Healthcare RISK MANAGEMENT

June 2013 | Vol. 35, No. 6 Pages 61-72

Do you have the right insurance broker? You can boost coverage, lower costs

Insurance brokers can be a key resource for hospitals, but risk managers often end up working with a broker for all the wrong reasons. Sometimes the broker has been with the organization for years with no one questioning the relationship, for example.

The right broker can help a hospital obtain the best coverage for a wide range of employee benefit and liability concerns, and for the lowest cost. A lazy broker or one who is not well-connected and up to date on current trends could end up costing the hospital millions. Considering how important it is to work with the right broker, the relationship should not be left to chance or based on how such relationships have been handled in the past.

Brokers can be found online or in the phone book, but risk managers should ensure that their organizations put great care into selecting one, says **Renee Guariglia**, executive vice president of Falcone Associates in Syracuse, NY, which provides brokerage services. For starters, the broker should be affiliated with industry organizations such as the National Association of Health Underwriters.

Certification also can be important, suggests **Brad Greenbaum**, president and benefits consultant with Altigro Benefits in Fairfield, NJ. Look for chartered life underwriters, chartered financial consultants, registered health underwriters, or brokers with other degrees from the American College of Financial Services. "These are recognized designations, meaning it's not a course you go to one afternoon and get a few letters after your name," Greenbaum says. "It's a course of study to get the credential and then usually ongoing study to keep it."

The best contacts often are made

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INSIDE

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through referrals by other healthcare providers, so when looking for a broker, inquire with your affiliated organizations — physicians' groups and laboratories, for example — about which broker they use, Guariglia suggests.

When you ask about their brokers, Guariglia says to ask about their contact with him or her. Ask, "How often do you meet with your broker? Does he meet with you once a year or often throughout the year to ask questions and offer advice? Does your broker provide you with timely information?"

However, Guariglia cautions that it can be a waste of time to ask a broker for references or contact information for clients. No one is going to provide a bad reference, and the clients will be cherry-picked for their satisfaction with the broker, she says. Coming from the other direction, by asking those in your industry what brokers they have worked with and recommend, achieves much better results, she says. *(See the story on p. 63 for more on how to select a broker.)* "When you work with someone who is in the same industry as yours, you get a feel for who has the same needs for insurance and benefits for their employees as you do," Guariglia says. "When you talk to a risk manager at another hospital or a group practice, you both are on common ground in terms of what you need from a broker."

Executive Summary

Choosing the right insurance broker can improve your healthcare organization's coverage while at the same time reducing costs. Avoid working with a broker simply because he or she has been your hospital's broker in the past.

- ✦ Ask affiliated providers for referrals.
- ✦ Conduct a formal interview process to select a broker.
- ✦ Look for additional services beyond insurance.

Another quality to look for is dedicated account management, says **Michael Grant,** executive managing director of employee benefits services at Crystal & Company in New York City, which provides strategic risk and insurance advice. This dedicated account management is the service aspect of a broker. Look for a broker who is going to take some work off your desk, he suggests. "That could be anything from the transactional pieces like COBRA administration to utilization review, and advising them about new products that are coming on the market," Grant says. "It's very common for administrators to be approached about a new product and think it sounds good for the hospital, but they need a broker they can trust and ask about what it really means."

A good broker also should be able to pull in other resources to benefit you, Grant says. An example would be an underwriter or financial analyst. Brokers also should take a proactive, offensive position in renewing coverage before waiting for the insurance company to provide terms, he says.

It is easy to become complacent with the broker your organization has used for a while, Grant says. He offers these

Healthcare Risk Management® (ISSN 1081-6534), including HRM Legal Review & Commentary™, is published monthly by AHC Media, a division of Thompson Media Group LLC, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodicals Postage Paid at Atlanta, GA 30304 and at additional mailing offices.

POSTMASTER: Send address changes to Healthcare Risk Management®, P.O. Box 105109, Atlanta, GA 30348.

AHC Media is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation. This activity has been approved for 15 nursing contact hours using a 60-minute contact hour.

Provider approved by the California Board of Registered Nursing, Provider #14749, for 15 Contact Hours.

This activity is valid 24 months from the date of publication.

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Editorial Questions

Questions or comments? Call **Greg Freeman,** (770) 998-8455.

warning signs that you might need to look for a new broker:

• **You are surprised by premium increases when it's time to renew a policy.** At a minimum, a good broker will warn you about the coming increase. A better broker will present a plan to the insurer before the renewal date that avoids or minimizes the premium increase.

• **The broker does not seem to have a deep bench of resources to call on directly or to refer you to, especially regarding the changing healthcare scene.** Brokers should have ready access to experts who address healthcare reform, compliance challenges, and the impact on your benefits and coverage. One person cannot be an expert in all of these areas, so the broker should have ample resources.

• **The broker does not respond promptly to your inquiries.** You should receive a response, or at least an acknowledgment of your inquiry, within 24 hours.

• **You don't hear much from your broker about new technologies and options available to reduce costs or improve benefits.**

A broker's willingness to help with day-to-day issues such as claims disputes should be a significant factor, suggests **Dave Oscar**, president of Xanthus Benefits in Fairfield NJ. Many brokers show up once a year for renewal and then leave again.

"They need to be more interactive than that," Oscar says. "You're paying for more than someone to just come in annually and do the paperwork, then say 'bye' and they'll see you next year. Expect a lot more than that."

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Interview brokers, and ask how they can meet your needs

Don't go easy on brokers who want your business, says **Renee Guariglia**, executive vice president of Falcone Associates in Syracuse, NY, which provides brokerage services. Make them prove that they are a good match for your needs.

Once you have a list of candidates, Guariglia recommends a formal interview process with the top three to five brokers. The goal is find out about broker individually but also the agency in which the broker works.

"Don't discount the personal impression. When you meet that broker, do you feel a connection to him or her?" Guariglia says. "There's something to be said for first impressions. Be careful about putting too much faith in what you see on somebody's website. It might be a nice website, but it's the person you're going to be dealing with on some very important matters."

Don't be afraid to ask about similar clients and how the broker has helped them. Also, be sure to explain your needs and ask what the broker can do to meet them.

"That's different from letting the broker go through a presentation of all the great things they can do for you and letting you try to match that to your needs," she says. "Tell them what you need, and make them show you they can address each of those in a specific way."

Before settling on a broker, check your state insurance commissioner's website to see if the broker has been cited or fined for any infractions, or had a license suspended or revoked. ✦

Robotic surgery problems can involve hospitals

A Colorado surgeon is under investigation for 14 robotic surgeries with poor outcomes or adverse events, and the Food and Drug Administration (FDA) is investigating what might be an unexpectedly high rate of problems with surgical robotics. In response, a malpractice attorney is cautioning risk managers that high-tech treatments with great marketing potential can lead some hospitals to overlook problems on which they might otherwise act.

The Colorado Board of Medical Examiners has charged Warren Kortz, MD, of with 14 counts of unprofessional conduct after a series of failed procedures with the robotic surgery arm owned by Porter Adventist Hospital in Denver. According to the complaint filed by the board, from 2008 to 2010 Kortz cut and tore blood vessels, left sponges and other instruments inside patients after closing, injured patients through improper padding and positioning, subjected some to overly long surgeries, and had to abort kidney donations because of mistakes.

The board also alleges that Kortz failed to properly document some of those problems. The state is asking an administrative judge to discipline Kortz's license to practice medicine. In a related development, the FDA

announced recently that it is investigating robotic surgery devices in response to a number of reports of accidents and adverse outcomes. The FDA has received reports of at least five deaths involving robotic surgery since early 2010, but a statement from the FDA says the agency does not yet know if there is any trend or if robotic surgery is responsible for the deaths or other problems. "Since it is difficult to know why the reports have increased, the FDA has elected to talk with surgeons to better understand the factors that may be contributing to the rise in report numbers," the statement says.

The FDA database of problems related to medical devices includes 500 reports since Jan. 1, 2012. Some are duplicates, reported by the hospital and the manufacturer, and there is no evidence that any of the problems were caused by the robot. Many of the reports did not involve a patient injury.

Hospitals and device makers are required to report adverse outcomes related to medical devices, but the increase in reports could reflect only wider use. Intuitive Surgical in Sunnyvale, CA, which makes the popular da Vinci surgical arm, reports that in 2012 there were 367,000 robot surgeries versus 114,000 in 2008. The da Vinci is the only robotic system cleared for soft-tissue surgery by the FDA, but other robotic devices are approved for neurosurgery, orthopedics, and other procedures. *(See the story on p. 65 for the manufacturer's response to the FDA concerns.)*

The Denver hospital is entangled in the Porter case partly because it knew of problems with Porter's robotic outcomes, explains **Daniel P. Slayden**, JD, a partner with the law firm of Hinshaw & Culbertson in Joliet, IL, which handles medical malpractice. The hospital issued a statement confirming that it suspended Kortz's robotic-surgery privileges for three months in 2010. The medical board's complaint states that the hospital reported Kortz had complications with 11 surgeries using a hospital robot.

Slayden notes that many of the patient complaints against Kortz related to informed consent, with some claiming that he did not properly explain the risks of the robotic procedure or offer a traditional surgery option. That issue is one for the physician rather than the hospital, he says.

"It could become a hospital issue, though, if the plaintiff shows when the doctor started having too many accidents, too many poor outcomes, a higher return-to-surgery rate and asks why the hospital didn't suspend him until 2010," Slayden says. "If the data show that his rates were higher than the average, and especially if they were higher when using the robotic arm, someone is going to argue that you should have suspended him in 2009. That's when it becomes a hospital risk management issue." *(See the story below for more on how hospitals can manage risks that comes with cutting-edge technology.)*

Executive Summary

A doctor's performance with robotic surgery is being questioned, and the hospital is entangled because it knew of the problems. The case shows how cutting-edge technology might affect how a hospital supervises physicians.

✦ The Colorado Board of Medical Examiners has charged the doctor with unprofessional conduct.

✦ The hospital suspended the doctor's privileges at one point.

✦ Risk managers should ensure surgery with high-tech devices receives the same oversight as any other procedure.

SOURCES

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Hospital's oversight of robotic surgery could be a critical issue, lawyer says

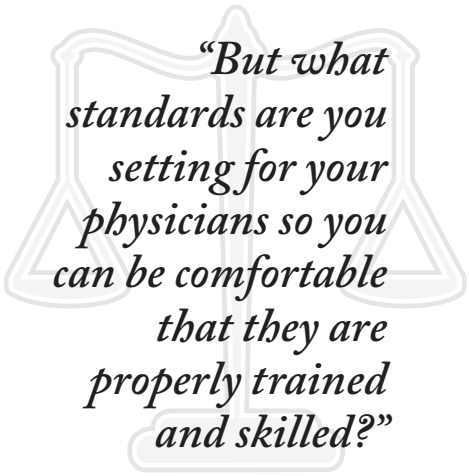
In the case involving allegations of unprofessional conduct against Warren Kortz, MD, of Denver, the use of a robotic surgery arm might be only a distraction, say two malpractice attorneys. No matter what equipment was used, the real issue might be whether the hospital adequately credentialed him and required him to meet the same performance standards as any other surgeon, with or without the robot.

Porter Adventist Hospital in Denver could be held liable if the plaintiff shows that the surgeon was insufficiently trained or skilled on the robotic device, because the hospital allowed him to operate there, explains **Daniel P. Slayden**, JD, a partner with the law firm of Hinshaw & Culbertson in Joliet, IL.

Moreover, the hospital marketed the robotic surgery and included Kortz in the marketing efforts. A plaintiff could claim that the hospital gave the doctor a pass on surgical outcomes that would raise a red flag with other doctors because he was generating significant revenue for the hospital, Slayden explains.

The hospital is more likely to be drawn into such a case when the state has no liability cap, explains **Rodney K. Adams,** JD, a shareholder with the law firm of LeClairRyan in Richmond, VA. The plaintiff will look to the deeper pockets of the hospital and allege negligent credentialing, failure to have a safe environment and similar issues. "In Virginia, for instance, most physicians are insured to the cap, and so the plaintiff doesn't need four or five defendants," he says.

Although some facts are not known about the Denver case, Slayden notes that it does highlight a particular risk of working with new technology. Like lasers 20 years ago, robotic surgery is now a cutting-edge, high-tech treatment option that can draw in more patients to the hospital, but Slayden cautions that risk managers must apply the same patient safety standards. "Patients with choices will decide where they want to be treated based on marketing that shows the latest, most up-to-date technology in use," Slayden says. "But what standards are you setting for your physicians so you can be comfortable that they are properly trained and skilled? It can be a gray area, because if it is new technology, the only training might come from the company that makes the device, and they certainly want doctors to be certified so they can sell the product."



Adams notes that patients can drive the use of such technology and physicians will want to respond. The equipment can cost millions of dollars, so hospitals sometimes are heavily incentivized to market the technology and look the other way if outcomes are not good, he says.

Risk managers must watch for any tendency among administrators and clinical leaders to accept lower quality or more threats to patient safety when cutting-edge technology is used, Slayden says. "Those temptations will always come up with any new technology. That's the nature of the beast," he says. "Your job has to be to hold the line on what is an acceptable record and not change that because your doctor or your hospital really wants to use this device."

But expect some push back on that, Adams cautions. "That's going to create some tension with the marketing department. We saw the same thing with bariatric surgery, when so many hospitals wanted to get into that field because it is very lucrative and there's a big demand for it," Adams says. "A lot of hospitals have since gotten out of it because bariatric surgery requires a lot of training and brings some real challenges for the facility and a high complication rate. The marketing department and the accountants might have wanted to keep it, but someone had to step in and say `this isn't the best thing for us to offer.'" ✦

Da Vinci maker says incident increase is just statistical

In response to the Food and Drug Administration's (FDA's) announcement that it is investigating a possible increase in surgical problems related to the da Vinci robot, the device's maker issued a statement saying the increase is only in the number of reports rather than the number of incidents.

Intuitive Surgical in Sunnyvale, CA, which makes the da Vinci surgical robot, confirms that it has filed more medical device reports (MDR) in recent years. However, the noted rise does not reflect a change in product performance but rather a change in MDR reporting practices, the company says.

In September 2012, Intuitive Surgical revised its MDR practices, which resulted in increased reports of device malfunction MDRs, the vast majority of which were related to instruments and not to systems. None of these device malfunction MDRs involved reportable injuries or deaths, the company says. "We self-identified the reporting issue, notified the FDA, and revised our practices," **Dave Rosa**, senior vice president for emerging procedures and technologies, said in the statement.

MDRs can be found in the FDA database, which is updated regularly. *(The database is accessible online at http://tinyurl.com/maudedatabase.)* The most common type of report filed under the company's revised MDR practices involves instrument cable breaks. These cable breaks render the instrument non-functional and require an instrument change, which can be accomplished quickly, the company says.

The company also made an administrative change in how MDRs previously reported as adverse events were subcategorized. This change has not increased the total number of adverse event reports, but it does result in an increase in events in the "serious injury" subcategory and a corresponding decrease in the "other" subcategory. Total adverse event rates have remained low and in line with historical trends, the company says. ✦

Stark exceptions make it safer to provide docs with EHRs

The Centers for Medicare & Medicaid Services (CMS) recently proposed a rule that revises the exception, known as the Stark Exception, to the federal physician self-referral prohibition (the Stark Law) for certain arrangements involving the donation of electronic health record (EHR) items and services to physicians or other allied health providers.

At the same time, the Office of the Inspector General (OIG) of the Department of Health and Human Services proposed its own rule revising the safe harbor regulation concerning EHR items and services under the Federal Anti-Kickback Statute.

Together, they would amend the 2006 rules from CMS and OIG that encourage the adoption of EHR systems and promise financial rewards to providers showing meaningful use of EHRs. *(See the story below for a summary of the changes from the rules.)*

The rule changes are intended to address some of the financial barriers to adopting EHRs that have been known for some time, explains **Robert Wah**, MD, global chief medical officer for CSC, a technology consulting company based in Falls Church, VA. Wah was deputy national coordinator of health information technology in 2006 when exceptions to Stark and the anti-kickback law were first adopted.

"If the hospital has already made the capital investment in an EHR system, the marginal expense of the expanding that out to bring the physician into the network was relatively low, yet the benefit to the physician was fairly high," Wah explains. "There were hospitals interested in pursuing that, but they were concerned about the Stark regulation and anti-kickback. That was the origin of these exceptions, and now the government is expanding that in light of what we know now."

The revisions should give hospital risk managers a good idea of how regulators will handle this issue, Wah says. When the rules first came out in 2006, some hospital leaders were skeptical because there was no clear precedent to show how the donation of an EHR system would be handled by regulatory agencies, he says. "We have precedent now, after these years, and that body of experience can give people some information when looking at these arrangements," he says.

Wah points out that the benefits of providing access to your hospital's EHR system are even greater now than they were in 2006. With many of the changes taking place in healthcare, streamlined communication will be a priority, and digital communication is the way to go, he says.

"When hospitals are thinking about the risks and benefits of this type of collaboration, that's one thing to consider," Wah says. "Can this get them to the goal of thriving in the new health system reform environment? Consider the risks, but think about the benefits as well."

SOURCE

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Executive Summary

Proposed rules from the Centers for Medicare & Medicaid Services (CMS) and the Office of the Inspector General of the Department of Health and Human Services eliminate some of the self-referral risk when a hospital provides or subsidizes an electronic health record system for physicians. Risk managers should understand the limitations.

✦ CMS is extending the period in which the Stark exception and the safe harbor are available for this purpose.

✦ Electronic prescribing capability will no longer be required for donated software.

✦ Interoperability requirements will be eased.

Rules extend the Stark exception and remove prescribing requirement

Proposed rules from the Centers for Medicare & Medicaid Services (CMS) and the Office of the Inspector General (OIG) of the Department of Health and Human Services will allow hospitals to provide an electronic health record (EHR) system for physicians without running afoul of anti-kickback and self-referral laws.

Robert Wah, MD, global chief medical officer for CSC, a technology consulting company based in Falls Church, VA, provides this summary of the significant changes:

• **Deadlines extended:** The Stark exception and the safe harbor are scheduled to sunset on Dec. 31,

2013, but the proposed rules extend the sunset dates to Dec. 31, 2016, or Dec. 31, 2021, which is when Medicaid's "meaningful use" incentive program ends.

• **Electronic prescribing provision removed:** CMS and OIG propose deleting the mandate that donated software must contain electronic prescribing capability. The requirement originally was meant to encourage the adoption of electronic prescribing, but both agencies now say there are other drivers for that goal.

• **Interoperability provisions:** The rules currently require that donated EHR software be certified as "interoperable" within the 12 months before it is given to the recipient. The changes would require only that the software be certified as interoperable at the time of the donation. ✦

ONC yanks certification for two EHR systems

If you are using an electronic health record (EHR) provided by EHRMagic in Santa Fe Springs, CA, you have a problem. The Office of the National Coordinator for Health IT (ONC) has revoked the certification for two of that company's products. This action marks the first time the government has revoked an EHR certification.

Two of the company's electronic health records, previously certified as products to be used as part of the Medicare and Medicaid Electronic Health Record Incentive Programs, have had their certifications revoked, according to an announcement by **Farzad Mostashari**, MD, the national coordinator for health information technology. "The products do not meet standards, and providers cannot use these products to meet the requirements of the Medicare and Medicaid EHR Incentive programs," Mostashari's announcement said.

EHRMagic-Ambulatory and EHRMagic-Inpatient no longer meet the EHR certification requirements. The EHRs must be certified by an authorized certification body (ACB) before regaining certification.

The ONC and an ONC ACB received complaints from healthcare providers that the EHRMagic products did not meet the required functionality, and the products should not have passed certification, the announcement said. InfoGard analyzed the additional information from the notification and contacted EHRMagic, and this action launched the surveillance activities required by the ONC-authorized certification body. InfoGard concluded that it was necessary for the EHR products to be retested for select requirements. EHRMagic participated in retesting and failed.

"We and our certification bodies take complaints and our follow-up seriously. By revoking the certification of these EHR products, we are making sure that certified electronic health record products meet the requirements to protect patients and providers," Mostashari said. "Because EHRMagic was unable to show that their EHR products met ONC's certification requirements, their EHRs will no longer be certified under the ONC HIT Certification Program." ✦

Diagnostic errors are your biggest medmal risk

Twenty-five years of U.S. medical malpractice claim payouts show that diagnostic errors accounted for the largest fraction of claims, the most severe patient harm, and the highest total of penalty payouts, according to recent research from The Johns Hopkins University in Baltimore, MD.

Diagnosis-related payments amounted to $38.8 billion between 1986 and 2010, says **David E. Newman-Toker**, MD, PhD, an associate professor of neurology at the Johns Hopkins University School of Medicine and leader of the study published online in *BMJ Quality and Safety*. "This is more evidence that diagnostic errors could easily be the biggest patient safety and medical malpractice problem in the United States," Newman-Toker says. "There's a lot more harm associated with diagnostic errors than we imagined."

While the new study looked only at a subset of claims — those that rose to the level of a malpractice payout — Newman-Toker says other research indicates that the number of patients suffering misdiagnosis-related, potentially preventable, significant permanent injury or death annually in the United States ranges from 80,000 to 160,000.

"Overall, diagnostic errors have been underappreciated and underrecognized because they're difficult to measure and keep track of, owing to the frequent gap between the time the error occurs and when it's detected," Newman-Toker says. "These are frequent problems that have played second fiddle to medical and surgical errors, which are evident

more immediately."

He says experts have often downplayed the scope of diagnostic errors not because they were unaware of the problem, but "because they were afraid to open up a can of worms they couldn't close." *(The research is available online at http://tinyurl.com/diagnosiserrors. The abstract is free, but there is a fee for accessing the entire study.)*

"Progress has been made confronting other types of patient harm, but there's probably not going to be a magic bullet solution for diagnostic errors because they are more complex and diverse than other patient safety issues," Newman-Toker says. "We're going to need a lot more people focusing their efforts on this issue if we're going to successfully tackle it."

Newman-Toker and his colleagues analyzed medical malpractice payments data from the National Practitioner Data Bank. They found that of the 350,706 paid claims, diagnostic errors were the leading type (28.6%) and accounted for the highest proportion of total payments (35.2%). Diagnostic errors resulted in death or disability almost twice as often as other error categories.

> *"There's a lot more harm associated with diagnostic errors than we imagined."*

They also found that more diagnostic error claims were rooted in outpatient care than inpatient care (68.8% vs. 31.2%), but inpatient diagnostic errors were more likely to be lethal (48.4% vs. 36.9%). Most diagnostic errors were missed diagnoses, rather than delayed or wrong ones. Per-claim payments were highest in cases of serious neurologic harm, including quadriplegia and brain damage resulting in the need for lifelong care. Those payments, the researchers found, were higher even than for errors resulting in death.

Newman-Toker noted that among malpractice claims, the number of lethal diagnostic errors was roughly the same as the number that resulted in permanent, severe harm to patients. This quality suggests that the public health impact of these types of mistakes is probably much greater than previously believed because prior estimates are based on autopsy data, so they only count deaths and not disability, Newman-Toker says.

SOURCE

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TJC warns about alarm fatigue putting patients at risk

The constant beeping of alarms and an overabundance of information transmitted by medical devices such as ventilators, blood pressure monitors and ECG (electrocardiogram) machines is creating "alarm fatigue" that puts hospital patients at serious risk, according to a *Sentinel Event Alert* issued recently by The Joint Commission (TJC).

The TJC alert urges leaders at hospitals to take a focused look at this serious patient safety issue. Over a recent four-year period, a Food and Drug Administration (FDA) database shows that there were more than 560 alarm-related deaths. The Joint Commission's sentinel event database includes reports of 80 alarm-related deaths and 13 serious alarm-related injuries during a similar period. *(The alert is available online at http://www.jointcommission.org/sea_issue_50.)*

Many patient care areas have numerous alarms, and the barrage of warning noises tend to desensitize caregivers and cause them to ignore alarms or even disable them, TJC noted. Other issues associated with effective alarm management include too many medical devices with alarms or individual alarms that are difficult to hear. Pre-set or default settings also might cause problems because the device sounds a warning even when no action or decision by a caregiver is required. Rather than calling attention to a patient's needs, these settings might distract caregivers.

TJC recommends that healthcare organizations take the following actions:

- Ensure that there is a process for safe alarm management and response in areas identified by the organization as high risk.
- Prepare an inventory of alarm-equipped medical devices used in high-risk areas and for high-risk clinical conditions, and identify the default alarm settings and the limits appropriate for each care area.
- Establish guidelines for alarm settings on alarm-equipped medical devices used in high-risk areas and for high-risk clinical conditions; include identification of situations when alarm signals are not clinically necessary.
- Establish guidelines for tailoring alarm settings and limits for individual patients.

• The guidelines should address situations when limits can be modified to minimize alarm signals and the extent to which alarms can be modified to minimize alarm signals.

• Inspect, check, and maintain alarm-equipped medical devices to provide for accurate and appropriate alarm settings, proper operation, and detectability.

• Base the frequency of these activities on criteria such as manufacturers' recommendations, risk levels and current experience.

The Joint Commission alert also recommends training and education for all clinical care team members on safe alarm management and response in high-risk areas. In addition, organizations should consider how to reduce nuisance alarm signals and to determine whether critical alarm signals can be heard in patient care areas. TJC has proposed a National Patient Safety Goal to help healthcare organizations address this issue. *(Editor's note: To see how alarms played a role in a recent court case, see "Dialysis mistakes lead to a wrongful death and a seven-figure settlement" in this month's* Legal Review & Commentary *supplement.)* ✦

Survey finds healthcare risk managers and executives struggle with patient safety

Maximizing patient safety is the top priority for hospital C-suite executives and risk managers in the United States, but the "lack of teamwork, negative culture, and poor communication" will present barriers to patient safety in the future, according to a survey commissioned by American International Group (AIG) in New York City.

The results revealed a tension between what hospital leaders perceive as their number one priority in 2013, patient safety (64% of C-suite and 62% of risk managers), and their number one threat, failing to maximize financial sustainability (60% of C-suite and 62% of risk managers), said **Russell Johnston**, casualty product line executive, in releasing the results.

While nearly all respondents (96% of C-suite and risk managers) say their hospital has a "culture of patient safety," one-third (33% of C-suite and 37% of risk managers) acknowledge that their hospital needs to undergo major changes to maintain that culture in the future.

"This study is designed to better understand what drives patient safety, the barriers our healthcare system must overcome to achieve it, and what can be done to help keep hospitals safer over the next three to five years," Johnston said.

Most respondents said the largest barriers to patient safety are lack of teamwork, negative culture, and poor communication (42% of C-suite and 55% of risk managers). The primary communication and coordination problems cited include:

• the perception that nurses fear retribution if they discuss patient safety (26% of C-suite and 29% of risk managers);

• documentation burdens (69% of C-suite and 60% of risk managers);

• the number of patient "handoffs" among hospital staff (56% of C-suite and 61% of risk managers);

• the quality of coordination and communication between departments at their hospitals (59% of C-suite executives and 69% of risk managers).

The study also revealed inconsistent perceptions of who is "responsible for" patient safety and who "owns" it. Virtually all hospital executives (98% of both C-suite executives and risk managers) agree that "every staff member in my hospital is responsible for patient safety." But half of both C-suite executives and risk managers (52% and 51%, respectively) believe that nurses "own" it. Interestingly, executives see nursing staff turnover as one of the least influential items on overall hospital risk, including patient safety, regardless of the fact that they place the onus of patient safety on nurses.

Further complicating the situation, the introduction of new technology, regulation, metrics, and patient education aimed at helping patient safety are sometimes perceived has having the opposite effect:

• Three-quarters (75%) of C-suite executives see reporting of quality metrics as beneficial to safety, yet one in five (20%) sees negative impacts on other areas of quality as a result of having to report these metrics.

• While most (84% of C-suite executive and 88% of risk managers) agree their hospital effectively uses technology to improve patient safety, more than half (59% of C-suite executive and 53% of risk managers) say it takes clinical staff away from patient care.

• One in four executives (23% of C-suite executives and 24% of risk managers) admit that their hospital is more focused on driving publicly reported metrics rather than truly impacting patient safety. Also, most hospital leaders agree the public does not understand how to interpret publicly reported patient safety metrics (83% of C-suite executives and 89% of risk managers).

The full survey results can be found at http://tinyurl.com/aigriskreport. ✦

Hospitals to close after allegations of recruiting homeless for unnecessary care

The hospitals involved in a controversy in recent years involving the fraudulent recruiting of indigent patients will close. Hospital owner Pacific Health Corp. (PHC) in Tustin, CA, announced recently that it will close its three remaining Southern California hospitals.

Pacific cited the fallout from a federal fraud case in 2012 in which the company admitted paying to recruit homeless people off Skid Row in Los Angeles and billing the government for unnecessary care. The company's announcement said the decision to close hospitals stemmed from "the settlement we reached with the Department of Justice last year, as well as other legal matters from our past, which have made it impossible for us to continue operating in this especially challenging economic climate for all healthcare providers."

The four Pacific hospitals that will have services suspended are Bellflower Medical Center, Los Angeles Metropolitan Medical Center, Newport Specialty Hospital, and Anaheim General Hospital. The closures will cause as many as 1,900 full-time and part-time employees to lose their jobs, according to the company.

State officials fined Pacific Health more than $7 million in March 2013 for not paying employee wages and bouncing payroll checks. In 2012, Pacific entered into a settlement agreement in which they agreed to pay the government and the state of California $16.5 million for engaging in an illegal kickback scheme in Los Angeles.

The company admitted paying to recruit homeless people off Skid Row in Los Angeles and billing the government for unnecessary care.

The civil settlement resolved a U.S. and state investigation of three Pacific Health-affiliated hospitals for engaging in a scheme in which the hospitals paid recruiters to deliver homeless Medicare or Medi-Cal beneficiaries by ambulance from the Skid Row area in Los Angeles to the hospitals for treatment that often was medically unnecessary, according to information from the U.S. Department of Justice. The government contended that these services were induced by illegal remuneration in violation of the anti-kickback statute and the resulting billings to Medicare and Medi-Cal violated the False Claims Act. *(For more on that story, see* Healthcare Risk Management, *October 2012, p. 119.)*

As part of that plea agreement, the company said it had paid more than $2.3 million in illegal kickbacks to patient recruiters from 2003 to 2008, and as a result, some of its hospitals received nearly $16 million in improper payments from Medicare and Medi-Cal, the state's Medicaid program for the poor. ✦

Shorter hours for interns can increase patient handoff risk

Johns Hopkins researchers say they have uncovered an unintended consequence of the move in recent years to reduce the legendarily long and onerous work hours of interns. Shorter work hours can increase the risks of patient handoff, they say.

Limiting the number of continuous hours worked by medical trainees also failed to increase the amount of sleep each intern received per week, but it dramatically increased the number of potentially dangerous handoffs of patients from one trainee to another, the research from Johns Hopkins suggests. The reductions in work hours also decreased training time, the researchers found. *(The study is available online at http://bit.ly/16dCzFB.)*

In 2011, stricter national regulations, reducing the continuous-duty hours of first-year resident physicians from 30 to 16, were put in place with the theory that limiting trainees' work hours would lead them to sleep more and that less fatigue would translate to fewer serious medical errors. But lead researcher **Sanjay V. Desai**, MD, an assistant professor of medicine at the Johns Hopkins University School of Medicine and director of the internal medicine residency program at The Johns Hopkins Hospital in Baltimore, MD, says data from his work do not sup-

port that idea. Instead, he says, his research suggests that unintended consequences of the new rules could be making patients less safe and compromising resident training.

"The consequences of these sweeping regulations are potentially very serious," Desai says. "Despite the best of intentions, the reduced work hours are handcuffing training programs, and benefits to patient safety and trainee well-being have not been systematically demonstrated."

He says the 16-hour limit was put in place without evidence of whether it would improve patient safety and outcomes. "We need a rigorous study," Desai says. "We need data to inform this critical issue."

"... the consequences of these sweeping regulations are potentially very serious."

Desai and his Johns Hopkins colleagues compared three work schedules in the months leading up to the 2011 change. For three months, groups of medical interns were assigned randomly to a 2003-compliant model of being on call every fourth night, with a 30-hour duty limit, or to one of two 2011-compliant models. The latter included being on call every fifth night but working only 16 hours straight, or a night float schedule, which essentially had interns working a regular week on the night shift not exceeding 16 hours.

Although interns on the 16-hour limit schedule did sleep an average of three hours longer during the 48 hours encompassing their on-call period than those working 30-hour shifts, there was no difference in the amount of sleep they received across a week. "During each call period, the interns had 14 extra hours out of the hospital, but they only used three of those hours for sleeping," Desai says. "We don't know if that's enough of a physiologically meaningful increase in sleep to improve patient safety."

In the study, the researchers found, the minimal number of patient handoffs between interns increased from three for those working 30 hours to as high as nine for those working 16-hour shifts. When handoffs increase, there is less continuity of care and more room for medication and other treatment and communication errors, past research has shown.

Meanwhile, the minimal number of interns caring for a given patient during a three-day stay increased from three to as high as five. Whether, or in what way, that number affects patient care or patient satisfaction is another unknown, Desai says. ✦

COMING IN FUTURE MONTHS

- ✦ Data showing value of apology/offer
- ✦ Hospital reduces falls by 64%
- ✦ Simple strategy for reducing OR fire risk
- ✦ Five ways to improve your career

CNE OBJECTIVES

Upon completion of this educational activity, participants should be able to:

- describe the legal, clinical, financial and managerial issues pertinent to risk management;
- explain the impact of risk management issues on patients, physicians, nurses, legal counsel and management;
- identify solutions to risk management problems in healthcare for hospital personnel to use in overcoming the challenges they encounter in daily practice.

CNE INSTRUCTIONS

Nurses participate in this CNE program and earn credit for this activity by following these instructions.

1. Read and study the activity, using the provided references for further research.
2. Log on to **www.cmecity.com** to take a post-test; tests can be taken after each issue or collectively at the end of the semester. First-time users will have to register on the site using the 8-digit subscriber number printed on their mailing label, invoice or renewal notice.
3. Pass the online tests with a score of 100%; you will be allowed to answer the questions as many times as needed to achieve a score of 100%.
4. After successfully completing the last test of the semester, your browser will be automatically directed to the activity evaluation form, which you will submit online.
5. Once the completed evaluation is received, a credit letter will be e-mailed to you instantly. ✦

CNE QUESTIONS

1. **According to Renee Guariglia, executive vice president of Falcone Associates, what is the best way to find a new insurance broker?**
   A. The best contacts often are made through referrals by other healthcare providers.
   B. The best contacts come from your local chamber of commerce.
   C. Ask your current insurance broker for a referral.
   D. Ask your current insurer for a referral.

2. **According to Michael Grant, executive managing director of employee benefits services at Crystal & Company, which of the following is a sign that you might need to replace your current insurance broker?**
   A. The broker is part of a large agency.
   B. The broker does not seem to have a deep bench of resources to call on directly or to refer you to, especially regarding the changing healthcare scene.
   C. The broker does not appear to have a significant number of clients other than your organization.
   D. The broker is a not part of a large agency.

3. **In the case of Warren Kortz, MD, accused of 14 counts of unprofessional conduct after a series of failed procedures with the robotic surgery arm owned by Porter Adventist Hospital in Denver, which of the following is true?**
   A. The hospital did not take any action in response to poor surgical outcomes.
   B. The hospital suspended Kortz's robotic-surgery privileges for three months in 2010.
   C. The hospital permanently prohibited Kortz from performing robotic surgery in 2010.
   D. The hospital revoked all surgical privileges for Kortz.

4. **According to Robert Wah, MD, global chief medical officer for CSC, what is the benefit of recent revisions to the Stark and anti-kickback laws regarding electronic health records (EHRs)?**
   A. The revisions should give hospital risk managers a good idea of how regulators will handle this issue.
   B. The revisions make it clear that hospitals cannot donate an EHR to a physician practice.
   C. The revisions specify what remuneration is required from the physician practice to make the transaction acceptable.
   D. The revisions specify how hospitals can provide funds for a physician practice to purchase its own EHR.

Legal Review & Commentary

A Monthly Supplement to HEALTHCARE RISK MANAGEMENT

Dialysis mistakes leads to wrongful death and a seven-figure settlement

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News: The five children of a 65-year old woman settled a wrongful death suit against a dialysis clinic. The children alleged that the clinic made many mistakes while treating their mother, and they claimed that those mistakes caused her death. The dialysis clinic agreed to pay the children a seven-figure amount to settle their claims against it, but did not admit wrongdoing. The children accepted.

Background: The 65-year old mother of five was suffering from congestive heart failure (CHF) and kidney failure. She was living in a nursing home for about a year, but her five adult children wanted to care for her themselves. As such, the children made arrangements for outpatient dialysis treatment with the clinic, and they moved their mother back into the family home.

The mother required dialysis treatments three days a week. During her first week home, she presented to the clinic for her first two treatments without incident. However, about three hours into her third treatment, a staff person at the dialysis clinic called the children and said that the clinic was rushing their mother to the hospital. The clinic would not tell the children why. The doctor at the hospital told the children that something went wrong with their mother's dialysis treatment at the clinic. Two days later, the doctor said that there was nothing he could do to save their mother. The children decided to take her off life support, and she died a few days later.

The children claimed that after the incident, they attempted to contact the clinic numerous times to determine what happened during their mother's third dialysis treatment. The children said that the clinic never responded to their inquiries. As a result, the children filed a lawsuit against the clinic and its employees.

The children alleged that the clinic made several "major" mistakes during the dialysis treatment and these mistakes caused their mother's death. The children specifically alleged that an unqualified patient care technician did a reversal of the mother's dialysis lines and failed to secure them properly. They claimed this action caused their mother to start hemorrhaging. Additionally, they alleged that machine alarms went off but were ignored, which pushed their mother into critical condition.

The clinic would not comment on its treatment of the mother and cited privacy concerns. It offered the children a seven-figure settlement to resolve their claims against it, but did not admit wrongdoing. (The specific settlement amount remains confidential, but it was confirmed to be seven figures.) The children accepted this settlement.

What this means to you: This unfortunate outcome involves a patient who suffered from CHF in addition to the kidney failure; those co-morbidities made this patient a higher risk. Renal failure can result in fluid retention and that, in turn, has an influence on CHF, so both need to be carefully monitored. She had been living in a nursing home

Financial Disclosure: Executive Editor **Joy Daughtery Dickinson** and Nurse Planner **Maureen Archambault** report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study. **Christopher U. Warren**, **Leilani Kicklighter**, and **Jonathan D. Rubin**, co-authors, have no relevant relationships to disclose.

for about a year; her CHF was controlled, and her routine hemodialysis treatments three times a week were uneventful. From the information we are given here, we can presume the dialysis clinic the patient's children identified through their research was not one operated by the same company used by the nursing home, as her care was not transferred to a different clinic within the same organization.

We don't know if this 65-year-old was a candidate for kidney transplant or the underlying reason for her kidney failure. We do know she was living a positive quality of life at home with her children for less than one week before this tragic event.

Additional background information related to this event included a visit by surveyors from the Centers for Medicare and Medicaid Services (CMS) about nine months after this event. What triggered this inspection is unknown. However, the report (a public record) of this inspection reflects, among other things, that staff members were not following infection prevention procedures as observed by not changing gloves or washing hands or alcohol cleansing between patients, and by not using equipment and supplies on one patient only, i.e., tape, scissors, etc. Other observations noted were that patients were not always receiving dialysis for the ordered time, and there was no documentation regarding why the time was cut short. The second amended complaint alleged that the oxygen tank at the time of this event was empty. All of these areas raise concerns from the viewpoint of risk management and quality of care.

While this unfortunate event occurred in a freestanding dialysis center, the issues would apply to any dialysis setting regardless of ownership. The scenario crosses many domains within an organization. For example, here we have a patient care technician (employee) who stepped outside his job description and qualifications to manipulate the patient's dialysis lines, an activity for which he was not qualified. The licensed nurse who is responsible for this activity and also responsible for monitoring the patient allowed this practice or was not closely monitoring the patient assigned. Background information in this case references that this practice had been brought to the attention of the clinic management, and no action had been taken to intervene.

This practice falls into the human capital domain. A policy and procedure should be in place regarding handing of such employee issues on a timely basis. Licensed nurses are responsible for overseeing the care of patients to whom they are assigned and to all patients in general. If an employee is observed carrying out an activity for which he or she is not trained or qualified, it is up to the nurse to intervene and immediately report the event. It is then the responsibility of management, with the input and support of human resources staff, to address the issue that includes counseling or other appropriate action, depending on the issue. Risk management should facilitate this area to be sure this situation is appropriately addressed and corrected.

Immediately, on the day of this event, the dialysis machine and all tubing and other supplies and equipment used by this patient should have been collected, labeled, and sequestered under lock and key in case there was a need to conduct any further studies or evaluation. The chain of evidence should have been maintained under the direction of legal counsel through the facility/organization risk manager.

One of the known human error risks that was the basis for a *Sentinel Event Alert* from The Joint Commission (TJC) is the misconnection of medical lines, i.e., intravenous lines (IV), tube feedings, and dialysis, to name a few. Misconnection of the hemodialysis lines is a known risk and, as such, policies and procedures and education should be addressed with all employees whose role involves handing the lines. Some manufacturers are attempting to address these issues by making square connectors only connect with other square connections or red with red and green with green, for example.

Another *Sentinel Event Alert* from TJC is failure or slow response to alarms due to alarm fatigue often brought about because of the frequency of alarms. Rather than ignoring an alarm, all alarms should be addressed at the source. Alarm fatigue often causes alarms to be turned down, turned off, or ignored. Any of these activities can result in an untoward outcome such as in this situation in which it is alleged that the alarms were ignored. Sometimes the settings need to be adjusted to prevent alarms from sounding unnecessarily, but in all cases, the reason an alarm is sounding should be addressed and evaluated at its source.

In addition to the moral and ethical correct thing to do, the American Medical Association (AMA), TJC, the Accreditation Association for Ambulatory Health Care (AAAHC), and many states require disclosure of adverse events to patients/families. This adverse event was one such event with which a disclosure discussion should have been coordinated, yet the family had to resort to filing a lawsuit to gain information regarding what happened to their mother while in the dialysis facility for care. The facility risk manager should have facilitated a disclosure meeting with the family. The organization should have a process and access to legal counsel knowledgeable about health law to advise in those instances when an adverse event occurs regarding the disclosure process.

Heartfelt condolences to the family for the event should be extended

as well. Lack of communication and anger (often fostered by the lack of communication) are frequently the genesis of many an asserted lawsuit. A disclosure meeting might not prevent a lawsuit, but it might prevent the anger and does start the statute of limitations to roll.

As soon as feasible after such an event as this one, the risk manager should have initiated a root cause analysis (RCA) to be convened to identify why this untoward event happened. Depending on the laws of the state, legal counsel might need to be involved in this process to ensure the attorney-client privilege, but in any case this process is a part of the investigation that should be undertaken while memories are still fresh. In addition, the professional liability insurance carrier of the facility should be made aware of this event, and that carrier's advice should be heeded as well.

Annually, as part of the evaluation of each employee, his or her job competency should be evaluated as well. We have no information whether this evaluation was a part of this organization's processes, but it should be for all organizations. It is during this evaluation process that aspects of professional responsibilities and practice boundaries can be discussed and emphasized.

We have nothing to support the allegation that the oxygen tank was empty, but it does raise the issue of daily checking to verify that all emergency equipment is in working order, should it be needed at any time. One such check would include the oxygen level in the active tank and in the backup tanks. Other checks would include the crash cart contents and current expiration dates and availability of drugs in the crash cart. Policies and procedures should govern these activities, and risk management should verify the monitoring checklist to ensure the daily and other periodic checks are being carried out.

This facility needs to re-educate all staff as to their job description and responsibilities, and administrative staff should be monitoring compliance. When non-compliance is identified, immediate steps should be taken to intervene and correct those who are stepping outside their position boundaries. ✦

Gender discrimination leads to a $7 million settlement and a pain clinic to be named in the plaintiff's honor

News: A female doctor claimed to have suffered years of gender discrimination from a hospital's chief of surgery. The doctor claimed she presented complaints to the hospital's CEO, and she said he did nothing. She also claimed that the discriminatory treatment culminated with her demotion from chief of anesthesiology. As a result, the doctor sued the hospital, the chief of surgery, the hospital's CEO, and the hospital's physician group. The lawsuit resulted in a $7 million settlement, and the hospital's pain clinic will now be named in the female doctor's honor.

Background: The female doctor joined the medical staff of the hospital in 1980. Over the next 20 years, she wrote two books, expanded the hospital's pain clinic into an internationally known program, was promoted to a full professor, and in 2000 became the first woman to head the hospital's anesthesia department. A year after she became the head of anesthesiology, the hospital appointed a new chief of surgery.

The female doctor claimed that the new chief was abusive and demeaning toward her. She claimed that he let doors shut on her when she was following him and that he replied to her male colleagues when she spoke to him. She also claimed that she had compiled emails, internal hospital memos, and testimony from other doctors and nurses which confirmed that the chief was uncomfortable working with women generally, and that he preferred to hire residents who were "tall, light skinned Western-taught men."

The female doctor claimed that when she complained to the hospital's CEO, he did nothing. Instead, the female doctor claimed that the CEO accused her of "playing the victim" and that he viewed the situation as a problem between her and the chief. She additionally claimed that he told her that she created a "culture of whining" and on another occasion told her that "Joe can't help himself."

Lastly, the female doctor claimed that the chief tried to have her fired for incompetence while she was on sabbatical in 2007. She stated that soon before her return, the CEO demoted her as anesthesiology chairwoman by email. When the CEO met with her colleagues the next day, the female doctor claimed that he told them she was demoted because she was too aggressive and had failed to maintain a good relationship with the chief.

As a result, the female doctor filed a lawsuit against the hospital, the chief of surgery, the CEO, and the hospital's physicians group in 2008. She alleged that she had been discriminated against based on her gender, and she cited her claims above. The defendants sought to move her claims to arbitration based on an employment arbitration agreement; however, the courts ruled that she could proceed with her claims.

The parties agreed on a settlement

in which the female doctor would collect $7 million. As part of the settlement agreement, the hospital also agreed to name its pain clinic after her, to "reaffirm and clarify its policies and procedures" for employees reporting discrimination and retaliation, and to sponsor an annual lecture series on women's health and the academic contributions of women in surgery.

What this means to you: Human capital is an important aspect of any business. In healthcare, it is the human factor that provides direct patient care. Stressful work environments can negatively influence efficiency and safe patient care, among other outcomes, such as increased absenteeism and high turnover rate.

This case should be a wake-up call for all businesses, not just healthcare. In healthcare organizations, CEOs, administrators, deans, department and division chairs of medical staffs, and management at all levels should be aware of the factors in this case and undertake assessments to identify hostile workplace environments. Human resource (HR) department personnel should study this case and provide education to all staff from the C-suite to all rank-and-file employees. Such educational sessions should be ongoing as staff and environmental changes occur. The organization's board members should be included in these educational sessions as the board ultimately is responsible for HR issues such as discrimination, harassment and wrongful termination. Directors' and officers' insurance brokers or carriers might have specialists within their organizations who can intervene when such an individual hostile workplace situation is identified or suspected or in developing processes to prevent such a situation. Legal counsel with expertise is this area also can play a role in developing preventive and intervention practices.

Not all leaders are good managers of personnel. This area is one that should be assessed by management at all levels, with the assistance of HR. Educational courses can be developed to include basics of management styles; legal aspects of human resources; budgeting; basics of finance; basics of oral, written, and social media communication; and other pertinent aspects of successful business and personnel management.

Risk management and HR should collaborate to monitor employee complaints, formal and informal, to identify trends or issues. While gossip is always discouraged, monitoring gossip in an organization often can identify areas of employee discontent. Risk management, legal counsel, and HR should review the employee handbook, especially the section relating to reporting hostile workplace situations, and revise it as necessary. If revisions are undertaken, all employees should be provided a copy of the revised handbook or section and return a written acknowledgement of receipt and understanding. This acknowledgement should be maintained in the individual employee's personnel file or physicians' medical staff file. While all members of the medical staff probably are not employees of the organization, they should be included in the distribution and acknowledgment of receipt of the policy and procedure and expected behavior while in that respective organization.

Bullying and harassment are social issues affecting schoolchildren of all ages, workers, and even the elderly and disabled. In healthcare, the disruptive physician is a frequent issue addressed with varying degrees of success.

An increasing number of hospitals are employing physicians and buying physician practices. The ongoing changes to healthcare delivery settings will continue to reflect the changes in employment practices of physicians and physician extenders/allied health professionals. The medical staffs of hospitals, ambulatory surgery centers, and other healthcare organizations are made up of independent practitioners, contracted physicians, and employed physicians. Members of the medical staff serve as members of committees, and in such capacity, they are agents of the organization. In many states, physician professional liability insurance policies exclude coverage for claims for activities arising from participation in medical staff peer review and other types of hospital/organizational committees. This exclusion puts the appropriateness of these activities squarely in the lap of the organization to monitor or oversee.

This case is a sad commentary on the negative relationships between some physicians and in particular between any person of power and a subordinate. Such negative relationships often are played out between physicians and nurses and are frequently under-reported and unreported.

In this case, others were aware of the interactions between the principle parties, and the claimant actually made a formal complaint that was disregarded. One wonders how many others were treated in this hostile manner by this chief of surgery. In reading the facts of this case, the female head of anesthesiology reported this information directly to the CEO, who also exhibited gender bias rather than initiating a referral to the dean, if appropriate, and to the hospital's HR department to initiate a full HR investigation. The CEO should have been sensitive to the ramifications of this situation, engaged risk management to collaborate with HR in this investigation, and set out a directive to control and intervene so it would not escalate.

Had this organization instituted a policy of zero tolerance for harassment at any level and a culture of valuing its employees at ALL levels, and had all levels of the organization "walked the talk," this situation might never have occurred, or it would have been identified early and addressed in a positive way to benefit all employees.

Reference

SJC-10375 (Mass 2009). ✦