersey law regarding information that hospitals and other health care facilities can share about their staff. State Sen. Joseph Vitale (D-Woodbridge) reported that the Health, Human Services, and Senior Citizens Committee would convene hearings on patient safety reform.

Green's bill is intended to close the loopholes that allowed Cullen's alleged actions to go unnoticed as health care providers repeatedly hired him. It would require a provider to report to the

state any questionable conduct by nurses, home health aides, and other health care professionals. Reportable conduct would include voluntary resignation during an investigation and termination because of misconduct. ■

In-house education: It may have a big payoff

Educating physicians about risk management issues can be difficult and time-consuming, so it's tempting to let your insurer send in a speaker once in a while and leave it at that. But the risk manager at a Texas hospital says you'll get better results by developing your own in-house education program for physicians.

It's not as hard as you might think, she says, and the effort will pay off in the end.

Scott & White Memorial Hospital in Temple used to have a typical physician education program, says **Lisa Havens-Cortes**, JD, MSN, RN, CPHRM, director of risk management. The hospital brought in one or two speakers a year, usually from its insurer, with the sessions presented twice over two days. The results weren't great, she says.

"It was difficult to maximize attendance because we have regional clinics, and we just didn't think we got much for the money we spent," she says.

The hospital decided to develop its own in-house education program with the hopes of making the sessions more accessible, with multiple sessions at different locations, and more directly applicable to the hospital's concerns. Those improvements should improve attendance, Havens-Cortes hoped.

Flexibility was considered a key component. Instead of speaking in generalities, case studies are tailored to the specialty physicians in attendance to make the discussion relevant.

"We have not made our program mandatory, but we wanted to make it as convenient as possible," she says. "We've found that if we offer a program several times and market it that way, we get much better attendance."

The program sessions were developed with internal data, such as lessons from defending malpractice cases. Havens-Cortes took the risk manager position at Scott & White after serving as the hospital's outside counsel for years.

The sessions also deal with the most common patient complaints, and requirements of the Joint Commission on Accreditation of Health Care Organizations, along with federal and state laws.

Most of the educational sessions involve a discussion of the current literature on a subject, along with a review of malpractice verdicts and settlements. Havens-Cortes says she realized early on that it was crucial to provide continuing medical education (CME) credits for the sessions as a way to encourage attendance. Doing so requires adhering to certain CME requirements, such as providing a sign-in sheet for each session and post-session evaluations. Some sessions also provide nursing continuing education credit.

In addition to speakers, the educational sessions also include videotapes in which patients tell their stories. For physicians who can't attend the sessions, the hospital provides an educational packet that includes the same material in printed form, and CME credit is available for reading the packet.

Publicize sessions two weeks ahead

Havens-Cortes discussed the hospital's in-house education efforts at the recent meeting of the American Society for Healthcare Risk Management in Nashville, TN, along with **Carolan Wishall**, BA, CPHRM, director of patient relations. Wishall is involved with much of the planning and execution of the education sessions, which are offered at least a half-dozen times per year.

Credibility is an important issue for physicians attending in-house education sessions, Wishall says. She recommends using a physician or attorney in presentations, and also in developing the content of the sessions. Outside counsel is an excellent resource, she says.

For each topic you want to address, Havens-Cortes suggests developing an outline that starts with a statement of the problem, regulation, or mandate. Then move on to supporting studies, research, or internal data. Use case studies and depositions to add interest and increase impact.

Publicize the sessions with various methods, including any in-house news publications such as newsletters and fliers. E-mail is another good option, as are posters in key locations such as break rooms and lounges.

"Give them about two weeks' notice. That's not so soon that they'll forget about it, but it's not too late for them to plan," she says. "When you're publicizing it, note the advantage to the physician for

attending. Say something like, 'Do you want to lower your risk of malpractice?'"

Communication issues difficult to teach

Havens-Cortes and Wishall offer this other advice for educating physicians in-house:

• Consider using a remote control voting apparatus.

These gadgets allow participants to answer a speaker's questions anonymously, with the results showing up immediately on a monitor. The speaker can ask about the attendees' experience with a particular topic or their opinions about how a matter should be handled.

"It helps promote great discussions," Havens-Cortes says. "Even when we're talking about a real no-brainer where you think everyone should know the answer, there is rarely complete agreement."

• Be prepared for resistance when you start talking about improving communication.

Most physicians are not interested in learning about better communication, Wishall says.

"They think they have it down already. The fact is that most do not," she says. "They don't understand empathy. They express sympathy instead."

• Avoid the touchy-feely approach.

Make the sessions useful and show a practical benefit for attending, such as reducing the physician's malpractice risk. Doctors will be turned off by any impression that the session is all about personal improvement or becoming a "nicer" doctor. The physicians will quickly tell you they don't have time to attend.

• Don't throw only negatives at the physicians.

With case studies and patient testimonials, it's easy to concentrate only on the negative and show doctors what they do wrong. That has a place in the education sessions, but it shouldn't be the only thing they hear.

"People do say positive things and the attendees need to hear that, too," Wishall says. "If they hear the positive things patients say about them, they will begin to recognize what they should say to elicit that response."

• Bait your session with food.

"Feed them, feed them, feed them. That's the best advice I can give to increase attendance," Wishall says. "I don't know what it is about food that brings them in when the topic won't."

• Don't expect too much from any one session.

Educating physicians needs to be seen as a long-term, cumulative effort, Havens-Cortes says. You may think that your session is a wonderfully comprehensive, compelling explanation that should immediately change the way physicians practice, but it might not.

"It's not a panacea. Don't throw this at them and say, 'Gosh, now they'll behave,'" she says. "You'd just be setting yourself up to be disappointed and frustrated. But if you can get them to take away some new ideas or information they hadn't considered, it's worth doing, no doubt." ■

Enterprise liability: These tips can help spot trouble

"Enterprise liability" is a legal concept that some advocates say can help health care organizations achieve patient safety, but it could represent another reason for risk managers to worry, says **Fay A. Rozovsky**, JD, MPH, DFASHRM, DSA, senior vice president of Marsh, a consulting firm in Richmond, VA.

Rozovsky addressed risk managers' concerns about enterprise liability at the recent meeting of the American Society for Healthcare Risk Management in Nashville, TN.

She explained that the concept calls for liability for errors and omissions to shift from the individual clinician to the health care organization.

Enterprise liability was suggested as a solution to medical errors in *To Err is Human*, the landmark report released by the Institute of Medicine in 1999, because it can encourage individuals to report errors if they are not afraid of being held personally responsible.

"But enterprise liability is fraught with risk management concerns," Rozovsky says. "Rather than enhancing patient safety, enterprise liability may serve to exacerbate underlying issues that give rise to questions about quality, safe patient care."

Emergency department a risky area

A focus on enterprise liability could result in hospitals being held responsible for the actions of physician groups or other entities that are legally separate, she says. Liability is most likely to occur in emergency departments or other departments in which the patient cannot

easily make the distinction, Rozovsky says. Notifying the patient of such distinctions with signage and consent forms may be ineffective and provide a false sense of security, she adds.

Exposure also is possible when state licensure laws and regulations delineate specific, nondelegable responsibilities to a health care organization, Rozovsky says. Hospital leaders may assume there is no liability risk because the responsibility was delegated, but the law may prohibit such delegation.

She suggests looking for these warning signs that your organization could be exposed to enterprise liability exposure:

- The health care organization uses signage in the emergency department indicating that the unit is managed or operated by a separate physician group.
- Consent forms are used in the emergency department that acknowledge that the department or unit is managed or operated by a separate physician group.
- Health care organization policy and procedure appears to delegate nondelegable duties to a committee.
- In agreements with physician groups and other vendors to whom responsibility is given to manage or operation a department or unit, the terms and conditions are not reviewed for purposes of enterprise liability exposure.

Check state laws for nondelegable duties

- In agreements with physician groups or other vendors to whom responsibility is given to manage or operate a department or unit, state law is not checked with respect to nondelegable duties of care.
- With respect to enterprise liability, only a save harmless and indemnification provision is included in agreements with physician groups or other vendors to whom responsibility is given to manage or operate a department or unit.
- Private contracts attempt to or actually create an enterprise liability between the health care organization and care providers.
- The structure of the integrated delivery system reflects a corporate style conducive to interpretation of an operation functioning as an enterprise.
- Managed care organizations receive complaints or lawsuits premised on organizational negligent care or service.
- Integrated delivery systems receive complaints or lawsuits premised on organizational negligence or service.
- The integrated delivery system has a centralized credentialing service that is the subject of complaints or lawsuits premised on negligence.
- Orientation training does not describe enterprise liability.
- Orientation training does not provide descriptions of enterprise liability.
- Contracts are not reviewed for liability insurance coverages for purposes of enterprise liability.
- Captive management programs do not include an assessment of enterprise liability exposure. ■

Reader Question

It's no EMTALA violation to get insurance info first

Question: Can we collect insurance information after triage in the emergency department but before the medical screening examination? We hear conflicting explanations about whether this violates the Emergency Medical Treatment and Labor Act (EMTALA). Sometimes, there is plenty of time between triage and the examination, so it would be helpful to get the paperwork in process.

Answer: You can go ahead with collecting insurance and other payment information between triage and the medical screening examination, says **Daniel J. Sullivan**, MD, JD, FACEP, president of the Sullivan Group, a consulting company in Oak Brook, IL, that specializes in EMTALA interpretation. He answered the question at the recent meeting of the American Society for Healthcare Risk Management in Nashville, TN.

You still need to be careful about how the emergency staff goes about this process, he says, but EMTALA does not prohibit gathering that information at that point, he says. That has always been the case; the recent release of the final EMTALA rule did not change the procedure for when you can collect payment information.

"There cannot be any delay in the medical screening examination to obtain financial information," Sullivan says. "But if it does not delay the medical screening examination,

it is not a violation."

Confusion arises because, in the past, risk managers have incorrectly interpreted EMTALA to mean that no financial information could be collected until the law had been satisfied by the medical screening examination. Some hospitals enacted rules prohibiting the collection of any payment information until after the examination, and Sullivan says that led to inefficiencies when the patient was off-limits to staff during the wait and then the information had to be gathered afterward when treatment had begun.

Avoid delays

Risk managers are reconsidering such restrictions and considering how to comply with EMTALA in the least restrictive way, Sullivan says. The key is to avoid any delay. It is not acceptable for the examination to be delayed even for a short time because other staff still are talking to the patient about financial information, he adds.

Sullivan also cautions that any discussion of payment arrangements must not discourage the patient from staying for the examination and possible treatment. This is another reason that some risk managers have chosen to ban such information gathering until after EMTALA has been satisfied by the screening examination: Any discussion of the ability to pay could cause the patient to leave before the examination and that could be interpreted as an EMTALA violation, even if that outcome was entirely unintended.

You can continue to play it safe by waiting until after the examination, but practical considerations are forcing many hospitals to play it closer to the line, Sullivan notes.

"EMTALA has been interpreted in the past to mean that you should never collect financial information before the medical screening examination, but in today's full, very overcrowded emergency departments, it can be OK if carefully constructed," he says. ■

FDA warns of fire danger from electric hospital beds

In a special "Dear Colleague" letter aimed at risk managers and other hospital leaders, the Food and Drug Administration (FDA) warns that some electrically powered hospital beds may pose a risk of fire. The letter notes that the FDA has received 95 reports of fires involving electrically powered hospital beds since 1993.

To help prevent incidents of this kind, the FDA offers safety tips that apply to both electrically powered and manual health care beds and adjustable medical beds. The advice may be particularly useful for older-model beds, notes **David W. Feigal Jr**., MD, MPH, director of the FDA's Center for Devices and Radiological Health. In the warning letter, he explains that the Safe Medical Devices Act of 1990 requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices.

Feigal reports that the FDA's safety tips assume that normal behavioral policies such as prohibitions against smoking and lighting candles are already in place. The fire risks posed by oxygen administration to a patient in bed are not addressed in this list of safety tips.

Proper power supply is key

To address the fire concerns specific to electrically operated beds, the FDA offers this advice:

• **Connect the bed's power cord directly into a wall-mounted outlet. Make** sure that the wall-mounted outlet will accommodate a heavy duty or hospital-grade plug and that the outlet is in good working order. The plug of the power cord should have two blades and ground pin that fit tightly into the wall outlet. Power cord plugs that have the ground pin removed should never be used.

• **Do not connect the bed's power cord to an extension cord or to a multiple outlet strip.** Whenever possible, avoid the use of extension cords or multiple outlet strips in patient rooms for any medical electrical equipment since they are highly vulnerable to physical damage that can cause fires. If the use of extension cords or multiple outlet strips cannot be avoided, use only heavy-duty or hospital-grade connectors that are approved by the facility's engineering department. Extension cords and multiple outlet strips only should be installed by properly trained electrical maintenance personnel.

• **Visually inspect the bed's power cord for damage.** The bed's power cord, as well as power cords from other medical electrical equipment, can sustain damage from crushing, pinching, shearing, cutting, or from being worn through from cleaning solutions. Bed movement, deterioration from use

or aging, or human or equipment traffic, also can damage them.

Inspect bed for dust, lint buildup

• **Do not cover the bed's power cord or any power cord with a rug or carpet.** Rugs or carpets can prevent normal airflow, which can lead to greater heat buildup. Covered power cords also are more prone to being walked on or having furniture placed directly on them. The bed maintenance staff should place the cord in a low- or no-traffic area.

• **Ensure that appropriate staff inspects all parts of the bed frame, motor and hardware, mattress, and the floor beneath and near the bed for buildup of dust and lint.**

• **Test the bed to assure that it moves freely to its full limit in both directions. In many facilities, wall-mounted outlets are located directly behind the hospital bed.** Be sure that the vertical motion of the bed does not interfere with the bed's power cord or plug. In addition, the bed's hand control cable and all other power cords should not be threaded through mechanical parts of the bed or bedrails where normal bed movement may damage or cut the cable.

• **Test the bed's hand and panel control, including the patient lockout features, to assure that the bed is working properly.**

Report any problems to maintenance

• Inspect the covering of the bed's control panel and the patient control panel to assure that the covering is not cracked or damaged. Cracked or damaged covers can allow liquids or other conductive material to penetrate to the switches.

• Check patient bed occupancy monitors and all other equipment in the patient's room with plug-in power supplies for indications of overheating or physical damage. Make sure that the power supplies are plugged into a wall socket where they cannot be contacted by bedclothes, bedding, etc.

• Report to the bed maintenance personnel, any unusual sounds, burning odors, or movement deviations observed in the controls, motors, or the limits switch functions.

• Assure that all manufacturers' recalls, urgent safety notices, etc., have been followed.

Additional, more detailed advice for maintenance staff is available on-line at www.fda.gov/cdrh/safety/bedfires.html. ■

Doctor in pain case must attend education courses

The Medical Board of California has issued a severe reprimand to a physician accused of providing inadequate pain relief to a dying man, requiring him to attend advanced training to improve his performance. The action caps a series of legal settlements stemming from the case of patient Lester Tomlinson.

Lawsuits were brought against several providers in Concord, CA. The plaintiffs settled against a hospital, a nursing home, and two physicians. One physician, Eugene Whitney, MD, faced formal charges from the state medical board in addition to his settlement.

According to the "Stipulation for Public Reprimand" filed by State Attorney General Bill Lockyer with the Division of Medical Quality Medical Board, Whitney is required to enroll in a clinical training or education program that will include a two-day assessment of his physical and mental health, and his competency to practice medicine. The course also must provide at least 40 hours of training in the areas relative to the alleged deficiency, and in addition, Whitney must enroll in a physician/patient communication course.

The action reflects "momentous change" in how authorities respond to allegations of inadequate pain relief, says **Kathryn Tucker**, JD, director of legal affairs for Compassion in Dying, a pain management advocacy group that supported the lawsuits. "It is a major victory for patients when compared to the resolution of the 1998 Bergman complaint where the medical board declined to take any action on similar facts." ■

CE objectives

After reading this issue of *Healthcare Risk Management,* the CE participant should be able to:

1. Describe legal, clinical, financial, and managerial issues pertinent to risk managers in health care.
2. Explain how these issues affect nurses, doctors, legal counsel, management, and patients.
3. Identify solutions for hospital personnel to use in overcoming challenges they encounter in daily practice. Challenges include HIPAA and EMTALA compliance, medical errors, malpractice suits, sentinel events, and bioterrorism.
4. Employ programs used by government agencies and other hospitals (such as EMTALA, HIPAA, and medical errors reporting systems) for use in solving day-to-day problems. ■

CE Questions

Nurses participate in this continuing education program by reading the issue, using the provided references for further research, and studying the questions at the end of the issue. Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing this activity each semester, you must complete the evaluation form provided and return it in the reply envelope provided in order to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you.

5. According to JCAHO president Dennis S. O'Leary, MD, recent unannounced surveys have revealed that ___ of organizations are not marking the operative site to prevent wrong-site surgery.
A. 14%
B. 26%
C. 36%
D. 73%

6. According to O'Leary, where should the operative site be marked?
A. As close to the incision site as possible.
B. Six inches from the incision site.
C. Anywhere on the correct limb or side of the body.
D. Anywhere, as long as the surgeon can tell what the mark means.

7. According to information released by the Somerset Medical Center in Somerville, NJ, why was the nurse charged with killing patients at the hospital hired despite previous employment difficulty?
A. The previous employers claimed the nurse had been an exceptional employee with a spotless record.
B. The previous employers did not reveal that the nurse had been under investigation for questionable conduct.
C. The questionable conduct revealed by the previous employers did not seem serious enough to prohibit hiring the nurse.
D. The nurse offered suitable explanations for questionable conduct reported by previous employers.

8. According to Daniel J. Sullivan, MD, JD, FACEP, when is it OK to collect insurance information after triage but before the medical screening examination?
A. Never.
B. Always, because it is not possible for this activity to violate EMTALA.
C. Only when you can do so without causing any delay in the medical screening examination.
D. Only when the emergency department has activated its disaster plan and is overwhelmed with a large volume of patients.

Answers: 5-C; 6-A; 7-B; 8-C.

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

Hospital, couple disagree on embryos' storage: Confidential settlement reached

By **Jan J. Gorrie,** Esq., and **Blake J. Delaney**, Summer Associate
Buchanan Ingersoll Professional Corp.
Tampa, FL

News: A university hospital harvested and stored 28 embryos for a couple who had been unsuccessful in conceiving a child. Ten years later, the hospital disposed of the embryos, believing that the failure on the part of the couple to respond to notices that the hospital was going to take such action indicated their concurrence to have the embryos destroyed. When the couple later sought to have the embryos implanted, they were no longer available, and they sued the providers. The case settled in mediation for an undisclosed amount.

Background: Twenty-eight eggs were retrieved from a woman in the hopes that she might bear a child. The eggs were prepared for in vitro fertilization. After being fertilized, some embryos were successfully implanted, and the 15 remaining embryos were cryopreserved and stored, pursuant to a contract with the college of medicine associated with the hospital.

Ten years later, the hospital sent a message asking if she and her husband wanted to continue having the embryos stored. The couple claimed that they told the hospital four times that they wanted to keep the embryos. The hospital counterclaimed that it never heard anything back.

After the couple decided to have five embryos implanted and the remaining 10 donated to another patient, they learned that the embryos no longer existed. The couple sued for negligence and breach of contract. The defendants countered that the couple failed to provide instructions for continued storage and that the fees for such storage had not been paid. The parties reached a confidential settlement in mediation.

What this means to you: This could have been remedied at the very beginning by a written contract specifying the terms under which the embryos were to have been kept.

"Unfortunately, in the absence of additional information regarding the contract, this case came down to 'he said, she said,' and the plaintiffs prevailed," notes **Leilani Kicklighter**, RN, ARM, MBA, CPHRM, director risk management services, Miami Jewish Home and Hospital for the Aged and past president of the American Society for Healthcare Risk Management.

The case notes do not indicate if the contract was written or implied.

"A contract specifying that all notices between the parties are to be sent via certified return receipt mail would have been beneficial to all concerned. This would have provided the hospital with a clear means of communication with the couple, and the couple with the means to contact the hospital. As it was, we really do not how the providers gave notice to the plaintiffs and if there was any record of receipt. The plaintiffs claimed that they did contact the hospital, but it is not clear to whom they

talked or wrote. The contract should have given them a specific contact person — hopefully, identified by title, not necessarily name, since people change positions. Further, the contract should provide reversionary terms, so that after a certain time, without notice or storage fee payment from the couple, ownership of the embryos would revert to the facility," she adds.

In the process of entering such contracts, "hospitals and providers would be best served by providing or suggesting that they involve a counselor so that issues of ownership following divorce, viability of the embryos over time, and other ethical considerations would be clearly discussed, explained, and documented," notes Kicklighter.

"Finally, inservicing — facilities and providers offering such services have a moral obligation to follow through on contacts by patients involving these matters," says Kicklighter. "Providers engaged in sensitive issues, like reproductive medicine, should train staff members on how to field various inquiries, for it could have been in this instance that the couple talked to the facility's telephone operator or a secretary who had no clue where to direct them."

Reference

• Harris County (TX) District Court, Case No. 2001-05985. ■

A baby's death and a $5 million settlement

News: A woman in labor told an attending nurse that she thought the hospital and the obstetrician were not attending to her in a timely manner. The labor and delivery nurse contacted her obstetrician, but he failed to appropriately respond. The nurse should have contacted her supervisors about the woman's concerns and the physician's failure to take action, but didn't.

The fetus suffered severe brain damage because of a delay in delivery and subsequently died 11 months later. After filing suit against the obstetrician, the hospital, and the hospital's parent company, the parents settled with the hospital and the corporate owner for $5 million; the physician paid nothing because he did not carry medical malpractice insurance.

Background: A couple in their 30s became pregnant with their second child. The mother was under the care of the obstetrician who delivered their first child. The doctor had performed the first delivery by cesarean without any complications.

As the mother prepared to enter labor with her second child, she began to worry that the hospital was not attending to her in a timely manner. She relayed her concerns to the attending nurse, who had little, if any, experience in obstetrics.

The nurse told the obstetrician about the mother's fetal distress, but the doctor refused to take action. The nurse did not relay her concerns about the patient or the physician to her supervisors.

The doctor failed to respond to the repeated calls for direct medical intervention until the fetus had already suffered severe brain damage. The infant was born blue and limp. He died due to residuals of the fetal brain damage at the age of 11 months.

The parents filed suit against the obstetrician, the hospital, and the hospital's parent company, which had recently acquired the hospital. The plaintiffs alleged that the defendants' actions fell below the standard of care and caused the death of their baby boy.

During discovery, the parents learned that the obstetrician should not have been allowed to deliver their baby. Three years prior, the doctor worked at a hospital owned by the same corporation that owned his present hospital. The former hospital had been concerned about the obstetrician for several reasons, including the doctor's continual failure to document reasons for surgery and list medications taken by patients. The parent company initiated an investigation of the doctor's work and had recommended his privileges be revoked. The obstetrician resigned from that hospital. The next year, the state licensing board restricted the doctor's future practice. Although the board did not take formal disciplinary action, the doctor had to agree to not accept any new obstetrics patients and to improve his record-keeping and chart entries.

As part of its claim for negligence, the plaintiffs maintained that the company owning the hospital should have told the couple about the obstetrician's prior problems. In its defense, the company held that when it investigated the obstetrician, it provided notice to a national databank that collects reports of adverse actions against doctors. The hospital's internal peer reviews, on the other hand, such as the one

following the investigation of the obstetrician, are not made public. The reviews are kept private to create a safe place for doctors to report medical errors and to identify institutional problems. If the parents wanted to know about their obstetrician's record, the company contended, they should have asked the doctor.

In his defense to the claim of negligence during the delivery, the obstetrician pointed out that the delivery was the fourth of five deliveries that day and night. As a result, the doctor claimed, he was heavily dependent on the nursing staff to maintain adequate observation and clinical judgment regarding the mother's progress in labor. The nurses did not notify him quickly enough, he said, and that caused the delay in delivering the baby.

The doctor further maintained that when he was finally notified by the nurses about the mother's serious condition, he delivered the baby within seven minutes. In response to the parents' assertion that he should not have been practicing at that hospital, the obstetrician said he was unaware that his privileges to practice at the hospital had lapsed. He believed that the prior investigation had been resolved in his favor.

Furthermore, the parent company had just recently acquired the hospital, and so the doctor did not realize the hospital now was controlled by the same corporation as the hospital where he had been investigated.

Before going to trial, the plaintiffs settled for $5 million with the hospital and the parent company. Those defendants acknowledged that they had violated the standard of care. Corporate negligence, they maintained, played a part in the infant's injuries and death. The obstetrician, on the other hand, was relieved of any financial liability as a result of the settlement. He had no medical malpractice insurance coverage. He only had to acknowledge that his actions during the delivery "fell below the standard of care of a reasonably prudent obstetrician."

What this means to you: This case illustrates the dangers that lay in wait for hospitals that fail to perform adequate credential reviews on individual physicians.

"It appears from the commentary that the physician's credentials were not sufficiently investigated by the defendant hospital. If the hospital had followed nationally accepted guidelines of checking not only the national databanks but also the state licensure board and previous employment references, information would have been obtained that could have barred this physician from staff privileges," observes **Lynn Rosenblatt**, CRRN, LHRM, risk manager, HealthSouth Sea Pines Rehabilitation Hospital in Melbourne, FL.

The state board of medicine has primary oversight of a disciplined physician. In most states, physicians and hospitals must report any revocation of privileges and/or disciplinary actions taken against the physician to the board.

"In this instance, the case record indicates that the board had been aware of some problems, as they had entered into an agreement with the physician to restrict his practice. Had the hospital verified the physician through the board, these restrictions would have come to light," adds Rosenblatt.

"Even more disturbing is that the defendant hospital appears to have not verified the physician's professional history with the facilities where the physician had previously practiced. The fact that both hospitals had the same corporate governance does not excuse the defendant facility from obtaining references from any other facilities where the physician had practiced. In fact, it makes the negligence of not having done so more egregious," she adds.

The proceedings of medical staff committees generally have some measure of confidentiality regarding peer review. Likewise, the state medical boards' investigatory actions usually remain confidential, until such time that formal disciplinary action is taken.

The formal actions of the boards are most always public. If the hospital's peer review committee felt that after completing its investigation the situation warranted reporting the physician to a national databank and terminating his privileges, the action against the physician was serious enough that the second facility should have been duly warned — had they checked. The fact that the physician had resigned did not clear the record nor should have it cloaked the action from public view.

With the rising costs of medical malpractice insurance, practitioners are increasingly going bare. This can lead to hospitals becoming the deep pocket in instances of medical malpractice where both practitioner and facility can be named and found at some degree of fault.

"Another disturbing fact in this case is that the physician had no medical malpractice insurance. In most states, physicians are required to carry at

least a minimum amount of coverage or provide some alternate arrangement to compensate victims of medical negligence. The hospital carried the full financial burden in this case because the physician practiced bare," adds Rosenblatt. "Health care, like any other business, has its share of unscrupulous professionals who arrogantly believe themselves above the rest. The credentialing process and all the various agencies/boards that are involved are designed to protect the public from situations where they are vulnerable and lack control. This case clearly points to the corporate responsibility that hospitals have in assuring professional safety and personal liability are at the forefront of its medical staff policies. Without exception, the re-credentialing process should occur on a regular scheduled basis generally at the time of licensure renewal or more often as the situation dictates."

Obstetrics is considered a specialty service within the hospital where a higher standard of professional oversight is required.

"The case facts indicate that the physician had delivered five infants in a 24-hour period — an incredible load for a single practitioner. Medical staff policies generally have provisions regulating the actual amount of time a physician may provide service within such areas as the operating room and labor and delivery during a continuous period. This is designed to prevent fatigue and diminished judgment that accompanies it. The supervisory nursing staff should have questioned the situation and alerted risk management and/or administration for assistance," notes Rosenblatt.

Documentation seems to have been an outstanding issue as well.

"There is an indication that the nursing documentation may have fallen below the standard for obstetrical practice. Standard of care in this setting includes the nurse's initials and time on the monitor strip with a corresponding entry in the medical record at regular intervals that are established by the patient's progress. The documentation should include when and in what manner the obstetrician was notified and any deviation from expected norms the nurse may have observed," says Rosenblatt.

"In addition, the nurse should carefully document the physician's response (or lack of) to the situation," she continues. "Any evidence of fetal or maternal distress and/or any indication of unusually rapid or prolong labor becomes an emergency situation to which the physician's immediate response is necessary. If the attending obstetrician is not available, there should be an on-call or backup plan to assure continual medical oversight of the patient.

"In this case, the hospital and its parent corporation failed to assure that a reasonable duty of care was met. Because the hospital failed to identify a potentially dangerous physician by not following well-established practices related to staff credentials, the facility assumed costly responsibility for a physician who fell below the standard of care of a reasonable prudent obstetrician. The question now is whether the obstetrician is still practicing and where," Rosenblatt says.

Reference

• King County (WA) Superior Court, Case No. 00-2-29778-5. ■

HIPAA Regulatory Alert

Supplement to Healthcare Risk Management and Hospital Access Management

Privacy expert urges clarification for privacy regs

Health Privacy Project advocates increase in technical guidance

Health Privacy Project executive director **Janlori Goldman** said that while many glitches and misinterpretations of the HIPAA privacy regulation have been resolved, others remain and should be addressed by the Department of Health and Human Services (HHS) or Congress.

Goldman made her comments in testimony before a subcommittee of HHS' National Committee on Vital and Health Statistics.

"Where misinterpretation persists," she said, "we urge that both the HHS Office of Civil Rights and the professional and trade associations representing providers, plans, and others affected by the law aggressively step up their technical assistance and guidance. We believe that resources should be devoted to proper and vigorous implementation, and not to using misunderstanding and mishap to build public opposition to the law."

Goldman told the subcommittee that the HHS Office of Civil Rights has received thousands of complaints from consumers since the implementation of the privacy regulation, and a number of the complaints have been referred to the Justice Department as possible criminal violations of the rule. However, no penalties have as yet been imposed.

Five changes sought

She listed five areas in which the privacy rule should be strengthened:

1. Enforcement provisions should require a covered entity to disclose information to law enforcement only in response to a court order issued by a neutral magistrate under a Fourth Amendment probable-cause standard.

2. The section on use of health information for marketing purposes should be strengthened by expanding the definition of marketing and should reinstate the rule's original safeguards that required covered entities to give consumers notice if a communication was generated by a third party with remuneration to the covered entity and allowed consumers to opt out of further such communications.

3. The scope of the rule should be expanded so that the list of covered entities includes employers, life and disability insurers, pharmaceutical companies, and others who collect sensitive information directly from consumers.

4. People should be given the right to sue under the privacy regulation if their rights are violated.

5. HHS should be required to conduct periodic compliance reviews of covered entities and make a bigger effort to educate the public about its rights under the privacy rule, if it is going to rely on complaints from the public for enforcement.

(For more information, go to www.healthprivacy.org.) ■

The HIPAA privacy rule: Sorting myths from facts

Expert responds to 13 persistent HIPAA myths

In testimony late last year before the Department of Health and Human Services' (HHS) National Committee on Vital and Health Statistics' Subcommittee on Privacy and Confidentiality, Health Privacy Project executive director **Janlori Goldman** submitted 13 common myths that persist about the HIPAA privacy regulation and the facts that respond to those myths.

Myth: One doctor's office cannot send the

medical records of a patient to another doctor's office without the patient's consent.

Fact: No consent is necessary for one doctor's office to transfer a patient's medical records to another doctor's office for treatment purposes.

Myth: The HIPAA privacy regulation prohibits or discourages doctor/patient e-mails.

Fact: The Privacy Regulation allows providers to use alternative means of communication, such as e-mail, with appropriate safeguards.

Myth: A person cannot be listed in a hospital's directory without his or her consent, and the hospital is prohibited from sharing a patient's directory information with the public.

Fact: The privacy rule permits hospitals to continue the practice of providing directory information to the public unless the patient has specifically chosen to opt out.

Myth: Members of the clergy no longer can find out whether members of their congregation or their religious affiliation are hospitalized unless they know the person by name.

Fact: The regulation specifically provides that hospitals may continue the practice of disclosing directory information "to members of the clergy," unless the patient has objected to such disclosure.

Myth: A hospital is prohibited from sharing information with a patient's family without the patient's express consent.

Fact: Under the privacy rule, a health care provider may "disclose to a family member, other relative, or a close personal friend of the individual, or any other person identified by the individual," the medical information directly relevant to such person's involvement with the patient's care or payment related to the patient's care.

Myth: A person's family members no longer can pick up prescriptions for a patient.

Fact: Under the regulation, a family member or other individual may act on a patient's behalf to "pick up filled prescriptions, medical supplies, X-rays, or other similar forms of protected health information."

Myth: The privacy regulation mandates all sorts of new disclosures of patient information.

Fact: HHS has said disclosure is mandated in only two situations — to an individual patient upon request, or to the HHS Secretary for use in oversight investigations.

Myth: The HIPAA privacy regulation imposes so many administrative requirements on covered entities that the costs of implementation are prohibitive.

Fact: The White House has projected a net saving of $12 billion to the health care system over 10 years as a result of implementation of the standards. The cost of implementing privacy over 10 years is estimated at $17 billion, and savings from putting transaction standards in place are estimated at $29 billion over 10 years. Additional long-term savings are expected as patients develop more faith in the health care system and thus are less likely to withhold vital information from their doctors and will more readily seek care.

Myth: Patients will sue health providers for not complying with the HIPAA privacy regulation.

Fact: The regulation does not give people the right to sue. They must file a written complaint with the HHS Office for Civil Rights. Although the agency has authority to assess civil penalties, it has said that enforcement will be complaint driven and that penalties will be imposed only for willful violations.

Myth: Patients' medical records can no longer be used for marketing.

Fact: Use or disclosure of medical information is explicitly permitted for certain health related marketing activities under the regulation.

Myth: If a patient refuses to sign an acknowledgement of receipt of a health care provider's notice of privacy practices, the provider can, or must, refuse to provide services.

Fact: The regulation grants patients a "right to notice" of privacy practices for protected health information, and requires that providers make a "good-faith effort" to get patients to acknowledge that they have received the notice. But the law does not give providers either the right or the obligation to refuse to treat people who do not sign the acknowledgement, nor does it subject the provider to liability if a good-faith effort is made.

Myth: The regulation imposes many new restrictions on hospital fundraising efforts, making it almost impossible.

Fact: According to the rule, a hospital may use, or disclose to its "business associate" or an

institutionally related foundation, demographic information and the dates of health care provided to an individual "for the purpose of raising funds for its own benefit, without an authorization" from the patient. Such use or disclosure is not permitted unless disclosed in the notice of privacy practices.

Myth: The press no longer can access vital public information from hospitals about accidents or crime victims.

Fact: HIPAA allows hospitals to continue to make public, including to the news media, certain patient directory information, including the patient's location in the facility and condition in general terms, unless the patient has specifically opted out of having such information publicly available. ■

Hospitals having problems with privacy reg, AHA says

Three aspects of rule creating unnecessary burdens

American Hospital Association (AHA) attorney **Lawrence Hughes** said there are aspects of the privacy rule that still are not working well and are creating unnecessary burdens for hospitals, with little benefit to patients.

One of the biggest concerns that hospitals have, Hughes told a subcommittee of the Department of Health and Human Services (HHS) National Committee on Vital and Health Statistics, is the burden associated with the accounting of disclosures requirement. "This burden requires that hospitals, even if they haven't received any requests for accounting, create an enormously burdensome paperwork system to be prepared to respond to any accounting," Hughes said.

He reported that the AHA has put together a proposal for a less burdensome approach to the need to get information to patients and has discussed it with HHS staff.

Another area of concern for hospitals, according to Hughes, is the "burden of trying to negotiate and deal with folks who are requesting that they become business associates." He said it seems that many organizations want to become business associates under a mistaken impression that being a business associate would give them the opportunity to get information and use it in multiple ways that are prohibited under the Privacy Rule.

According to Hughes, hospitals have to deal with such requests daily, and there is a need for education and guidance directly from the HHS Office of Civil Rights because organizations that want to become business associates often don't seem to believe what hospitals tell them. "So," he said, "they need some sort of backup educational materials coming directly from OCR that would help them in addressing those kinds of mistaken impressions about business associate agreements." ■

Survey shows physicians not ready for HIPAA

Fewer than 50% perform background checks

Rhode Island's Seacrest DocSecurity surveyed more than 500 physicians nationwide late in 2003, questioning them on requirements that insurance companies ask for before underwriting physicians and hospitals for insurance, and concluded that while physicians generally believe they are HIPAA-compliant, in fact they have only met a portion of the HIPAA requirements, leaving them vulnerable to lawsuits.

"Records, quite literally, are the lifeblood of a medical practice," the company's report says, "and doctors take, keep, and transmit those records in any of a number of ways, from walking a folder down the hall to faxing them to consulting physicians to storing information in centralized, digital directories. Protecting the information in all of these different forms is easier said than done."

Among the survey's findings:

• 36.2% of those surveyed said that because they or their employees have been through privacy training, they are HIPAA-compliant. Seacrest says typical training programs don't even touch on the digital or physical security aspects of HIPAA and don't take into account the maintenance and destruction of records as specified by the law.

• Fewer than 50% of the physicians surveyed perform background checks on employees. Seacrest points out that physicians' offices are small businesses and as the business owners, the physicians are responsible for the actions of their employees. "If a staff member steals medical information and sells it to a third party, it is the

doctor/owner who is responsible for that action," the company says. Seacrest says that physicians should not confuse a background check with a reference check when considering new employees. A true background check, it says, would involve discovering and assessing any criminal activity a potential employee was involved with. It notes estimates that as many as 14% of hospital employees have criminal records.

• Nearly 40% of physicians surveyed do not secure electronic data transmissions. At the very least, according to Seacrest, physicians should be taking steps to keep hackers from accessing files as they are being transferred. It's one thing if the practice is using e-mail for simple office transactions, but file transfers often contain billing information, which requires diagnosis coding that is personal information. "Not encrypting the data is similar to dropping a bill in the mailbox without an envelope," the company says. "The fact that four in 10 don't bother with encryption is disturbing."

Even at this late date, 14% of practices said they had not isolated or locked file cabinets or record rooms, and 27% said that fax machines were not kept in a secured, locked area.

[Additional information is available from Seacrest at (401) 851-2022 or e-mail info@seacrestdocsecurity.com.] ■

HIPAA Q & A

Question: Does the security rule specify how a risk analysis must be conducted?

Answer: The security rule requires all covered entities to perform an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic protected health information in its possession, says **Robert W. Markette Jr.**, an Indianapolis attorney. "The rule does not specify how a covered entity should perform this assessment," he says. "Frankly, even computer security experts don't all use the same methods."

The goal of a risk analysis is to identify potential risks and their likelihood of occurring, he explains. A risk assessment can be performed by hiring outside consultants or can be performed by the surgery staff, Markette says. "Programs will need to use their own judgment when deciding whether to handle the risk assessment on their own or to hire outside consultants." The decision may depend on the program's individual staff resources and expertise, he adds.

Question: How should passwords be chosen to ensure security?

Answer: There are rules of thumb for choosing passwords, Markette says.

"First, do not use words from the dictionary or obvious words such as relatives' names or pets' names," he emphasizes. "Do not use your birth date or a relative's birth date," he says.

Birth dates and names are learned easily and often are the first things a hacker will choose when guessing a password, he explains.

"Generally, a password should be a combination of letters, numbers, and, perhaps, even other ASCII characters," Markette suggests. "Of course, this is a two-edged sword." The more complicated the password, the more difficult it is for a hacker to guess, but it also is more difficult for an employee to remember, he adds. Complicated passwords are of absolutely no value for security purposes if the employee writes it on a note that is stuck to the computer screen, he says.

There are a couple of ways you can come up with difficult-to-guess but easy-to-remember passwords, Markette adds. "You can combine somebody's initials with the last four digits of another person's phone number, or take the first letter from each word in an easily remembered phrase and combine it in some way with a birth date or phone number," he suggests. For example: The phrase "Asta la vista baby" combined with the last four digits of a phone number could become any of the following: alvb5543, a5l5v4b3, 5543alvb, 5a5l4v3b.

"None of these passwords are easily guessed, but for the employee, they should be simpler to remember than trgh678# or some other randomly generated password," he explains.

Question: Can a home health agency post thank-you letters from patients on a bulletin board that can be seen by staff and other patients?

Answer: "In my opinion, they cannot post the letters unless the letters are de-identified so they no longer constitute protected health information," Gilliland says. "De-identification" is a process under the privacy rule by which health information is made to no longer be individually identifiable. "Typically, it requires removing all of 18 identifiers stated in the privacy rule including names, geographic subdivisions smaller than a state, most zip codes, telephone numbers, and medical record numbers," he says. ■