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New Joint Commission surveys to be more difficult, risky for providers

Random record-pulls expose hospitals to new liabilities

If you thought Joint Commission surveys were stressful before, just wait until you get a knock on the door for a random unannounced survey. Instead of being able to choose which records the inspectors see, they will tell you which ones to produce.

The new policy announced recently by the Joint Commission on Accreditation of Healthcare Organizations in Oakbrook Terrace, IL, is bound to make the entire accreditation process much more difficult and dangerous for risk managers, says **Grena Porto**, RN, ARM, DFASHRM, director of clinical risk management and loss prevention services at VHA Inc. in Berwyn, PA, and president of the American Society for Healthcare Risk Management.

There is a greater chance that your organization will run afoul of some Joint Commission expectations under the new policy, so the entire accreditation process becomes more difficult, she says. **(See "OIG: Joint Commission too easy on hospitals," September 1999 *Healthcare Risk Management*, pp. 107-108.)**

Executive Summary

Subject:

Risk managers will see dramatic effects from the recent changes in the way on-site surveys will be conducted by the Joint Commission on Accreditation of Healthcare Organizations. The changes may mean more work for you, and the risk of a poor score is greater than under the previous policy.

Essential points:

- ❏ Providers will be subject to random unannounced surveys.
- ❏ The Joint Commission will decide what records they want to see, instead of letting you choose.
- ❏ You may need to revise your job description to accommodate the extra work under the new policy.

"This is very much a significant change for risk managers," Porto says. "It used to be that if you had your triennial survey done in March, you know the next one will be March 2002. They might change it to February or April or May, but you know well in advance when you're due for an on-site survey. You only got a surprise inspection if you had some really big blow-up at your facility."

Changing the policy so providers can be subjected to unannounced random surveys completely changes the way risk managers must participate in the accreditation process, Porto says. Some of those effects are good, eliminating what she says were inherent weaknesses in the process, but some of the effects also will make your life more difficult.

Stricter policy in response to OIG audit

The changes were made in response to a report from June Gibbs Brown, PhD, inspector general of the Department of Health and Human Services (HHS) in Washington, DC. In her report, "External Review of Hospital Quality," she said the Joint Commission has been too easy on hospitals, trying to foster a collegial atmosphere instead of ensuring that its on-site surveys would ferret out any problems. The Joint Commission is unable to detect substandard care or identify incompetent doctors because Joint Commission inspectors announce their visits in advance and rely on hospital employees to select the records that will be reviewed, the report says.

When the HHS report was released, the Joint Commission wasted little time in responding. President **Dennis O'Leary**, MD, indicated that he accepted most of the criticism without argument, but he noted that oversight does not have to be adversarial. Almost immediately after the critical report, the Joint Commission's board of commissioners reported that it was modifying its policy for on-site surveys. Under the revised policy, which is expected to go into effect Jan. 1, 2000, providers will receive "no advance notice for random unannounced surveys." The random unannounced surveys may be conducted any time between nine months and 30 months after the provider's triennial full survey.

"The scope and focus of review during an unannounced survey will vary from organization to organization and will be based on information relating to recommendations made during the organization's previous triennial survey, known sentinel events, and other relevant information regarding the organization's performance," according to the Joint Commission announcement. The group also is considering a change in the way it awards Accreditation with Commendation to exemplary providers, based on the HHS criticism that the award becomes meaningless when too many providers earn it.

Porto says that the Joint Commission's new approach is understandable to some extent because even the providers who benefited from the older policy admit that it was a bit lax. With three years to prepare for the next survey, it was too easy to put on the best face no matter what was going on at your facility the rest of the time, she says.

"I think most everyone would agree that a triennial survey really was not any indication of continual compliance. It's an indication that you're in compliance every three years when you're surveyed," she says. "In the past, they would say they wanted 100 charts, and, if you had half a brain, you pulled 100 charts that looked pretty good. Now this policy will create more of a burden for hospitals, but the old system was fundamentally flawed."

Still, Porto says she is not entirely happy with what she hears of the Joint Commission's new approach. Even if some of the measures are justified, she says she is uncomfortable that the Joint Commission reacted so quickly to the Office of the Inspector General report without consulting industry leaders or proposing new options for feedback. The Joint Commission always announces it wants to consult the industry before making big changes, she says, "yet here's another instance of them making a huge change without consulting anybody."

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It would have been more productive to sit down with those responsible for compliance and work out ways to make the process more productive without placing an unreasonable burden on hospitals, she says.

Confidentiality problems could result

Not all risk managers think the changes were needed. The previous policy was better than switching to unannounced visits, says **Peggy Nakamura,** RN, MBA, JD, DFASHRM, executive director of risk management and associate counsel at Adventist Health in Roseville, CA. Nakamura also is an immediate past president of the American Society for Healthcare Risk Management in Chicago. She tells *Healthcare Risk Management* the recent changes would be more appropriate for a regulatory body, not an accrediting body like the Joint Commission. The process could be counterproductive if providers see the prospect of random surveys as more of a regulatory activity, some observers say. **(For more on that possibility, see story, p. 117.)**

"I don't see that there is an appreciation by the Joint Commission of what it means to be an accrediting body," she says. "The more they do this sort of thing, the more they seem like a regulatory body. It's sort of a policeman mentality, and I don't think that encourages quality."

The biggest problem with the new approach is the way the Joint Commission will request records for review, Nakamura says. With no advance request, it will be difficult for the hospital to just turn over all the records immediately. When medical records are involved, it is never easy to just hand them over without a thorough review of whether such a release is acceptable. The question is not so difficult when dealing with regulatory bodies, such as the state health department, because state laws usually provide clear exclusions that make it acceptable for the hospital to hand over the records, she says. But with the Joint Commission, it's a different story.

The records could involve behavioral medicine patients whose records must be kept confidential, for instance, or they could involve potentially compensable events that the hospital wants to protect from discovery. Under the previous method, the hospital would know far ahead of time if certain records or types of records were requested, and there would be adequate time to investigate the situation and determine what to do.

"Now we're going to just have to hash all that out in real time, after they give us a list of what they want," she says. "I think that's asking a lot for people to be able to make these decisions on the spot. It's hard to sort out all the multiple layers of regulations and statutes that apply when you're on the front line and someone's asking for the records right now."

At the very least, Nakamura says, the process will be extremely inefficient for both the Joint Commission representatives and the hospital. There won't be any choice in some situations but to just tell them to wait while you decide whether you can release the record, she says. One tip: Nakamura suggests that when you have to delay handing over a record, ask what else you might provide in the meantime. That helps diminish the appearance that you might just be stalling or uncooperative.

Sentinel events could pop up in review

Another possible problem with the record review is that the Joint Commission might get wind of a potential sentinel event it didn't know about already. Especially if the incident is recent and you are just beginning the review process, you may be faced with a situation in which the Joint Commission has requested records related to that event, but you don't yet know whether you should release those records. And there always is the possibility that the records will reveal a sentinel event you chose not to report, one that the Joint Commission never would have heard of otherwise.

It is a good idea to have legal counsel involved in the review of records requested by the Joint Commission, Nakamura says. **(See p. 116 for more advice on who to involve in the on-site visit.)** "My greatest concern is that, with unannounced appearances and the request of medical records, it's going to bring the hospital to a standstill," she explains. "What if your medical records director is on vacation? With staffing constraints, who knows if all the right people will be available when the Joint Commission appears?"

The "minuteman" aspect of the new policy is what seems to make risk managers uneasy. While many would agree that the previous policy was too lax to be truly effective, the new policy of random unannounced visits seems to go too far in the other direction.

Now risk managers, and the rest of the hospital, have to be on their toes every day, ready for

a Joint Commission team to walk in with clipboards.

Porto says she has heard that hospitals might get 24 hours notice, but that's not much. Still, some might say that if your facility is in compliance, as it should be at all times, then what's the problem with having inspectors come with little or no notice? That makes sense theoretically, Porto says, but it ignores the reality of running a busy hospital.

"In reality, we know that's not the way life works. You're operating 365 days a year, 24 hours a day, and there are going to be natural slips, ebbs, and flows in that operation," Porto says. "If you were only open Monday through Friday, nine to five, maybe you could ensure the same high level of quality all the time. But, in a hospital, there will be times things are suboptimal and times when they are superoptimal. I think that's what everyone is scared about."

Attention will be diverted on short notice

Even when you could expect to see Joint Commission inspectors just every three years, it took a great deal of time and effort to prepare for the survey, she notes. Now you may have to throw all that attention to the inspectors with little or no notice. Having enough time to hide your problems should not be the goal, of course, but Porto says she worries that risk managers will be diverted from other concerns by the ever-present possibility of an inspection.

"You need some amount of time to prepare, not because you're out of compliance but because you're running a business," she says. "If you suddenly pull all your department heads away from their jobs to meet with the Joint Commission inspectors, something is going to slip. It's like if any company suddenly announced to the employees that they're going away on a three-day retreat starting tomorrow. What happens to the work they should be doing?"

The constant need to be ready also changes the job description for risk managers involved in the accreditation process, Porto says. You may need to make your boss aware of how the new policy changes your daily activities so that he or she understands why you suddenly have more on your plate.

Another likely downside from the new policy is that the scores from unannounced visits are likely to be lower than those for which you've fastidiously prepared, Porto says. It would be nice if the Joint Commission took into consideration the surprise nature of the visits when scoring, but there has been no indication that will happen. To the contrary, the Joint Commission appears eager to shed the image that it is too easy on hospitals during on-site surveys.

The constant need to be ready for a site visit changes the job description for risk managers involved in the accreditation process.

"They're looking to find things," Porto says. "They're not interested in giving a lot of high scores. The OIG pointed out that an extraordinary number of facilities got high marks, so the implication is that the OIG would like to see more failing scores. My guess is that if they start showing up unannounced in hospitals, lots of people will start getting low marks in some areas."

It also is possible that, for a short time at least, there will be a double standard for Joint Commission scores. An Accreditation with Commendation achieved this year might not mean the same thing as an Accreditation with Commendation achieved next year, she says. ■

Put key players on call for fast response to JCAHO

Decide in advance who should be notified

When the Joint Commission comes knocking, you have to be able to respond quickly. It is to your advantage to have all the right hospital leaders and consultants on hand to assist, so you must plan now for a system that gets all those players in place with little notice.

You should decide ahead of time who you need to be involved in an unannounced Joint Commission visit and devise a system for rallying them, suggests **Peggy Nakamura,** RN, MBA, JD, DFASHRM, executive director of risk management and associate counsel at Adventist Health in Roseville, CA. She also is immediate past president of the American Society for Healthcare Risk Management in Chicago.

The first step, she says, is to determine who needs to be notified and/or present as the Joint

Commission pokes around your hospital.

The first person who should be notified is yourself. The risk manager must be told as soon as possible when anyone — *anyone* — at the hospital gets word that the Joint Commission is on grounds or on the way. The receptionist, the security guard, the chief executive officer's secretary — anyone who might first encounter Joint Commission representatives or receive their calls — should know that this is a high-priority event and that the risk management department should be notified immediately. Nakamura recommends classifying this right up there with major adverse events that require quick notification of the risk manager.

A paging system may be desirable

Depending on your exact circumstances, you might even want to institute a paging system that alerts all the key players with a special code on their pagers, for instance. In most cases, however, it probably is sufficient to use a phone tree in which the first person to hear of the visit calls the risk manager, who then is responsible for calling everyone else who is needed.

Nakamura suggests including the chief executive officer, the director of medical records, the director of quality management or quality improvement, and possibly the compliance officer. Others within your own organization might be appropriate. In addition, Nakamura strongly urges you to contact legal counsel the minute you hear of the Joint Commission's visit.

If you have in-house legal counsel, that person should be included on the response team. But even if you use outside counsel, Nakamura says it would be money well spent to have that person present. It will be necessary to explain ahead of time about the possibility of a surprise Joint Commission visit and why such a visit would require the attorney to drop everything and get to the hospital immediately. Don't be surprised if the attorney says that could be difficult; you still need to press for an immediate response if at all possible.

"I think we'll have to treat it almost like an emergency," Nakamura says. "You don't have any time to waste before people start handing over things they shouldn't or before the Joint Commission starts to think you're just trying to cover up something. Get your folks in there and get some good decisions on what you can turn over." ■

Review process might fail if seen as 'gotcha' game

Surveys should share beneficial initiatives

A risk manager who has worked closely with the Joint Commission says the new system for random on-site visits and record requests might be counterproductive if providers get the impression that the Joint Commission is just out to get them.

There is no doubt that the recent changes from the Joint Commission on Accreditation of Healthcare Organizations will have a major impact, says **Nancy Guilliom**, BSN, FASHRM, CPHQ, risk manager with Norton Healthcare in Louisville, KY, and chairwoman of the Joint Commission Task Force for the American Society of Healthcare Risk Management. Patient care has been improved in recent years with the assistance of the Joint Commission's triennial, random, and for-cause surveys, she says. The new system of unannounced surveys might be counterproductive if providers feel threatened, she says.

"Accreditation is not a 'gotcha' game," she says. "It should be a collaborative effort between the Joint Commission and health care facilities to promote quality patient care. Once resulting data is compiled during the accreditation process, the Joint Commission's focus should be on sharing concrete initiatives with facilities that could benefit from improved systems to enhance patient safety."

Unannounced surveys feel more regulatory

The move to unannounced surveys probably will have a more "regulatory" feel for hospitals, Guilliom says. She says the recently announced changes are unnecessary and that the system already was compelling hospitals to maintain high standards.

"I think the days are long gone when hospitals would gear up the year before a scheduled Joint Commission visit and then let things slide," she says. But if any hospitals still follow that practice, "those facilities will be at the greatest risk for a poor score if they are selected for a random, unannounced survey."

For more information, contact Nancy Guilliom at (502) 893-1207. ■

Amnesty offered for returning 'bonus capital'

It's state money you shouldn't have kept anyway

You have until the end of this month to return those state funds you shouldn't have kept. Return them by then and no one gets hurt. Miss the deadline and you could face a hefty fine.

Thirty-nine states have agreed to an amnesty program that ends Oct. 31, 1999, encouraging health care providers to turn over money that rightly belongs to the state. The funds come from patient credit balances, uncashed payroll checks, and other sources within the health care institution. Hospital officials often think they are free to keep these unclaimed funds and just apply them to the institution's bottom line, but that is not so, says **Patricia Barganier**, a senior manager in Ernst & Young's National Tax Department in Atlanta.

Unclaimed funds often rolled into capital

Most health care organizations accumulate a certain amount of "bonus capital" over time, in the form of unclaimed funds. Paychecks, stock dividends, credit balances, refunds, insurance reimbursements, customer overpayments, and vendor payments all can be left in the hospital's hands for one reason or another. After awhile, most organizations just decide that the funds have been unclaimed and roll them over into the hospital's operating capital, Barganier says.

"The problem is that the money isn't theirs to keep," she says. "Under the law, it belongs to the state, and failure to turn it over can be a costly mistake."

Even if you don't actually convert the funds to your own use, you still may be liable for not turning them over to the state, she says. The laws are structured in such a way that an organization that has never pocketed a single unclaimed dime may nevertheless find itself liable for hundreds of thousands of dollars. States are becoming increasingly aggressive in enforcing property reporting requirements, she says.

All 50 states require companies to file unclaimed property reports and to retain records substantiating these reports. And, unlike many tax laws, most states do not make any exemption for nonprofit companies.

To enforce compliance with unclaimed property laws, many states have contracted with third-party auditors to audit health care providers. Under these agreements, states typically compensate third-party auditors based on the amount of unclaimed property recovered, along with interest and penalties assessed. Many states' unclaimed property laws have long statutory limitation periods or may not have any statutory limitation at all, Barganier says. As a result, the audits typically involve a 10-year audit period.

The legal principle involved is "escheat," which means the reversion of property to the state in the absence of legal heirs or claimants. Though all states, the District of Columbia, Puerto Rico, and the Virgin Islands require that unclaimed funds be turned over, compliance and enforcement of the laws has been spotty at best.

A small number of companies, such as the Fortune 500, electric utilities, financial institutions, and insurance companies, report and turn over unclaimed funds regularly because their noncompliance might be recognized easily. Most other companies, including health care providers, rarely report abandoned funds, Barganier says.

In the early 1990s, states did not bother to go after them, either. But now states are recognizing that these funds are a rich untapped source of revenue.

"While all types of organizations are fair game, health care institutions have a special vulnerability," she says. "The reason has to do with the health care industry's unique financial model. Since medical services are likely to be paid for by multiple parties — the patient himself, one or more insurers, Medicare, or Medicaid — overpayment is not uncommon."

In other industries, corporations routinely apply credit balances to the customer's account, she notes. Hospitals, however, don't seek or depend on repeat business, so that means it is uncommon to keep a running account for the patient. If all went well, the patient will not be back at the hospital any time soon.

"As a result, most hospitals simply keep the money, unaware that they are building up sizable potential liabilities over time," she says.

Barganier also cautions that poor record keeping can increase your liability or even result in liability when you actually did not keep any unclaimed money. When auditors look over your records, your organization may be required to document fully that certain funds were provided

to their rightful owners. If you made the payment but can no longer show that the transaction actually took place, the state's auditors may consider the transaction unproven and require you to pay that money to the state. Without proper documentation, you can be forced to pay even when you appropriately disbursed the funds years earlier, she says.

The best strategy for reducing the potential liability is to know your state's law and make sure your organization has systems in place to comply on an ongoing basis, she says. You should investigate how your state defines unclaimed property and what exclusions, if any, may be provided for your type of organization. Also, familiarize yourself with the record-keeping requirements and reporting deadlines.

Thirty-eight states and the District of Columbia have agreed to participate in the amnesty program ending Oct. 31. Health care providers in those states may turn over any unclaimed funds by that date without suffering any penalties or interest. These are the 39 participants in the amnesty program: Alabama, Alaska, Arizona, Arkansas, Connecticut, Delaware, District of Columbia, Hawaii, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Michigan, Minnesota, Missouri, Nebraska, New Hampshire, New York, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming.

For more information, contact: Patricia Barganier, Senior Manager, Ernst & Young, 600 Peachtree St., Suite 2800, Atlanta, GA 30308-2215. Telephone: (404) 817-8761. ■

Hospital says it didn't experiment on patient

Advanced procedures can present the highest risks

It comes as no surprise that patients want to know when they're about to undergo an experimental procedure. You might be surprised to learn, however, that providers can get caught in sticky situations when they perform procedures that are advanced and risky but not necessarily experimental. Doctors may see such procedures as cutting-edge measures needed to help their patients, but some patients may think their doctors are simply experimenting on them without informed consent.

If so, a lawsuit is inevitable, and the potential loss is huge. That's the situation facing Thomas Jefferson University Hospital in Philadelphia, where a patient has filed a lawsuit alleging that doctors subjected him to experimental treatment for a brain condition without his consent. The man was left incapacitated after the surgery.

The patient, George Phillips, was a 33-year-old auto mechanic when he sought treatment at the hospital in 1995 for bad headaches and numbness in his right arm. Tests revealed he had an arteriovenous malformation (AVM) in his brain, a tangle of blood vessels that had been bleeding. The condition was life-threatening.

A lawsuit filed recently by Phillips' wife, Nancy, contends that doctors used her husband as "a human guinea pig" for research that was not approved by the hospital and that did not meet federal standards for human research. The Philadelphia Common Pleas Court allowed the couple to include punitive damages and allegations of civil conspiracy and fraud. That substantially ups the ante for the hospital, creating the possibility of a payout far beyond the typical malpractice case.

Doctors at the hospital deny the charges, contending that what they did was cutting-edge and daring, perhaps, but not experimental. A trial is scheduled for some time in 2000.

Phyllis Fisher, spokeswoman for Thomas Jefferson University Hospital, confirms that the university employs the physicians in question, therefore the university is handling the defense

Executive Summary

Subject:
Some advanced medical procedures pose a liability risk because patients may see them as experimental. Because providers don't see them that way, they don't obtain consent for experimental procedures. A hospital in Philadelphia is facing such a charge.

Essential points:
- ❑ The risk is greatest with "gray area" procedures that are advanced but not technically experimental.
- ❑ Surgeons should be reminded to inform patients carefully about the nature of advanced procedures.
- ❑ Good documentation of the informed consent process is key to defending against such charges.

of all of the parties. While she was unable to comment on the defense of the case because the litigation is pending, she confirms a number of facts previously made public.

Phillips had a large AVM that was difficult to treat, partly because of its location in his brain. Surgeons ruled out surgery to remove the AVM or cut off its blood supply, according to court documents filed with the case. The surgeons then turned to another possibility, stereotactic radiosurgery, in which a beam of radiation is focused on the AVM to shrink it. The surgery is considered risky because the radiation can damage or destroy healthy brain tissue along with the AVM. One of the surgeons testified recently that he had used the technique on up to 40 patients before Phillips, but he had used a single dose of radiation on each of those patients.

In Nancy Phillips' deposition, she said that the surgeons told her there would be only one dose of radiation and the likelihood of success was 80%. She says she learned later from a nurse that there would be multiple radiation sessions. Court papers show that the decision to switch to multiple sessions came after the case was discussed by senior surgeons at the hospital, who decided all such AVM patients should be treated with multiple doses of radiation because that would be more effective and safer than a single dose.

The Phillipses contend that the decision to use multiple doses of radiation pushed the treatment beyond aggressive to experimental, and that there was no informed consent process to obtain permission for experimental treatment. Phillips had six radiation sessions but was unable to return to work because of continuing problems, including new difficulties with seizures and speaking. In November 1995, Phillips had a stroke that left him unable to speak or do anything else. He now lives in a nursing home, and his wife says she does not know how much he comprehends.

According to court papers filed in response to the lawsuit and depositions by the accused, the surgeons were pursuing a course of therapy they knew to be aggressive, but they say the patient had little other choice. They deny that the multiple radiation treatments crossed the line into experimentation. The parties also disagree on how much information was given the Phillipses before the procedure. The plaintiffs contend they were assured that the risk was not exceptionally high, while the hospital contends that surgeons fully explained the unproven nature of the treatment and the high risk it entailed.

The outcome of the case will not be determined for some time unless there is a quick settlement. Nevertheless, the case raises some difficult questions for risk managers, says **Steve Johnson**, director of risk management for Wellstar Health System in Marietta, GA. Normally, any experimental treatment must be approved by the facility's institutional review board (IRB), which can say yes or no to a request and will monitor any approved experimentation. The Phillipses' lawsuit contends that one of the surgeons went to the IRB after the treatment, not before. Documents filed by the hospital contend that the surgeon went to the IRB at that point only to formalize a protocol so treatment results could be presented at a conference. **(See p. 121 for more on surgeons' suggestions regarding IRB approval and for advice on how to lower the liability risk.)**

"If there is any doubt that the procedure is experimental, you usually take it before the IRB because it's not standard practice," Johnson says. "There is an opportunity to be approved or disapproved on its merits. And, more importantly, the IRB ensures that the patient acknowledges through an informed consent process that this is considered experimental, outside the norm."

When the treatment clearly is experimental, the situation actually might be easier to handle, he says. The IRB must be involved, and certain protocols must be followed. But when the treatment is in more of a gray area, such as the radiation treatment for AVM, things are more dicey for the hospital. The surgeons may not pursue IRB approval because they sincerely think they don't need to, but the patient or family may think otherwise. When the treatment involves something as complicated as brain surgery, there may be enough doubt to carry the case to a jury.

"The gray areas are dangerous because then you get providers pitted against one another, saying it is experimental or it isn't," Johnson says.

The Philadelphia case is being reviewed by the U.S. Office of Protection from Research Risks in Washington, DC. The office is responsible for safeguarding the rights of people involved in medical experiments.

For more details, contact: Phyllis Fisher, Public Relations, Thomas Jefferson University Hospital, 1015 Chestnut St., Suite 810, Philadelphia, PA 19107-4302. Telephone: (215) 955-6300.

Steve Johnson, Risk Management, Wellstar Health Systems, 805 Sandy Plains Road, Marietta, GA 30066. Telephone: (770) 792-7536. ■

IRB approval needed for aggressive surgery

Surgeons often face gray areas in which individuals might disagree over whether a particular treatment is merely aggressive or experimental, says **Gerald Fried**, MD, head of laparoscopic surgery at McGill University and head of gastrointestinal and laparoscopic surgery at Montreal General Hospital in Canada. The key sometimes is how much the procedure is different from whatever was done before, he says.

"If you're going to make small innovations, small changes, then there's really not a huge burden both ethically and legally," he says. Using a new type of instrument, or even a new type of access to the patient may be novel, for instance, but it poses little or no risk to the patient. Therefore, the need to seek approval and inform the patient is lessened.

Fried made his comments, along with several other surgeons, at a recent surgery conference in San Antonio. Unusual and daring treatment sometimes is justified by the situation, Fried says. The mere fact that a procedure is unproven does not necessarily mean it should not be used, he says, but he cautions that unproven treatments present more than the usual burden of informing the patient. In addition to the standard informed consent, an experimental approach demands that you explain the nature of the innovation so the patient clearly understands the situation.

"We must give our patients a clear description of what we're going to do to them, the risks and benefits, and the prior experience both worldwide and in our own experience," he says. "You must remember that patients are highly susceptible to our recommendations and our enthusiasm. You also must recognize that each of us goes into the situation with a built-in bias to do the procedure because we are surgeons and we want to advance science and build up our own experiences."

Surgeons should be urged to use a low threshold for seeking approval from the institutional review board (IRB), he says. Another word of warning comes from **Steven Stain,** MD, associate professor of surgery at the University of Southern California School of Medicine and director of the surgical residency program at Huntington Memorial Hospital in Pasadena, CA. Many surgeons think they know more about the requirements for clinical trials and institutional rules on surgical innovations than they actually do, he says.

"We define novel procedures as those that may be unproven, and they may pose additional risk to the patient," Stain says. Novel procedures can be distinguished from research, however. Research usually involves surgical procedures in which a certain task is performed or a certain approach used for the purpose of gathering data, rather than purely for the purpose of patient care, he says. Other factors, such as industry sponsorship, can push a procedure from the "novel" category to the "research" category.

A novel surgical approach is less likely to require IRB approval, Stain says. Research probably needs IRB approval.

Don't go overboard in depending on IRB approval as a risk management tool, however. IRB approval may not be especially helpful in defending a malpractice case, says **Kenneth Kern**, MD, attending surgeon and associate clinical professor of surgery at Hartford (CT) Hospital and the University of Connecticut School of Medicine in Hartford. Kern has studied surgery malpractice for years and says juries are likely to see IRB approval as merely an administrative endorsement.

"As far as I can see, IRB approval would be a negative if you didn't have it, but, if you did have it, I don't think it would offer any significant benefit in your defense," he says. ■

Documentation is key to case alleging experiment

The bread and butter of risk management is documentation, but it becomes even more important when you are accused of performing experimental therapy without the proper consent. If you can't prove that you thoroughly explained the situation to the patient and obtained the proper consent, you're dead in the water.

Risk managers should strongly encourage surgeons and other physicians to err on the side of caution when explaining aggressive treatment to patients and their families, says **Steve Johnson**, director of risk management for Wellstar Health System in Marietta, GA. "If there is even a hint that what they're doing could be considered by their peers to be outside the norm, then the patient should be fully informed of that fact," he says. "It could only help you. Go into as much detail as you want to explain the benefits and why

you've decided to do this, but be very thorough in explaining that this is an unusual procedure."

The risk increases when the procedure is highly complex and confusing, as with neurosurgery. It is imperative that the surgeon explain the situation as clearly as possible, avoiding medical terminology that will be meaningless to the patient, Johnson says. If the surgeon doubts that the patient fully comprehends the risks, and especially if death is a possibility, the surgeon should bring in a family member or friend to help the patient understand, if the patient agrees. Document that person's involvement.

"I would tell surgeons that you have to document, document, document in these gray areas," he says. "When you're in cutting-edge medicine, the more you can do to show that you've discussed this with the patient and they wanted to proceed, the better you are. You don't want to be left with just the doctor's word that he did everything he could to inform the patient." ■

Annual Compliance Institute comprehensive for all

Entire track to be devoted to case studies

Whether you are a veteran or new to health care corporate compliance, and whether you work in a hospital, home health agency, nursing home, or physician practice, the Health Care Compliance Association's (HCCA) 3rd Annual Compliance Institute will meet all your training needs.

This year's Institute, "Advanced Compliance: Discovering the Hallmarks of Effective Compliance Programs, a Critical Step in Compliance," scheduled for Oct. 24-27 at the Chicago Marriott, is designed to provide practical workshops for experienced compliance professionals.

To assist those attending the Institute, HCCA has labeled all sessions as either basic, intermediate, or advanced. The Institute also will devote an entire track to case studies, offering specific examples on various aspects of compliance programs.

For the beginner, HCCA will offer "Compliance 101," a three-hour compliance primer, during a preconference on Sunday, Oct. 24. To learn more about HCCA's Annual Compliance Institute or to register, call (888) 580-8373 or visit conference central on HCCA's Web site: www.hcca-info.org and register on-line. ■

NEWS BRIEFS

Hospitals may be fined for not reporting discipline

A proposal by the federal government could mean that hospitals and others will face fines of more than $10,000 for not reporting disciplinary actions against physicians to the National Practitioner Data Bank.

The Health Resources and Services Administration, part of the Department of Health and Human Services in Washington, DC, has proposed a system in which hospitals would be subject to federal civil financial penalties for failing to report disciplinary actions taken against physicians and dentists.

The HHS Office of the Inspector General recommended such a system recently in response to reports that hospitals and managed care organizations are not reporting all disciplinary actions.

The inspector general recommended a system in which hospitals and managed care groups would be fined up to $10,000 for each failure to report, but the Health Resources and Services Administration is considering a higher fine and broadening the scope of who is required to report. A spokesman for the administration says the proposal is under internal review but declined further comment. ▼

False Claims Act misused by Justice, GAO says

The U.S. Department of Justice (DOJ) has misused the False Claims Act in pursuing medical fraud, according to a report from the General Accounting Office. The report alleges the Department of Justice has been capricious with the False Claims Act, often using it against providers only because they were large, making them easy targets.

Individual attorneys, along with the DOJ, have used the False Claims Act in recent years as a powerful weapon to combat health care fraud. The

DOJ issued guidance in 1998 to help U.S. attorneys across the country use the False Claims Act properly, but the recent report from the GAO says the attorneys are not following those guidelines closely enough. Compliance with the guidelines "may be superficial," according to the GAO report.

GAO officials reviewed the activities of eight U.S. attorneys' offices and found that compliance with the guidelines varied. In five offices, GAO investigators found that letters had been sent to large numbers of hospitals implying violations of the False Claims Act, even though the attorneys had no evidence to suggest those violations.

One of the U.S. attorneys' offices had notified 24 hospitals in 1997 that they were being investigated for violations of the False Claims Act, but investigators learned that the hospitals had been targeted only because they were the largest billers of Medicare in the state and not because there was evidence of any specific fraud.

Reacting to the GAO report, American Hospital Association president **Dick Davidson** says it supports the association's previously stated position that hospitals had been unfairly targeted. ▼

Feds: Gainsharing deals for physicians not allowed

If your hospital administrators had the bright idea that they could encourage physicians to cut costs by passing on some of the savings to them, you might want to let them know it's not such a great idea after all. Federal regulators have issued a stern warning about such practices, threatening to go after hospitals that participate in such "gainsharing" arrangements.

The Health and Human Services (HHS) Office of the Inspector General issued a special advisory bulletin warning against gainsharing. The bulletin acknowledges that hospitals have a legitimate interest in encouraging physicians to eliminate unnecessary costs, but when Medicare and Medicaid payments are involved, the HHS makes clear that gainsharing is not allowed. Providers who make gainsharing payments to physicians can be fined and face other penalties, possibly even dismissal from participation in Medicaid and Medicare.

Gainsharing is not allowed because it poses too much risk of abuse and could adversely affect patient care, according to the HHS. In particular, gainsharing could lead to rewarding physicians for patient referrals.

The Office of the Inspector General issued the bulletin after receiving a number of queries about the legality of such arrangements. Gainsharing could be acceptable if there were regulatory safeguards to keep the system from being abused, but that would require congressional action before the HHS could allow it. ▼

Correction

A reference to Nancy-Anne DeParle on p. 107 in the September 1999 issue of *Healthcare Risk Management* incorrectly identified her title and affiliation. DeParle is deputy administrator of the Health Care Financing Administration.

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Study: Liability increases if health plans sued

A new study suggests that the cost of malpractice insurance for physicians will increase substantially if Congress votes to eliminate managed care's current defense against state causes of action.

The report comes from the Tillinghast-Towers Perrin consulting firm in Rockville, MD. Physician malpractice costs will rise 8% to 20% if patients are able to sue managed care companies, according to the analysis. Such lawsuits currently are prevented in most cases by the Employee Retirement Income Security Act (ERISA), but Congress is considering lifting that restriction.

A change in the ERISA law does not directly affect physicians, but the Tillinghast report says an increase in lawsuits against managed care companies inevitably will involve an increase in lawsuits against individual physicians and physician practices. Physicians will be named along with the managed care companies. Under the current ERISA prohibition, Tillinghast says, some potential cases are never filed because the managed care company is seen as the main wrongdoer and the physician is only a secondary party. But if the plaintiff is able to sue the managed care company, physicians will be named also. ▼

HCFA recognizes JCAHO's hospice accreditation

The Health Care Financing Administration (HCFA) in Baltimore announced recently that it now formally recognizes the Joint Commission on Accreditation of Healthcare Organizations' hospice accreditation program, easing some administrative burdens for hospice providers.

HCFA will consider a hospice provider to be in compliance with the Conditions of Participation for hospices when the provider achieves accreditation through the Joint Commission survey process. As of September 14, 1999, hospice organizations were eligible to seek deemed status. That includes the 1,100 hospice organizations accredited by the Joint Commission.

A hospice organization choosing the deemed status option will be evaluated by the Joint Commission using Joint Commission standards that include the Medicare Conditions of Participation and standards for hospice organizations. Accreditation remains voluntary, and seeking deemed status through accreditation is an option, not a requirement for Medicare certification. ▼

New JCAHO compliance manual available

Strategies for Successful JCAHO Homecare Accreditation 1999-2000 is a step-by-step guide to compliance with the Joint Commission on the Accreditation of Healthcare Organizations' 1999-2000 standards. It includes case studies with tips and advice from your peers who have survived the survey. Call (800) 688-2421 or e-mail American Health Consultants at customerservice@ahcpub.com. ■

PATIENT SAFETY QUARTERLY™

PLANNING FOR NATURAL AND MAN-MADE DISASTERS

Hurricane prep focuses on evacuation, staffing needs

Floyd's threat recalls preparation done for Fran

The recent evacuations from Southeastern coastal cities as Hurricane Floyd roared offshore repeated on a larger scale the evacuations called for when Hurricane Fran triggered the implementation of disaster plans.

At Memorial Health University Medical Center, formerly Memorial Medical Center, in Savannah, GA, the 320 patients evacuated this past September almost tripled the 114 patients the hospital evacuated in 1996.

According to **Gary Milewski**, the hospital's corporate safety officer, the patients were moved inland to hospitals in Macon and Augusta, GA. More than 100 patients who didn't require ventilation or other mechanical equipment remained at Memorial Health, which did not sustain any damage, he notes.

Milewski's experience in the previous storm caused him to change the disaster plan he had written a year before Fran struck. "Procedures for communicating with the receiving hospitals and now Memorial Health's A and B teams were dispatched and updated," he says, "and the A and B teams are established earlier on."

Members of team A can go home to see to their families' safety then return the hospital 12 hours before the storm's landfall. At that point, members of team B are allowed to go home and see to their families, he says. The result? "Everything went smoother. We moved patients in 26 hours vs. the 30 to 35 hours it took us with Fran, with fewer patients."

Potentially as lethal as hurricanes Andrew or Hugo, the storm raised the specter of massive structural damage, power outages, and worse — danger to the coastal hospital's more than 350 patients.

In a matter of hours, the hospital evacuated 114 patients, discharged 100 more, and moved about 140 to the interior of the hospital, Milewski says. "We started tracking the hurricane the previous week. We have a computer program that is tied into the national weather system."

Because the storm's early path appeared to be on a direct collision course for Savannah, on the Tuesday before it was to arrive, hospital officials made the decision to evacuate, he says.

"I call them [the receiving hospitals] and tell them what kinds of beds I need and they call back and tell me what they have," he says. It took the staff just 16 hours from the time physicians began evaluating patients to the time all of the those eligible for transport were moved.

"We would have liked to evacuate all of the patients, but many were not able to be transferred," Milewski says.

A command center was established in the administrative conference room. Complete with a bank of phone lines, computers linked to the Chatham County Emergency Management Agency, and HAM radio operators, the center was designed to maintain communication with the outside world even if power and phone service were lost, Milewski says.

Critical care patients on life-support equipment were transferred to power provided by the hospital's six backup generators.

The staff cancelled all elective surgery beginning Wednesday and began seeing only emergent patients, Milewski says. "We went through our

plan right up until the storm turned and headed up the coast."

All but one of the patients were transferred back on Friday after the threat of Fran had passed. "We had one woman deliver [while she was at another hospital], but the others are all back," he said after the storm.

Milewski credits the successful evacuation to the extensive inservice training Memorial's staff undergoes throughout the year.

The safety plan is divided into separate training modules and presented to employees at regular inservice days throughout the year, says **Suzanne Ingram**, the hospital's director of business and admitting. The modules detail procedures to be implemented in the case of flood, fire, and other disasters, as well as hurricanes, and all staff are tested on the information once each year, she says.

In addition to the modules, the emergency procedures for each department are spelled out in easily accessible reference sheets, allowing people to work in several different departments, depending on where they are needed most, Milewski says. "We can utilize other personnel. It doesn't have to be admitting [staff]; others can help out."

Weather emergencies present unique problems in terms of disaster planning, says Milewski, who worked with the Federal Emergency Management Agency for 12 years before coming to Savannah.

"It's a twofold operation," Milewski says. The entire hospital must be evaluated for safety, as well as its ability to treat patients.

At the Medical University of South Carolina in Charleston, the staff remain on alert almost constantly throughout the hurricane season, explains **Cindy Williams**, manager of admitting and financial counseling. Each time a hurricane threatens, Williams immediately begins setting up A and B teams of employees and separate "call trees" to keep the rest of her staff informed of changes in the hospital's status. Williams calls designated people on her list, and each person in turn is responsible for getting in touch with the next employee and delivering the information.

The current plan calls for personnel on the A team to be prepared to work at the hospital through the impending storm and stay there up to three days, Williams says. The B team is sent home and called in after the storm passes to relieve team A.

The importance of having enough personnel at the hospital prior to a hurricane is one of the lessons the staff at Medical University learned from their experience with Hurricane Hugo several years ago, says **Maureen McDaniel**, the hospital's coordinator for bed management.

"I don't think we really knew what to expect," she says. "We weren't ready to spend lots of time here before the other teams could get in."

Williams says she makes sure she has enough staff to operate for 24 hours straight, just in case the B team is unable to come in on schedule.

For example, Williams says, two admitting personnel are needed for each eight- to 10-hour shift to staff the emergency department. She calls in five people on the A team and sets up a smaller rotation of workers inside the A-B arrangement.

For each A and B team, two people are on duty for the first eight hours, while the other three are at the hospital, but are either off duty resting or helping prepare for the storm by covering computers with plastic and placing important records in high places, out of the reach of possible flood waters.

Discharge planning begins immediately when the hospital administration declares a weather emergency, says McDaniel. Each nursing station provides the bed management staff with a list of patients who are eligible for discharge, she says.

Though many patients are discharged ahead of a storm, many patients recovering at home are brought into the hospital because of anticipated power outages and water problems in the area.

In addition to scheduling enough personnel, the hospital also tries to tend to the needs of its employees, such as keeping the cafeteria open around the clock and setting up an on-site nursery for employees' children.

Another lesson learned from Hugo is the necessity of keeping staff up to date on the hospital's plans in an emergency, Williams says.

"You can't just spring on someone that they have to be here for the next 24 to 48 hours," she says. "You don't need [people working with] the anxiety of 'I wasn't prepared at home.'"

Both Milewski and Williams say their plans for Fran worked well, giving them added confidence for facing future hurricanes. "It's about everyone working as a team and knowing what to do," Milewski says.

He noted that this was the first time in the hospital's 41-year history that it evacuated patients.

Flexibility is also important to remember when dealing with a disaster situation, says Williams. "You have to stay on top of it. You can't say, 'This is the plan, and this is what will happen,' because those things can change." ■

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

Choked patient dies: $642,730 verdict against facility

By **Pearl Schaikewitz**, JD
Legal Consultant, Atlanta

News: The estate of a psychiatric patient who collapsed and died 45 minutes after being choked by another patient won a $642,730 verdict against the facility. The nurses didn't call a physician to examine her after the incident.

Background: The 70-year-old woman had been diagnosed with bipolar disorder and schizophrenia and was a longtime resident of the intermediate care facility for mentally impaired adults. On April 29, 1993, she was attacked by another patient, who choked her with a scarf and hit her in the face. That patient was a paranoid schizophrenic. Another resident immediately alerted the nursing staff. According to the nurses, the patient who had been attacked said she was not injured, so they allowed her to leave the nurses' office unattended to smoke a cigarette. About 45 minutes later, when the police wanted to interview the victim, the nurses found her in her room, short of breath. They asked her to walk to the nurses' station, but she collapsed and lost consciousness. She was pronounced dead on arrival at a nearby hospital.

The patient's daughter claimed that after the attack, her mother was bleeding from the mouth and had bruises on her face and neck. She maintained that the facility was negligent in failing to assess her mother's injuries, to call 911 or a physician, or to make appropriate efforts to resuscitate her. Experts testified for the plaintiff that the patient had sustained fractures to the hyoid bone and anterior neck cartilage, which, when left untreated, resulted in swelling, hemorrhaging, an obstructed airway, suffocation, cardiac arrest, and death. Those experts concluded that the patient's nursing care was inadequate and that her injuries would not have been fatal if treated in a timely manner.

The facility countered that the patient's vital signs were normal after the attack and that the nurses were unaware at the time of their initial assessment that the patient had sustained throat fractures. The facility's insurance carrier disputed coverage and refused to increase its settlement offer despite the recommendations of its trial counsel and two judges.

What it means to you: Phyllis Maxey, RN, director of risk management for Carolinas HealthCare System in Charlotte, NC, first wonders whether the attacker had a history of violence. "The victim had been a long-term resident, so the staff probably knew her pretty well. But we do not know how long the perpetrator had resided in the home, so we do not know how well the staff knew him. So my first concern was the history of both patients. Were they known not to get along?"

Incompatibility problems highlight the need for monitoring, Maxey stresses. "Where were these patients located when the incident occurred, and was there sufficient staff in attendance to monitor them? This case illustrates why, even though you believe psychiatric patients have progressed to a certain level, you cannot relax in your vigilance in monitoring them. Had an attendant witnessed the attack, that person

might have prevented the nurses from making an incorrect assessment. If you see a particularly vicious or aggressive attack, that will color how well you assess the patient," she notes. She suspects these patients were in the day room when this happened and says the facility should have a policy in place stating that those patients should be attended.

Another concern Maxey has is the daughter's allegation that her mother was bleeding from the mouth and had bruises on her face and neck. "We do not know what physical signs the nurses had to go on. But if there were signs of injury on the patient's face and neck, they would have to be taken very seriously, given the proximity to the airway. Similarly, allowing the patient to leave the nurses' station and go unattended to smoke a cigarette was dangerous, because that activity affects the airway.

"A patient who has suffered an attack needs to be watched to make sure that she is truly not injured, as she has reported. So, I would have to question the nurses' judgment. If they let her smoke, it was probably outside, and that is pretty far away from the nurses' station," she says. Maxey adds that the bruises might not have appeared at the time the nurses first saw the patient after the attack. "But if it is true that the patient was bleeding from the mouth and she had a large, swollen hematoma on her lip, it should have been apparent when the nurses saw her."

Patient's appearance, statement insufficient

Maxey also wonders about the details of the examination the nurses conducted after the incident. "Making an overall appearance assessment is not sufficient. One cannot rely entirely on a patient's statement that she is fine, because that is entirely subjective. The patient may be embarrassed and may wish to minimize the incident."

There is a standard to comply with, Maxey adds. "Vital signs should have been taken at the time. Then the nurses could have asked the patient to sit in a chair attended by the nurse for 10 minutes, checked her vital signs again, and then re-checked them after another 15 minutes."

The nurses should have looked for any signs of bruising, such as a red, pressure-looking area and then noted it, she says. "After an incident such as this, the skin needs to be assessed for any kind of force or tear. Elderly people have thin skin, and changes would probably be apparent on the skin. A bruise would probably appear within 15 to 20 minutes. And, of course, the assessment must be documented."

Finally, Maxey says she does not think the evidence justifies the experts' conclusion that the patient's nursing care was inadequate and that her injuries would not have been fatal if treated in timely fashion. "It is possible that she could not have been saved even if the nurses had noted that she had been injured, had called 911, and medics had arrived timely. I believe that most likely her vital signs were normal when the nurses did a basic exam after the injury and that it was not until later, when her airway began to swell, that her vital signs changed."

Reference

Rogers v. Columbus Manor Residential Care Home Inc., Cook County (IL) Circuit Court, Case No. 94-L-1519. ■

Allegation of poor nursing care: $500,000 settlement

News: A Veterans Affairs hospital settled for $500,000 with an elderly diabetic patient who suffered gruesome complications due to allegedly poor nursing care.

Background: The patient was a 75-year-old retired chef who had been admitted on Oct. 15, 1993, diagnosed with a mild stroke. The case centered around the care and treatment he received in the hospital until Nov. 22, 1994. The patient claimed his care began to deteriorate upon his transfer to the rehabilitative ward. He developed bedsores, which were complicated by diabetes and peripheral vein disease. He continued to receive poor nursing care, he claimed. Gaps in nursing notes appeared, occasionally for entire shifts, according to court documents.

In May 1994, the patient scratched himself near his groin, causing an open wound. The patient claimed poor nursing care caused infection and gangrene in the groin, necessitating surgical castration, a permanent colostomy, and cystotomy. He underwent 23 surgical debridements under general anesthesia. The patient also claimed that poor management of his foot ulcers ultimately led to an above-the-knee amputation of his right

leg. He has been bedridden since that time. The hospital was prepared to argue that due to his medical history, the patient likely would have developed these problems and that the surgery was necessary to save his life.

What it means to you: Margaret Radzwill, RN, BSN, offers an overview of the potential risk management and quality of care issues that arise in this case:

"It seems that this 75-year-old gentleman experienced multiple complications stemming from other chronic medical conditions, primarily diabetes and history of peripheral vascular disease [PVD]. As such, this case raises several issues concerning the appropriate management of his diabetes during his inpatient stay on the medical and rehab unit, as well as initial and ongoing nursing assessment and care management by all interdisciplinary team members who were likely involved with his care.

❑ **Appropriateness of initial and ongoing assessments.**

"Since the patient's primary diagnosis was a mild stroke, it is assumed that he was admitted to the rehab unit for neuromuscular rehabilitation. In this regard, it is not evident that this patient initially had a comprehensive assessment that focused on a complete systems review, with special focus on cardiovascular assessment and nursing safeguards taken for maintaining skin integrity and preserving circulatory status, given the patient's PVD history and later development of decubiti and foot ulcers.

❑ **Failure to report and act on patient's declining circulatory status.**

"Another consideration was whether the nurse and/or physical therapy staff reported the patient's declining circulatory status to the physician, and whether the patient received further evaluation of his PVD for medical or surgical treatment considerations.

❑ **Aggressive diabetes management during hospitalization.**

"It is not known whether the patient's blood sugars were appropriately monitored by nursing staff and treated accordingly by the proper consulting physician. Due to the patient's diabetic-related outcomes, it seems that his diabetes was poorly managed for some time.

However, poor glycemic control during his hospital stay may have contributed to his declining peripheral vascular status and his susceptibility to infection, which resulted in a bowel gangrene and subsequent surgeries.

Daily glucometer testing and periodic hemoglobin A_{1c} monitoring would have assisted staff in measuring the effectiveness of the patient's glycemic control, as well as served as a liability defense measure — provided the evidence showed that actions were taken to improve his glycemic control.

❑ **Processes for identifying patients who are no longer rehab candidates due to worsening medical conditions.**

"Another consideration is whether this patient was an appropriate rehab candidate once he began to develop loss of circulatory integrity. It seems that the patient may have benefited from transfer back to the medical floor for more aggressive evaluation and treatment intervention.

❑ **Nursing/staff documentation omissions — a risk management nightmare.**

"Certainly the gaps of nursing documentation necessary to support the level and extent of care provided to this patient raise serious concerns about the appropriateness of the nursing and rehab care he received. Those documentation omissions made this case difficult for the health care facility to defend from a professional liability perspective.

❑ **High-risk patient identification requires more nursing interventions during the care planning process.**

"All patients with complex co-morbid conditions, as described for the patient in this case, should be treated as high risk, and nursing interventions should be planned accordingly to prevent treatment complications. Vigilant attention to glycemic control and maintenance of skin integrity for such patients is essential for quality medical care and should be included in a multidisciplinary team effort to prevent complications. Nurses, aides, physical therapists, and the treating physicians all share in this role."

Reference

Porter v. U.S.A. (Bronx V.A. Hospital), U.S. District Court, Southern District of New York, Case No. 96 Civ 6266.

Margaret Radzwill, RN, BSN, is a consultant with Healthcare Management Consulting Services, in Houston. She specializes in clinical risk management, integrated utilization/quality management, and development of disease/case management programs for hospitals, medical groups, and managed care organizations. ■

Transferred patient's baby dies: $850,000 settlement

Claim made under federal anti-dumping statutes

News: A pregnant woman whose baby died after the mother was transferred to a second hospital by an ambulance that broke down during the transfer settled her case for $850,000. The woman and her husband made a claim under federal anti-dumping statutes.

Background: On Aug. 1, 1994, the patient, who was 32 weeks pregnant, woke up with a severe headache, sore jaw, and bloody tongue. She had two seizures. The patient called her obstetrician and went to W.W. Backus Hospital in Norwich, CT. After she arrived and underwent tests, her obstetrician had her transferred by ambulance to the University of Connecticut in Farmington. The trip 70-minute trip took 90 minutes because the ambulance broke down, and the patient and her husband had to wait for a second ambulance. The baby died on Aug. 5 due to injuries to major organs, the plaintiffs claimed.

The plaintiffs alleged that the baby should have been delivered at Backus in order to stabilize the mother's condition, eclampsia. The plaintiffs also claimed that the obstetrician and Backus violated federal anti-dumping laws, which would require them to pay double damages. These defendants denied the allegations, claiming that their actions were medically appropriate and did not violate the standard of care.

The ambulance company, which also was sued, contended that the ambulance broke down without warning and that the 20-minute delay caused by the wait for the second ambulance did not cause the infant's death.

What it means to you: Leilani Kicklighter, RN, ARM, MBA, assistant administrator of risk/safety management for the North Broward Hospital District in Fort Lauderdale, FL, initially questions whether the patient was in labor or suffering from one of the potential complications of pregnancy, eclampsia. Kicklighter notes that if the patient had been stabilized and transferred to a higher level of care at another facility because of the potential prematurity of the fetus and the eclampsia, with full disclosure by the physician of the risks and benefits, and if the transfer was not done based on insurance coverage or ability to pay, then it is unclear why the hospital was held responsible. Moreover, an ambulance company normally operates independently from the hospital; therefore, the hospital is not customarily held liable for the ambulance company's negligence, she adds.

More inservicing needed

Nevertheless, there was a settlement in this case, reinforcing the need to hold repeated inservices for both the emergency department staff and the OB staff regarding the appropriate assessment of pregnant patients, Kicklighter says.

"The Emergency Treatment and Active Labor Act [EMTALA] applies to all patients presenting to and requesting care from an emergency department, and to all patients in labor, regardless of ability to pay.

"First, the patient is evaluated and screened and receives full informed consent regarding the risks and benefits of a transfer. Then, if the organization does not provide the level of care or the specialty needed, a patient may be transferred to another organization, provided it is for care and not because of lack of ability to pay. All of these elements must be emphasized to physicians and other staff to assure compliance. Whenever there is a question of whether the EMTALA regulations are met, the risk manager should be called," she explains.

Enforce ambulance fleet management

Another issue that arises in this case is the ambulance company's fleet management program, specifically related to this vehicle, Kicklighter observes. She would want to know when the vehicle last underwent routine maintenance and what the routine daily vehicle inspection entailed.

"Often, when an organization such as an ambulance company is vehicle-dependent, there is a reluctance to enforce routine maintenance checks. That is because it often means the vehicle will be out of commission for at least a day, and that means lost business. While automobiles are quirky and can stall without warning, the risk manager must be sure there is an appropriate, broad fleet management program in place and that it is enforced with documentation to back-up compliance." ■