HEALTHCARE RISK MANAGEMENT

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Legal Review & Commentary:

Undiagnosed fistula leads to \$50 million verdict; hospital escapes 40% ostensible agency liability on appeal **FEBRUARY 2017**

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Legal Marijuana Requires Reassessing Hospital Drug Policies

volving state laws regarding the legal use of marijuana mean that healthcare providers' existing policies on drug use should be reviewed to ensure they do not violate labor laws or provide an opportunity for civil litigation, while still ensuring patient safety. Employees may still

be prohibited from using illegal substances or being impaired on the job, but legal experts say relaxed marijuana laws create gray areas that must be addressed.

Many states have relaxed marijuana laws in recent years, with some allowing medical use, others also allowing recreational use, and some decriminalizing possession. A total of 28 states, the District of Columbia, Guam, and Puerto Rico now allow medical marijuana, according to the National Conference of State Legislatures. Seven states and the District of Columbia have legalized marijuana for recreational use, including most recently California, Massachusetts, and Nevada, which all passed measures in November 2016 legalizing recreational marijuana.

MARIJUANA IS STILL ILLEGAL AT THE FEDERAL LEVEL, SO EMPLOYERS CAN PROHIBIT ITS USE AT WORK AND CAN STILL TEST EMPLOYEES FOR EVIDENCE OF USE. Marijuana is still illegal at the federal level, so employers can prohibit its use at work and can still test employees for evidence of use, says **John A. DiNome**, JD, partner with the law firm of Reed

Smith in Philadelphia.

"That creates a conflict because employees say the state allows them to use it medically or recreationally, or both, and now you're drug test-

ing them for something that is legal in your state. They were using marijuana at home, at the same time

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you were home drinking your beer or bourbon," he says. "Then they come to work Monday perfectly sober, but the drug shows in their system when you test them. So they ask why you're terminating them for the use of a legal substance at home."

That conflict is especially difficult for employees to accept when they use medical marijuana as prescribed, he says.

A Colorado Supreme Court case addressed this issue when an employer fired an employee who had used medical marijuana legally. The employer argued that it was complying with federal law, and in particular it was obligated to comply with the Drug-Free Workplace Act because it was a federal contractor. The Supreme Court ruled in favor of the company, saying that with an obvious conflict between state and federal laws, the employer can take the more conservative position of complying with federal law, DiNome says.

Some Hospitals Have a Choice

Federal contractors have no leeway on the issue, says **Danielle Urban**, JD, partner with the Fisher Phillips law firm in Denver.

"If you're a federal contractor, you

can't allow any marijuana use, regardless of what state law says," Urban notes.

For employers with a choice, the question becomes whether you really want to take this hard-line stance on marijuana, DiNome says.

"You may not attract the best work force in your state if the state allows the use of marijuana, medically or recreationally," he says. "You would have to consider that some educated, qualified people come to your state because that substance is legal, and whether you want to eliminate all of those people as potential employees."

One solution may be to use more advanced testing for the use of marijuana, DiNome suggests. Unlike a breath alcohol test that can determine how impaired a person is at the time of testing, the tests used to detect marijuana use only show that the person used the substance sometime in approximately the past 30 days. More specific tests are available, though they are likely to be more expensive and require a blood sample, DiNome notes.

"You still have to determine what is over the limit and I don't know that there is any uniform answer to that," he says. "But if you want to prohibit impairment at work without telling people they can't do

EXECUTIVE SUMMARY

Changing state laws regarding marijuana are forcing healthcare providers to reconsider their policies on drug use by employees. Risk managers should review their policies in light of labor laws and patient safety.

• State laws may conflict with federal law, which still prohibits the use of marijuana.

• At least one state supreme court has determined that an employer can choose to follow federal law.

• More precise drug testing may help differentiate between impairment and past use.

something legal on their own time, that would be the way to go about it."

If the organization does not prohibit employees' use of legal marijuana, caution is still necessary the same as with many other legal substances, DiNome notes. Employees who use prescribed or over-the-counter medications that can impair their ability to operate machinery safely, for instance, must be required to report that condition and avoid compromising safety. The same would apply to the medical use of marijuana, if there is any effect on the employee during working hours, DiNome says.

Patient Safety Trumps All

Some states put employers in an even more difficult position by making it illegal to discriminate against employees who use marijuana legally, notes **Joshua Horn**, JD, partner with the Fox Rothschild law firm in Philadelphia. In those states, employers are forced to choose between complying with state law or federal law, and many may decide that it is more likely the state rather than the federal government that will take action against them for discrimination.

Federal funding, however, could shift that balance in favor of federal law.

"An institution that relies on federal funding may be at risk with that funding if they don't test people for Schedule I drugs as part of hiring and retention in employment," Horn says. "I suspect that is something that is going to be litigated at some point until we get more clarity on these conflicts."

Safety considerations almost always trump an employee's right to use any substance that could affect performance, notes **Bob Morgan**, JD, special counsel with the Much Shelist law firm in Chicago.

"Whether your employee is driving a truck cross-country or working in your ICU, there is almost always a protection that allows employers to enforce policies to protect those that they're serving," Morgan says. "That applies no matter what the cannabis laws are in your state. You're dealing with employees that are directly impacting the health and safety of individuals, so the obligation of protecting the people you are serving is paramount."

Unemployment compensation also could be disputed. An employee fired for marijuana use could argue that he or she did nothing illegal to prompt the dismissal and is due unemployment compensation. That question also is not yet settled, Horn says.

"When you're terminated for using a Schedule I drug, that could be heroin or LSD, and marijuana is still lumped together for that," Horn says.

Horn advises healthcare risk managers to review their drug policies and employee handbooks against what state law says about marijuana use.

Understand How Drug is Used

Medical marijuana has been legal in California for 21 years, so employers in that state are more familiar

Cardholders May Be Protected

G ardholders" — those who are legally allowed to use medical marijuana — should be handled carefully in states that specifically prohibit discrimination against them, says **Danielle Urban**, JD, partner with the Fisher Phillips law firm in Denver.

Simply knowing that the person is a cardholder is not enough reason to take action, she says.

"Even if you have chosen to take a zero-tolerance position, you can't fire this person because you know he or she is a cardholder and presumably using medical marijuana," she says. "If you're going to take any action, I would advise against disciplining or firing the person unless you have a positive test showing the use of marijuana."

Arizona is an example of a state that included substantial protection for card holders in its statute, notes **Amanda Wingfield Goldman**, JD, an attorney with the law firm of Coats Rose in New Orleans. The law includes provisions that prohibit employers from taking adverse action, such as firing cardholders based on that employee's status as a cardholder, or even a positive drug test, unless the employee appears impaired during work hours.

The original statute left employers with no way to define impairment, so the law was revised to define impairment as evidence of negligence, carelessness, decreased coordination or dexterity, slowed or slurred speech, glassy or bloodshot eyes, and detectable odor of marijuana. The revision also gave employers protection to take adverse action in a good faith belief that the employee was impaired or using drugs during workplace hours.

with how to work with employees using the substance legally, notes **John Malanca**, co-founder of United Patients Group in Greenbrae, CA, which supports education on the medical use of marijuana. Employers should first understand how marijuana is used medically and that it does not always impair judgment or physical activity, he says.

"An employee battling a disease as awful as cancer can do a nonpsychoactive during the day, and at nighttime use the THC-dominant product to attack the disease at night," Malanca says.

The legal use of recreational marijuana also can be managed in the workplace, just as with any other legal substance that can impair performance, Malanca says.

"Cannabis is recreationally legal and alcohol is recreationally legal in this state. I'm not going to allow you to come to work smelling like liquor or intoxicated, and the same applies to cannabis," he says. "Like with opioids and other pharmaceutical substances, if the person comes to work and passes out from drug use, it's not OK just because he has a prescription and is using it legally. Employers can get the idea that legalizing cannabis means people will be under the influence at work, and that does not have to be allowed."

Consider Forms of Medical Use

Use of medical marijuana during the work day also is a concern for healthcare providers, notes Richard Kimball, managing partner of HExL, a consulting company based in New York City. If the organization does not take a zero-tolerance stance and acknowledges that employees may use medical marijuana legally, it may be necessary to establish policies on how the substance can be used on the premises, he says. Most employees would be able to avoid using it at work, but some may find it necessary to take the drug during the day just as people take other prescribed medications at different times of day.

The same issue applies if patients

need to use the substance while admitted.

"In that case, you're going to have to look at what's practical and safe in terms of the workplace," he says. "Smoking marijuana wouldn't make any sense in a hospital setting, vaporizing is questionable, and even edibles are probably questionable."

Kimball expects the acceptance of medical and recreational marijuana use to continue growing, so he says healthcare risk managers should expect to confront these issues soon, even if they don't have to immediately.

One potential avenue of litigation is the Americans with Disabilities Act (ADA), in which the definition of disabilities is very broad, says **Amanda Wingfield Goldman**, JD, an attorney with the law firm of Coats Rose in New Orleans.

"If you take a medication to alleviate any sort of problem you have, a lot of people could argue that's medication for a disability," she says. "It is not farfetched to think of an employee bringing an ADA case against the employer for interfering

Most Employers Ban Marijuana Entirely

When they have any choice at all, most employers opt to prohibit the use of marijuana no matter their state law, says **Tim Thoelecke, Jr.**, president of InOut Labs, a drug testing service company in Morton Grove, IL.

"I don't see the healthcare industry as having any unique concerns, other than access to narcotics on the job. Healthcare employees, in my view, should be treated as any other safety-sensitive workforce," he says. "To date, pretty much any case that has made it to court has come out in favor of an employer's right to a drug-free workplace. One could easily argue that providing a drug-free workplace is not only an employer's right, but also his/her duty, when it comes to safety."

Any substance that can impair judgment should be carefully monitored, Thoelecke notes. If a factory worker, for example, is on pain medication that could make him or her unsafe to him- or herself or a co-worker, many employee substance policies require the worker notify human resources so he can be put on light duty or in some other role.

"For medical marijuana, I suppose an employer could have the same rule, but since marijuana is still Schedule I, and illegal federally, it can be banned entirely if an employer chooses," he says. "Most do choose that route."

SOURCE

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with disability-related treatment and not making accommodations."

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Hospital Wins Lawsuit After Rape of Mental Health Patient

A hospital prevailed recently in a lawsuit alleging malpractice related to one patient raping another, and legal analysts attribute the verdict to the hospital successfully arguing that it should be tried as a malpractice case rather than a simple civil lawsuit alleging negligence.

The case involved a patient who was sexually assaulted twice while admitted to the psychiatric wing of Elkhart (IN) General Hospital in 2008. The woman had been admitted for psychosis and suicide risk, having been convinced that she had been left behind after Christians were taken to heaven in the rapture, according to a report in the *South Bend Tribune*. (*The full report is available online at http://bit.ly/2ig9VPX.*)

When the woman saw a middleaged man who had been admitted for detox services and who was wrapped in a bedsheet, she believed he was Jesus, according to court documents. She said she wanted to wash the man's feet, and threw water on a doctor treating the man. The man was admitted and — despite having behaved inappropriately and saying he had trouble with women — he was placed in a room next to the woman's. The plaintiff's attorneys claimed many other rooms were available on the unit.

Negligence Alleged After Rapes

Court documents say the man twice lured the young woman into his room and she submitted to sexual acts because she believed he was Jesus and she had to obey him. Hospital officials did not believe her report of the assaults at first, but a physical exam confirmed her story.

The plaintiff sued the hospital in 2009 for negligence, but the hospital argued it should be a malpractice case because it involved her treatment. The trial judge allowed a simple civil lawsuit, but an appeals court ordered that it should continue as a malpractice trial.

This was a win for the hospital, but not so surprising because Indiana makes it especially difficult for plaintiffs to win malpractice cases, explains **Gregg Bertram** of Pacific ADR Consulting in Seattle, who has mediated or arbitrated more than 600 claims, including allegations of hospital negligence. State law requires a review by three other doctors in the same field, and the panel's findings can greatly influence the jury.

Changing the case to malpractice didn't really make sense, Bertram says.

"That opinion seems to me somewhat strained to reach that conclusion. It didn't make a lot of sense in light of earlier cases that the court cited in the opinion itself," he says.

However, Bertram says the plaintiff holds some responsibility for choosing the wrong negligence charge for the complaint. His review of the records suggest that the plaintiff's case was not presented effectively.

"The complaint was not plead as well as it should have been to make the question of ordinary negligence vs. malpractice a closer one," he says. "The plaintiff's complaint focused on whether her own doctors were negligent in failing to inform her or the hospital of the possible consequences of the psychotropic medicines she was prescribed, because clearly she was delusional when she was admitted. Instead, they should have alleged that the negligence in the case was the hospital's failure to restrain or protect her from the other patient that she had sex with."

Focusing on what the doctors

did or didn't do made it easier for the defendant to argue for the case involving malpractice, Bertram says.

Law Favors Defendants

The case also should be a reminder to healthcare professionals not to dismiss a psychiatric patient's complaints or concerns too readily, Bertram says. The patient in this case was clearly delusional, but her complaint about the rapes were valid and the staff did not take them seriously until they performed a physical exam.

Medical malpractice is difficult for plaintiffs to prove in any jurisdiction, and Indiana especially so, he notes. The hospital understandably took advantage of state law to have the case tried as malpractice, even though that wasn't justified by the facts, Bertram says. The state's requirement for a physician panel to render judgment on the case, even though it is not binding, also greatly skews the odds in favor of the defendant, he says.

"Over the years, the number of times the percentage of cases in which these panels found negligence probably is incredibly minute," Bertram says. "Although the panel's decision is not binding on the jury, the jury hears it. How many times is a lay jury going to disregard a panel recommendation of physician members? Almost never." Bertram notes that the plaintiff was diligent in pursuing the case despite the odds stacked against her, and she continued for eight years, long after many people would have given up.

"It's not an evenhanded prospect in any respect," he says. "In addition to everything else, Indiana state law says that if there is even 1% comparative negligence assessed against the plaintiff, they lose. That is incredibly draconian."

Juries Can Be Wary

Bertram says the case illustrates other factors that work in favor of hospitals fighting medical malpractice charges. Long delays generally work in favor of the plaintiff because litigation is so expensive, he notes, and plaintiffs also can find it difficult to locate adequate expert witnesses to testify against other medical professionals.

"Defendants also have an easier time finding local experts," Bertram says. "In many times, the local experts carry more weight simply because they're local, from the same community and possibly a respected hospital or university. Plaintiffs often have to range very far afield to find someone who will testify for them, and the jury can see that person as an outsider flown in to say what the

EXECUTIVE SUMMARY

A jury found in favor of a hospital accused of malpractice after one patient raped another presenting with mental health issues. Hospital attorneys were successful in having the case tried as malpractice rather than a simple civil lawsuit.

- Indiana malpractice law is particularly challenging to the plaintiff.
- The complaint focused on physicians' alleged failure to warn of drug reactions.
- Staff initially dismissed the mental health patient's rape complaint.

plaintiff wants."

In addition, Bertram notes that psychiatric claims are especially hard to pursue.

"Some members of the lay public view psychiatry as something akin to witchcraft," he says. "It's different from something like orthopedic surgery that a lay person can wrap their head around. It's amorphous."

Assaults and other criminal activity in healthcare facilities also can be seen by juries as beyond the provider's responsibility, he says. Similar to how juries may see falls as something that inevitably happen in a hospital or nursing home despite adequate precautions, a jury may also be reluctant to hold a defendant responsible for criminal activity that has nothing to do with medical care, Bertram says.

"There is a not unreasonable general belief that no matter how vigilant an institution's staff, you can't watch everybody all the time," he says.

Fair Trial Questioned

The particulars of Indiana state law prevented the plaintiff from getting a fair hearing, says **Carole Lieberman**, MD, MPH, a forensic psychiatrist and expert witness in Los Angeles.

"Justice was not served here. First, the case was derailed by being forced to be a malpractice case instead of a negligence or intentional infliction of emotional distress or another type of case," she says. "Then, as a malpractice case, not only was the potential recovery award limited, but the panel clearly did not consider it in a professional and unbiased manner."

A patient in a hospital is entitled to be kept safe, she says. That is a major purpose and expectation of hospitalizing a patient, she says. "At a most basic level, they are to be kept safe from themselves and from others," Lieberman says. "As a psychiatric expert witness, I have to wonder how good the plaintiff's expert was. They should have been able to make the liability and damages clear to the panel and the jury."

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Reducing Diagnostic Errors Requires Multiple Approaches

R educing diagnostic errors requires a combination of strategies that address the reason most of these errors occur and the application of the latest data analytics.

When analyzed retrospectively, most diagnosis failures will be traced to thought errors, says **David Kashmer**, MD, MBA, MBB, FACS, a trauma and acute care surgeon, and chief of surgical services at Signature Healthcare, based in Louisville, KY.

"They're not usually errors with our hands or test results being wrong, though those things happen," Kashmer says. "They're errors of how we think about a situation. It's often failure to have a broad enough differential diagnosis when patients present to the emergency department or an acute situation of any sort. We didn't think of all the possibilities it could be, didn't take the time, or weren't sensitive enough to it."

For instance, 20% of patients in an ICU typically present with

adrenal insufficiency, but it often is not diagnosed because physicians just don't think about it, Kashmer says. When teaching young surgeons, Kashmer encourages them to think broadly about diagnoses with the mnemonic "VINDICATE." It reminds them of all the diagnoses they should entertain:

- Vascular,
- Infectious,
- Neoplastic,
- Degenerative, dietary,
- Iatrogenic,
- Congenital,
- Allergic, autoimmune,
- Trauma, toxic, and
- Endocrine.

Kashmer encourages the physicians to take the time to consider each possibility and prioritize what is most common and which one you have the least time to catch. They also need to think in terms of, "how can I be less wrong?"

"I've found that gets it on their

EXECUTIVE SUMMARY

Using better analytics and training staff in specific improvement strategies can reduce diagnostic errors. Physicians often need to broaden their differential diagnoses.

- Big data are more useful for improving patient safety than in past years.
- Physicians should consider the consequences of wrong decisions.
- Decision science can be used to determine financial risks.

radar, including things you might not think about as often, like adrenal insufficiency and right-sided heart attack, which is often missed in the ICU," Kashmer says. "I also teach to think about how they would manage uncertainty. How likely does it need to be that someone has something before you treat for it? That's a very different way to think about diagnoses than we're taught in medical school, where either they have it or they don't. It's very black and white."

Kashmer advocates for more use of "decision science," which is more often seen in the business world. This involves better decision-making with decision trees for things like pulmonary emboli, which will help determine how likely the diagnosis needs to be before the risk of heparin will equal the benefit of heparin.

The strategic use of big data also can help reduce diagnostic errors, Kashmer says. Big data involve extremely large data sets that are analyzed to reveal patterns, trends, and associations.

Big data can help eliminate or reduce diagnostic uncertainty or determine which tests to run, for instance.

"That can include decision trees and other tools that might tell you not to bother running this test because it's not going to change your mind about whether they have a certain disease because of how accurate the test can be," Kashmer says. "That's really powerful and comes to us only from decision science. Those things are typically not taught in medical schools."

A branch diagram, for instance, can even be used to predict the outcomes of certain decisions, including the potential financial cost for the hospital. The diagram might show that if you make this particular decision and it's wrong, the patient ends up losing five years of life.

"You can do the same thing with money," he says. "You can say the typical payout in our state for this situation is a million dollars if it goes to trial, and if settled, this is the typical amount. You can almost do triage and say if you miss inflammatory breast cancer, that's a big one and will pay out this much. Missed fracture in a trauma patient, maybe not as big a deal and a lower payout. So you can develop an understanding that you really can't afford to miss inflammatory breast cancer, so you adjust your decisionmaking in light of that."

The time is right to apply big data for improving diagnoses, says **Mark**

Wolff, PhD, chief health analytics strategist with SAS, a data analytics firm based in Cary, NC.

Big data analysis is increasingly useful because so much data are now available in a digitized form, making it possible to analyze faster and more thoroughly, he explains. Technological improvements also make it possible now to analyze massive amounts of information, Wolff says.

"We can now begin improving the process of population health analytics, which then allows us to better diagnose individuals and to actually make a prediction as to what will or won't work, what the outcomes might be, what drugs will work best and in what way, and what adverse events might be encountered," he says.

With big data, information on hundreds of millions of patients can be analyzed to look for patterns in symptoms and diagnosis, for instance.

"Technology will provide data to support a clinical diagnosis, and we have very good technology to analyze a disease state. But one of the challenges are limitations of human beings," he says. "Cancer researchers have said that it is unethical for human beings to diagnose cancer without the aid of technology, because we have approached the limit of human cognitive capabilities in terms of understanding the amount of information available and what is relevant in diagnosing and treating disease."

The point, Wolff says, is that the availability of data only makes it possible to improve diagnostic accuracy. For those improvements to actually come to fruition, the problem of information overload must be addressed with computational technology.

"Reducing errors relies on technology, but we still have people who don't trust technology," Wolff says. "Physicians sometimes don't want computers making diagnoses for their patients, but we're at a point where the technology can do that and save the complex cases for a physician's judgment."

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Patient Safety Improved with Centralized Hospital Command

O ptimizing patient safety often means knowing what is going on throughout the hospital and responding before an issue gets out of hand. At most hospitals, those in charge are in different places and without all the data they need to intervene quickly.

That was the situation at The Johns Hopkins Hospital in Baltimore, until it created a state-of-the-art, advanced command center that coordinates care throughout the facility. The command center is staffed by representatives from many departments, with access to a wealth of information that allows them to monitor and respond in real time.

The Judy Reitz Capacity Command Center opened in February 2016 and is similar in appearance to those in controlling space flights, albeit on a smaller scale. It combines the latest in systems engineering, predictive analytics, and innovative problem-solving to address safety, volume, and the movement of patients in and out of the hospital. Johns Hopkins worked with GE Healthcare Partners (GE) to design and implement the center.

The command center is staffed by about 24 people from different departments, working together in a single room filled with computer displays that show real-time and predictive information. They are empowered to take action to prevent or resolve bottlenecks, reduce patient wait time, coordinate services, and reduce risk. A main wall of computer monitors provides situational awareness and can detect potential problems, automatically triggering the command center team to take immediate action.

The system receives about 500 messages per minute on a typical afternoon, from 14 different Johns Hopkins IT systems generating real-time data, says **James Scheulen**, PA, chief administrative officer in the Johns Hopkins Department of Emergency Medicine and president of Johns Hopkins Emergency Medical Services.

"We came to the realization that the hospital was running constantly at a very high occupancy rate, and because of that our patients were facing more delays and we were not able to manage as many patients as we wanted to," he says. "We had a problem with the number of patients who were waiting for an extended period of time in the emergency department before being admitted, and we had problems with our operative system getting people into patient beds, so we ended up cancelling procedures."

The hospital also was not able to efficiently accept all the patient transfers from other hospitals. Prior to the command center, Johns Hopkins had a widely distributed system of control, rather than having key players together and others empowered to make decisions quickly. "We had groups of people who worked together every day, coordinating services and optimizing what we provide patients, but they were distributed throughout the institution," he says. "They had archaic communication modes, and even the process of doing their basic, fundamental work took too long because they didn't share systems and information, and they're physically in different locations. The simple process of getting someone in the hospital was taking hours instead of minutes."

Needed to Improve Efficiency

Expanding capacity was not a viable solution to those problems, so Johns Hopkins looked at ways to improve efficiency.

"Everything about operating this place is about how the process works. If you're trying to improve an operation with high utilization, you can either control the number of patients accessing your facility, improve the number of beds you have, and you can control the time they take in process," Scheulen says. "We can't address the first two more than we're doing already, so what we have to do is to manage our processes very efficiently so we don't waste time."

The Hopkins team began with a series of process improvement projects intended to identify the processes that most needed improvement and would produce the biggest effect on overall hospital efficiency. A first project was looking at perinatal delays and how to reduce OR holds.

Like at most hospitals, physical space is in high demand at Johns Hopkins, so finding a place to put the command center was a top priority. Fortunately, one of the people working on the project with Scheulen was in charge of a space that had recently been vacated and she made it possible to put the command center there. It happens to be in the exact center of the facility.

"We could have made it work in another location, but having it dead center in the middle of all hospital operations sends the right signal to people that this is an important function, and that its purpose is to bring all these different departments into the same room," he says.

Cross-training Possible

Development and construction of the command center took 17 months, after more than a year of discussion, Scheulen says. Activating the command center did not require hiring any new staff; people from many departments were transferred to the command center to more effectively perform the jobs they already had, Scheulen says. With the command center up and running, Hopkins is beginning more crosstraining for the command center staff.

"That interdepartmental support, with people understanding each other's jobs and being able to pick up the duties of someone in another department when needed, would never have been possible before," Scheulen says. "But now we're seeing that come together."

Real-time Information

A key benefit of the Capacity Command Center is that it gives front-line managers real-time information about their work so they don't have to rely on old data, Scheulen says.

One tile display in the command center is called Unit Under Pressure.

When a particular unit is overloaded or close to it, the display flashes red to alert command control staff.

"We realized that though we wanted to move patients in and process them as quickly as possible, there was a risk with that. If we didn't pay attention to the workload of the individual unit, we could potentially overload them and put patients at risk," Scheulen says. "We worked with the units to find the appropriate thresholds for when that might happen. So if a unit has just had three patients discharged, two patients admitted, and they're dealing with a rapid response, the command center needs to know that so that we don't send them more patients and can send resources to help them."

The command center replaces the traditional ways of doing many things in the hospital, such as using phones and email to assign beds, coordinate work between departments, and respond to problems, Scheulen says.

For instance, the technology in the Capacity Command Center keeps staff members informed 24/7 about when there is an influx of patients coming into the hospital, which hospital units need additional staff members, the status of how many patients are receiving treatment, the need for and availability of beds across the hospital, the highestpriority admissions and discharges, and other information essential for ensuring high-quality patient care.

There have many measurable benefits from the command center: Johns Hopkins has seen 60% improvement in the ability to accept the transfer of patients with complex medical conditions from other hospitals around the region and country, and ambulance pickup times have improved significantly. A Johns Hopkins critical care team is now dispatched 63 minutes sooner to pick up patients from outside hospitals. In the ED, a patient is assigned a bed 30% faster after a decision is made to admit him or her, and ED patients also are transferred 26% faster after they are assigned a bed.

Better coordination also helped reduce transfer delays from the operating room after a procedure by 70%. In addition, the number of patients discharged before noon rose by 21%.

"We went into this thinking we were building it for a few things — to work on boarding, accepting patients, and the OR flow problem," Scheulen says. "As we continue with

"WHAT WE'RE DEMONSTRATING HERE IS THE ABILITY TO IMPLEMENT SYSTEMS ENGINEERING TOOLS INTO HEALTHCARE."

the command center, it becomes clear that the capacity management function has really evolved from primarily easing the intake of patients to becoming the daily operational center of how patients flow through the hospital."

The software in the command center draws on data from the different software systems in use throughout the facility, applying logic and thresholds established for the command center, and displays it for the staff to see in real time. Staff response to a flashing display signaling trouble in a unit is governed by established protocols, which may include dispatching additional resources and staff, halting further admissions, or organizing a huddle with key people to find a solution.

"A lot of times you might think that the people involved should know what's happening and how to respond, but in many cases we get a trouble warning or signal that something is building up and we realize it before the staff on the unit does," Scheulen says. "That's from the real-time data and analytics, and it allows us to act on the problem and mitigate the issue immediately, and often before it even becomes a real issue."

Scheulen notes that hospitals can apply some of the lessons from the Hopkins command center even if building a new command center is not feasible.

"What we're demonstrating here is the ability to implement systems engineering tools into healthcare. These sophisticated tools of modeling, data simulation, and system availability can be pulled into healthcare to manage complex organizations," he says. "Think about the complexity of your own organization and tailor this kind of approach to your own needs. Not every hospital can afford this and not every hospital needs this, but the general principles behind it apply, whether you're a 50-bed hospital or a 50,000-bed hospital."

SOURCES

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Healthcare Cyberattacks on Rise, May Get Worse

C yberattacks affecting healthcare institutions in the United States increased by 63% year over year to a total of 93 major attacks, according to a recent report. Sophisticated cyberattackers were responsible for 31.42% of all major HIPAA data breaches reported in 2016, which is a 300% increase over the last three years.

The "2016 Year-End Healthcare Cyber Breach Report" comes from TrapX, a company providing cybersecurity defense. (*The full report is available online at: https://goo.gl/3lBQ50.*)

To give some context as to how pervasive attacks on healthcare institutions have been, the report notes that in 2014, cyberattackers were responsible for 9.77% of the total major HIPAA data breaches, which increased to 21.11% in 2015.

Medical Device Hijacking

The company also cautions that the hijacking of medical devices, called a MEDJACK, is on the rise. **Moshe Ben-Simon**, co-founder and vice president of services, said in a statement announcing the report that MEDJACKs can facilitate access to more than just the device.

"Through our ongoing research, TrapX Labs continues to uncover hijacked medical devices (MEDJACK) that attackers are using as back doors into hospital networks," he said. "Once inside the network, these attackers move laterally in search of high-profile targets from which they can ultimately exfiltrate intellectual property and patient data. Unfortunately, hospitals do not seem to be able to detect MEDJACK or remediate it. The great majority of existing cyberdefense suites do not seem able to detect attackers moving laterally from these compromised devices."

The list of devices vulnerable to a MEDJACK attack is large and includes diagnostic equipment such as PET and CT scanners and MRI machines; therapeutic equipment such as infusion pumps, medical lasers, and laser eye surgery machines; and life support equipment such as heart-lung machines, medical ventilators, extracorporeal membrane oxygenation machines, and dialysis machines.

Hackers More Sophisticated

Hackers have evolved and are now increasingly targeting medical devices that use legacy operating systems that contain known vulnerabilities, the report says. By camouflaging old malware with new techniques, the attackers are able to successfully bypass traditional security mechanisms to gain entry into hospital networks and ultimately to access sensitive data. *(A report on* that technique is available online at: http://bit.ly/28YKYDJ.)

Keep Up with Changing Defense Technology

To defend against these attacks, the company recommends that hospital staff review budgets and cyberdefense initiatives at the organizational board level and consider bringing in new technologies that can identify attackers that have already penetrated their networks. In addition, healthcare organizations need to implement strategies that review and remediate existing medical devices, better manage medical device end of life, and carefully limit access to medical devices, the company advises. Healthcare organizations also are increasingly vulnerable to ransomware attacks, Ben-Simon said.

"Lack of new technology and associated best practices make it very difficult for hospitals to detect and remediate ransomware attacks. We expect to see an increase in the number of incidents in 2017," he said.

CME/CE OBJECTIVES

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

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

COMING IN FUTURE MONTHS

- Risk matrix for employee use
- Nurse case management for workers' comp
- Hospital food: Avoiding liability
- Better team huddles



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CME/CE QUESTIONS

 According to John A. DiNome, JD, partner with the law firm of Reed Smith in Philadelphia, when can employers prohibit marijuana use by employees?

A. Always, because it is illegal under federal law.

B. Only if the state does not allow medical use.

C. Only if the state does not allow recreational use.

D. When the state has no statute regarding use in the workplace.

2. When a Colorado employee sued his employer after being fired for using marijuana legally, what did the state supreme court decide?

A. The court ruled in favor of the company due to an obvious conflict between state and federal laws.

B. The court ruled in favor of the employee, saying state law prohibited such terminations.C. The court remanded the case to the trial level for reconsideration of the positive drug test.

D. The court ruled that the employee was fired for reasons other than the marijuana use.

- 3. How many new staff were hired for the command center at The Johns Hopkins Hospital in Baltimore?
 - A. None
 - B. Two
 - C. Six
 - D. 14
- 4. In the "VINDICATE" mnemonic used for diagnosis by David Kashmer, MD, MBA, MBB, FACS, a trauma and acute care surgeon, and chief of surgical services at Signature Healthcare, what does the V stand for?
 - A. Value
 - B. Vascular
 - C. Volume
 - D. Veracity



Undiagnosed Fistula Yields \$50 Million Verdict

By **Damian D. Capozzola**, Esq. The Law Offices of Damian D. Capozzola Los Angeles

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ews: On Nov. 30, 2009, a 31-year-old woman delivered a baby. During the delivery, the patient's obstetrician noted that the baby's umbilical cord was wrapped around its neck. He performed an episiotomy, which resulted in the safe delivery of the baby.

Subsequently, the patient allegedly told the obstetrician that her vagina emitted an odorous gas. In response, the physician told her that the condition was a natural byproduct of the procedure, and that no treatment would be required.

The patient became pregnant again in April 2010, and was evaluated by a midwife who consulted with the original obstetrician regarding the odorous gas. Again, the condition was not addressed. After the delivery, another physician diagnosed the patient with a rectovaginal fistula.

The patient sued the obstetrician, the hospital, and the midwife, alleging that the physician's conduct amounted to malpractice and the midwife negligently failed to administer a test that would have revealed the fistula. The jury awarded the patient \$50 million in damages, assigning 90% of the liability to the physician and hospital, with the remaining

10% assigned to the midwife.

Background: On Nov. 30, 2009, the plaintiff, a 31-year-old female physiatrist's aide, delivered a baby. The delivery was performed by an obstetrician at a hospital. During delivery of the infant's head, the obstetrician observed the baby's umbilical cord wrapped around its neck, so he conducted an episiotomy, a cut of the skin that separates the anus and the vagina. The baby was subsequently delivered safely. That day, the patient allegedly

reported an odorous gas coming from her vagina. The obstetrician opined that the condition was a natural byproduct of the delivery, and stated that it did not require treatment.

In April 2010, the patient again became pregnant and was evaluated by a midwife. The plaintiff reported to the midwife that her vagina emitted odorous discharge, but the condition again was not addressed. On Oct. 31, 2010, the obstetrician recommended a vaginal delivery following a pre-delivery examination. The child was delivered the following day.

A different physician later determined

that the patient suffered from a rectovaginal fistula, which required 13 surgeries to repair. The patient asserted that the fistula arose out of the episiotomy performed by the obstetrician, that the episiotomy should not have been performed, and that the obstetrician should have diagnosed and treated the fistula. She contended that prompt diagnosis and treatment would have eliminated most or all of the fistula's effects.

The patient filed suit against the obstetrician, the hospital, the midwife, and the midwife's practice. Her complaint alleged that the obstetrician failed to properly manage the patient's two deliveries, that the physician failed to diagnose

A DIFFERENT PHYSICIAN LATER DETERMINED THAT THE PATIENT SUFFERED FROM A RECTOVAGINAL FISTULA, WHICH REQUIRED 13 SURGERIES TO REPAIR. and treat her fistula, that the physician's failures amounted to malpractice, and that the midwife negligently failed to conduct a test that would have revealed the fistula.

The patient and the midwife negotiated a settlement before trial. The midwife's insurer agreed to pay \$925,000 and the patient dismissed the suit against the midwife's practice, but the trial proceeded against the obstetrician and the hospital.

The patient's expert witness opined that the obstetrician did not follow accepted standards of medical care. He further opined that no episiotomy should have been performed and that the resulting lacerations were aggravated by unnecessary thrusts during the final stages of the first infant's delivery, and that the fistula was exacerbated by the delivery of her second child, which should not have been delivered vaginally. The expert also explained that the physician should have investigated the patient's reported odorous discharge, and that the fistula should have been detected and repaired prior to the delivery of the second child.

The patient further claimed that her odorous discharge persisted throughout the time between the deliveries of her children. She alleged that she reported the condition multiple times to both the midwife and the obstetrician.

The defense alleged that the patient's medical records indicated that her odorous discharge went unreported until after the delivery of her second child. The obstetrician claimed that he and the patient never discussed the condition; thus, he contended that he could not have provided earlier treatment of the fistula. The defense's expert opined that the fistula was not related to treatment rendered by the obstetrician, and contended that the fistula resulted from a cloacal malformation: a confluence of the rectum, urethra, and/or vagina.

On April 13, 2016, the jury awarded the plaintiff \$10 million for past pain and suffering and \$40 million for future pain and suffering over 43 years. The jury assigned 90% of the liability to the obstetrician, and thus the hospital under vicarious liability, and 10% to the midwife.

What this means to you: This case shows the value of developing reliable medical records for each patient. In an interview conducted after the trial, the obstetrician claimed the medi-

IT IS IMPERATIVE FOR ALL MEDICAL PROFESSIONALS TO PAY VERY CLOSE ATTENTION TO PATIENTS' COMPLAINTS TO ENSURE SYMPTOMS DO NOT EXPLODE INTO UNTREATABLE NIGHTMARES.

cal records supported his contention that the patient did not complain to him or any nurses about the medical problems she faced, counter to what she told the jury through her attorney. The jury did not agree.

A strong and comprehensive medical record can help eliminate false claims and protect medical professionals from liability. In this case, had the physician documented the patient's initial complaint, the expectation of both medical and non-medical reviewers would be to see documentation of the physician's response to her complaint, such as the result of the examination performed to ensure there were no post-episiotomy complications. Dismissing a patient's complaint without even a minimal and documented investigation places both patient and physician at risk.

The midwife's report to the physician relating to the same complaint apparently went unheeded as well. Here, the midwife, acting as patient caregiver and advocate, had a responsibility and an opportunity to pursue further investigation by the physician, knowing that the symptoms the patient is still experiencing are not likely to be "normal." It is imperative for all medical professionals to pay very close attention to patients' complaints to ensure symptoms do not explode into untreatable nightmares. Following up with patients is a simple solution that may seem costly or burdensome on the front end, but can serve to eliminate larger problems later.

This case also demonstrates the risks of vicarious liability, especially considering the obstetrician's refusal to settle. The obstetrician told an interviewer that he refused to settle the case because he believed he did nothing wrong. The jury did not agree. Individual doctors may have personal issues that prevent them from agreeing to rational settlements and motivate them to roll the dice, especially if an employer hospital also will be on the hook for any verdict.

Laws governing the status of physicians as hospital employees vary from state to state, so it is important to consult with qualified counsel, but a hospital may consider eliminating its employer-employee relationship with medical professionals to avoid vicarious liability. An alternative to removing the employee status is to implement incentives for exercising good care or punishments for exposing the hospital to liability.

One recent trend in this regard is that some hospitals are asking patients to sign or initial statements added to the Conditions of Admission form they sign to consent for treatment. The new language expressly documents the patient's understanding of the non-employee relationship between the physician and the hospital. Signs are posted often in such hospitals and in physician's offices, reiterating the physician's position as an independent practitioner who functions under the licenses issued by the medical board of a particular state, rather than as an employee of a particular hospital. Even with these safeguards, hospitals and their attorneys may remain challenged to successfully circumvent the ostensible agency phenomenon.

REFERENCE

Supreme Court, Twelfth Judicial District, Bronx County, New York. Case No. 308417/11 (April 13, 2016).

Hospital Escapes 40% Ostensible Agency Liability on Appeal

News: On Nov. 11, 2010, a 64-year-old retiree presented to a Los Angeles pain management center, where an anesthesiologist/pain management specialist had treated him for his severe neck pain since 2006. That day, the specialist administered four bilateral facet joint and selective nerve block injections at the top of the patient's spine with the help of another anesthesiologist.

The patient awoke with horrific facial pain and was prescribed pain medication. He then saw five physicians, including the anesthesiologist, about his pain, to no avail, and was eventually afflicted with quadriplegia due to a cervical spine infarction. The patient sued the anesthesiologists and the hospital, alleging a failure to obtain informed consent and negligence that resulted in his quadriplegia.

The patient won a jury verdict in his favor against the first anesthesiologist and the hospital on a theory of ostensible agency. The verdict totaled \$7.9 million and assigned 60% liability to the anesthesiologist and 40% to the hospital.

The hospital appealed, and on Oct. 4, 2016, the Court of Appeal of California reversed the judgment against the hospital as a matter of law, holding that the anesthesiologist was not an ostensible agent of the hospital.

Background: In November 2010, a 64-year-old retiree presented to a pain management center in Los Angeles for an appointment with an anesthesiologist/pain management specialist. He had received treatment there with the anesthesiologist since 2006 for his severe neck pain. The anesthesiologist administered four bilateral facet joint and selective nerve block injections at the C1-2 level.

When he woke from the procedure, the patient experienced tremendous facial pain, for which he was prescribed pain medication. He alleged that he remained bedridden for the next few days, with increasing pain in his neck and throat. The patient then saw five physicians, including the anesthesiologist, regarding his symptoms, but nothing helped.

On Nov. 20, the patient was taken to the hospital that managed the pain center's ED to address his developing neurological conditions. He eventually degenerated to quadriplegia due to a cervical spine infarction at the C2 level.

The patient sued the two anesthesiologists and the hospital that managed the pain center, alleging that failure to obtain his informed consent and negligence in treatment and injections caused the cervical spine infarction that resulted in quadriplegia. He also contended that the anesthesiologist was an ostensible agent of the hospital, and the hospital was liable for the negligence. (California generally prohibits physicians from serving as hospital employees, so the plaintiff needed to pursue a theory of ostensible or apparent authority.)

At trial, the patient claimed that, despite his pre-existing neck condition, he was a very active person before the procedure. His wife alleged that her life is now drastically changed, as she devotes almost all of her time caring for her husband. Plaintiff's counsel further contended that the procedure was executed using the iodine contrast Omnipaque, despite the patient's documented allergy to it.

Defense counsel argued that the patient's quadriplegia was unrelated to the procedure and the cervical spine infarction occurred after the procedure, as the patient was at risk for a stroke. The defense also argued that the plaintiff's life care planner grossly overstated his future medical costs.

Following the 21-day trial, the jury awarded the plaintiff \$7,978,185. The jury found the procedural anesthesiologist not negligent, but held the original anesthesiologist 60% and the hospital 40% liable for negligently causing the plaintiff's injuries. In contradiction to the appropriation of liability, the jury found that the hospital's negligence was not a substantial factor in causing the injuries.

The California Court of Appeals reversed the judgment as a matter of law as to the hospital, holding that the hospital was not negligent on the grounds that the anesthesiologist was not the hospital's ostensible agent. Notwithstanding the fact that the hospital's website and the anesthesiologist's business cards failed to inform patients of the absence of any principal-agent relationship, the court held that it was unreasonable for the patient to believe the anesthesiologist was an agent of the hospital. Informing the court's decision was the fact that the patient signed or initialed 25 times his acknowledgment that all physicians were independent contractors rather than agents of the hospital. The court also considered the patient's choice to be treated by the anesthesiologist. The court affirmed the judgment against the anesthesiologist.

The dissent argued, among other things, that the majority ignored the jury's finding by an 11-1 vote that the plaintiff's belief about the existence of an agency relationship was reasonable, and concluded that the majority supplanted the jury and decided the case as it believed it should have been decided.

What this means to you: This case embodies a need for clearly communicating the existence of agency relationships, or lack thereof, to patients to avoid the inadvertent creation of ostensible agency, which can arise to impute liability to the hospital for the actions of a non-employee if the plaintiff reasonably believed the

hospital had authorized that person to act on the hospital's behalf based on the actions or lack of action by the hospital. The conditional forms signed and initialed by the patient in this case stated, "physicians are independent contractors and are neither employed by nor agents of this facility. Patient recognizes that Physicians furnishing services to the Patient, including without limitation ... anesthesiologists, are all independent contractors with Patient for the purposes of the provision of professional services and are not employees or agents of [the hospital] for such purposes." The majority of judges on the Court of Appeal found this language to be sufficient, when coupled with the other facts of the case, to communicate the lack of relationship to the patient. These procedures can be enhanced by asking patients to review and initial or sign similar forms containing such language at multiple times in the admission and treatment process. Walking through these concepts orally with the patient (and documenting that process) also can be helpful, and can be easily conducted when reviewing (and documenting) all the patient's treatment options generally.

The plaintiff also contended the anesthesiologists conducted the procedure in question using a substance that was allegedly documented to cause allergic reactions to the patient. The counsel for the defense argued that there was no evidence to support the contention that the physicians used the substance in question in this matter (Omnipaque), but the jury nonetheless found the physicians to have committed medical malpractice. The lesson to be learned, again, is the importance of keeping very detailed records for medical procedures, since injuries happen that are often out of the physician's control. Hospitals must ensure there are adequate policies in

place for proper recordkeeping of all operations and the substances used for treatment. To this end, every patient is asked about allergies to medications on admission to a hospital and before a procedure. Both the physician and pharmacy releasing the drug for use on a particular patient must review the patient's stated allergies to ensure there is no known risk. However, reliability is only as certain as the patient's ability to know and report his or her allergies accurately. Once stated, the known allergy is entered into and remains part of the patient's medical record.

Finally, this case illustrates the importance of pre-screening patients to assess the risks of injury and informing them of those risks. The defense alleged that the patient suffered a stroke during the procedure coincidentally with, and independent of, the injections given by the anesthesiologists. They offered evidence to support the conclusion that he was at risk for a stroke before the injections were administered, but the jury was not swayed. Once it is determined that a patient is at risk, it is imperative to ensure that they are properly informed of the risks before the procedure begins to insulate hospitals and physicians from liability. This informed consent must be evident in the medical record before any procedure can begin. In addition, surgical staff are trained to ask patients if their physicians have explained the procedures to them. If the response is negative, physicians are contacted and asked to meet with their patients before proceeding further. These steps are mandated by both state and federal regulations.

REFERENCE

Court of Appeal of California, Second Appellate District, Division One, Case No. B260715, B262530 (October 4, 2016).