Healthcare RISK MANAGEMENT

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Most disturbing sex abuse case in healthcare history

Sexual abuse cases have torn through institutions such as The Pennsylvania State University in recent years, and the state of Delaware is grappling with what is being called the most heinous case of sexual exploitation in healthcare in history. A pediatrician is serving 14 life sentences plus 164 years, and the hospital is facing multiple lawsuits, including a class action lawsuit that could involve as many as 7,000 patients.

Sexual abuse in healthcare

The healthcare industry is ripe for more such lawsuits, some observers say, and risk managers should act quickly to reduce the risk and protect children in their care.

> *"Because of this case and other cases, the liability risk is even greater for hospitals that don't do what they ought to do."*

Beebe Medical Center in Lewes, DE, is struggling through a legal tangle even though none of the child sexual abuse is alleged to have occurred at its facilities. The convicted pedophile once worked as chief of pediatrics at the hospital. The lawsuits allege that Beebe employees and administrators should have detected signs that he was abusing children or that they suspected something was wrong but did not take adequate actions. The abuse took place at the pediatrician's clinic, in an annex next door to the hospital.

Hospital spokesperson **Kelly Griffin** tells Healthcare Risk Management that the hospital is committed to a mediation process that should resolve the lawsuits over the next three to six months. Until that time, she says, administrators cannot comment further. She notes, however, that the hospital has responded to the crisis with several significant improvements to reduce the risk of sexual abuse in its facilities, including a policy that provides for a chaperone to be present during physical contact with a child or anyone else who might be vulnerable. *(See the story on p. 54 for more on Beebe's improvements.)*

Hospital's credit rating lowered

The hospital was drawn into the case of 58-year-old Earl B. Bradley, MD, who was convicted in June 2011 of 24 counts, including first-degree rape, second-degree assault, and sexual exploitation of a child. Prosecutors charged that Bradley raped or assaulted more than 85 young children under his care over several years. *(See the story on p. 51 for more on Bradley's conviction.)*

The class action suit was approved by a Delaware judge in April 2011. It allows victims to combine dozens of civil lawsuits

INSIDE

Enclosed

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against Beebe and three physicians accused of failing to report suspicions of misconduct. Attorney **Bruce Hudson**, JD, who represents many of the victims, released a statement saying that class action status would require contacting up to 7,000 former patients for possible inclusion. At that time, Beebe Vice President **Wallace Hudson** issued a statement saying the hospital supported the class action lawsuit as an orderly way to address the numerous lawsuits the hospital faced. The hospital had acknowledged earlier that the lawsuits resulted in credit agencies lowering its credit rating.

Lessons to be learned from case

The extent of Bradley's crimes and the viciousness of his abuse has led many to call his case the most extreme example of sexual abuse in healthcare. But he is not alone. In the past 10 years, dozens of doctors have been accused of abusing hundreds of children, and many of those cases took decades to uncover.

As in other cases, many of the allegations against the hospital and physicians who worked with Bradley concern people not acting or acting insufficiently on their suspicions about his behavior. This case will create a higher expectation for healthcare professionals and employers, says **Linda Ammons**, JD, associate provost and dean of the Widener University School of Law in Wilmington, DE.

Ammons was asked by the governor of Delaware to conduct an independent review of the Bradley case in 2010. Her report found many faults in the Delaware healthcare system and Beebe Medical Center's actions, offering 70 recommendations for improvement. *(See the story on p. 53 for more on Ammon's report and recommendations.)* "We absolutely will have lower tolerance for people saying they just didn't know. They should have known," Ammons says. "Because of this case and other cases, the liability risk is even greater for hospitals that don't do what they ought to do. The question won't just be what did you know, it will be what should you have known, based on everything that has happened so far."

The Bradley case is probably the "most heinous" case of sexual abuse in healthcare, says **Grena Porto**, RN, MS, ARM, CPHRM, principal with QRS Healthcare Consulting in Hockessin, DE, and former president of the American Society for Healthcare Risk Management (ASHRM) in Chicago. The details of the Bradley case produce clear lessons for risk managers, she says. The first is that when any type of abuse

Executive Summary

Healthcare settings pose a higher than normal risk for sexual abuse. Industry leaders are responding with preventative efforts and improved training of employees.

- ✦ A hospital in Delaware is being sued for its involvement with a now convicted pedophile.
- ✦ Chaperone policies and other safety efforts can protect children.
- ✦ Increased awareness of the risk puts risk managers on notice and lowers tolerance for ignorance.

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is suspected, employees must report it immediately and administrators must act aggressively, she says.

"The problem here was that everyone had suspicions, and no one did anything about it," Porto says. "The doctors and nurse who worked with him said, 'Yeah, we called him the pedophile doctor,' but nobody acted on that. Some people reported their suspicions, but in the end, the administrators and the authorities didn't do anything to stop him, and more babies were raped."

Too often, Porto says, administrators refer abuse allegations to peer review rather than the police. *(See the story on p. 52 for more of Porto's advice.)*

Hospitals at high risk

Sexual abuse of children can happen anywhere, but healthcare facilities offer unique opportunities, says **Julie Logan**, president and CEO of Darkness to Light, a national non-profit dedicated to the prevention of child sexual abuse, based in Charleston, SC.

"Perpetrators are drawn to places where they can have access to children, especially private access, and that can be more of a risk in hospitals," Logan says. "They also are drawn to situations where they can have a trusting relationship with the child and the parents, and that can be a healthcare environment as well."

Bradley, for example, took children to a separate room without their parents for examinations, and parents allowed it because they trusted him, Logan explains. Risk managers should implement policies that prohibit such behavior and require others to report violations, she says. *(See p. 53 for more of Logan's advice.)*

The facts emerging from the Bradley case do not entirely surprise **Frederic G. Reamer**, PhD, a professor at the Rhode Island College School of Social Work in Providence. Reamer is the author of two books on crime, and he has been a member of the Rhode Island Parole Board for 20 years. Reamer says it is common for people to see warning signs about abusive behavior but to do nothing, or do too little.

> *"The question won't just be what did you know, it will be what should you have known, based on everything that has happened so far."*

"Once these offenses come to light, it is not unusual to hear co-workers comment or testify about concerns they had over a period of time, like odd or suspicious behavior, poor job performance, or impairment," he says. "Colleagues sometimes worry about blowing the whistle because of their concern about destroying a career, defamation, or the anxiety and stress involved in reporting a co-worker to authorities. I think healthcare professionals would do well to include the subject of professional impairment — warning signs, predictors, correlates, and how to respond — during in-service training."

Recognizing and reporting impairment is important because it can go hand-in-hand with sexual abuse, he explains. "Nearly all of the offenders I have worked with over the years manifest very troubling evidence of very troubled lives," Reamer says. "Common correlates and precursors include major mental illness like bipolar disorder and clinical depression, substance abuse, trauma histories such as being victimized themselves as children, social isolation, and dysfunctional interpersonal and intimate relationships."

Ammons urges risk managers to learn from the Bradley case and to study the recommendations in her report and Beebe's improvements. "It's unfortunate that this particular episode happened, but I think out of this tragedy we have developed some very good recommendations," she says. "If those are implemented and expanded upon, I think we can prevent a lot of tragedies for individuals and reduced liability or hospitals and healthcare facilities. I admonish people to pay attention and do what you need to do."

Porto calls on risk managers to always err on the side of caution when it comes to protecting patients, especially children.

"In all of these sex abuse cases, the organizations were all about protecting their doctors," she says. "Where in your mission statement does it say you're there to protect physicians? You're there to protect patients."

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Bradley case considered the worst ever in healthcare

The case of Earl B. Bradley, MD, is so sickening that no one wants even the most remote association with it. After Bradley was arrested and convicted of abusing children, the property housing his pediatric clinic, which was the scene of the crimes, couldn't be sold even for a pittance. The city demolished it and hoped to wipe away a terrible reminder.

Bradley was sentenced on Aug. 25, 2011, to 14 life sentences without parole for 14 counts of first-degree rape. He also was sentenced to more than 160 years in prison for multiple counts of assault and sexual exploitation of a child.

Sexual abuse in healthcare

Trial testimony indicates that Bradley was arrested in December 2009 after a 2-year-old girl complained to her mother that the doctor had hurt her. The girl had made an earlier complaint to her father after a previous visit.

The horrific nature of Bradley's crimes were compounded by the fact that he could have been stopped earlier. Bradley's own sister worked in his office and told police in 2005 that her brother was bipolar and taking medication from the office. She also reported that several parents had complained about Bradley inappropriately touching patients.

Two pediatricians interviewed by police in 2005 also told investigators about complaints from Bradley's former patients. Staff and colleagues expressed concern about lengthy, unnecessary vaginal exams of young patients, but an internal review by the practice determined they were acceptable.

Acting on the 2009 complaint, investigators arrested Bradley and searched his Lewes, DE, pediatric office, which was known as particularly welcoming to children because it was decorated with Disney themes and miniature amusement park rides. They seized dozens of homemade videos from an outbuilding where Bradley had lured patients with promises of treats and toys. With the tapes in evidence, Bradley waived his right to a jury trial. At a one-day bench trial in June 2011, prosecutors presented testimony from two police investigators and produced more than 13 hours of videos showing sex crimes against more than 80 victims, most of whom were toddlers.

State police detective Scott Garland described the rapes caught on video as brutal and violent. He explained how some videos showed Bradley with his hands wrapped tightly around the heads of young children, violently forcing them to perform oral sex on him and also terrorizing children by screaming at them. When Bradley was finished with the assaults, he would lift up the young victims by the head and throw them several feet onto a couch in the rear of the building, Garland testified.

The children often were nearly unconscious from the assaults. Bradley sometimes would perform "rescue breathing" and chest rubs to revive the semiconscious victims, the detective added.

In response to the Bradley case, Delaware enacted a law that requires criminal background checks of physicians every six months. The law would not have helped catch Bradley, who had no criminal background. ✦

Call police, do not refer abuse cases to peer review

Risk managers should remind employees that calling the police can be the right thing to do, says **Grena Porto**, RN, MS, ARM, CPHRM, principal with QRS Healthcare Consulting in Hockessin, DE, and former president of the American Society for Healthcare Risk Management (ASHRM) in Chicago.

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As in the Penn State sex scandal, in which a coach says he notified his university superiors rather than calling police when he witnessed a boy being raped, Porto says healthcare employees must understand that a crime is a crime. Calling your boss shouldn't always be the first priority.

"This is not like something you report for peer review," she says. "These were people who suspected a man was sexually abusing little babies. Why didn't they just call the police? If I'm your risk manager, and you tell me you thought someone was raping a child in the examination room, I'm going to be livid that you didn't call the police instead of sending me a memo the next day."

Another important lesson is that healthcare administrators should be willing to believe parents when they report suspicions of abuse, Porto says. In some cases of healthcare abuse, parents' concerns were dismissed because administrators assumed the doctor was above reproach and the parents were out to get money from the hospital, she says. "Any complaint like this in which there is even a risk of illegal behavior has to be reported to law enforcement," she says. "They are the only ones with the skills and objectivity to do a thorough investigation. In all the cases I've seen, that never happens. The allegations are reviewed internally, and that is grossly inappropriate."

Do not ever refer such cases to peer review, Porto says. The peer review process is inappropriate and will always yield a "no finding" type of conclusion, because the peer review committee is incapable and unwilling to conduct such an investigation, she says. But that "no finding" report will be used by the accused as evidence that the hospital investigated and found nothing to act on.

Porto says she is surprised that criminal charges against healthcare employees or administrators who suspected abuse have not yet been brought in a sexual abuse case.

"I'm surprised no one has been criminally charged, but I don't think the last word has been written on that," Porto says. "I think people at the hospital, people he worked with, should be worried. They not only didn't do anything about the hospital, but they allowed it to continue. That's aiding and abetting a criminal." ✦

Have zero tolerance with protection rules

Implementing policies to protect children from abuse and then enforcing them with zero tolerance will achieve two things, says **Julie Logan**, president and CEO of Darkness to Light, a national nonprofit dedicated to the prevention of child sexual abuse, based in Charleston, SC.

Sexual abuse in healthcare

First, it eliminates having employees make judgment calls about what is "bad" behavior versus a minor mistake, she says. Second, it puts potential abusers on notice that they are being watched.

"Abusers are not easily identified, and almost every time you hear of someone being caught, the people around them are shocked. They say he was a great doctor, the last person they would have expected to do something like that," she says. "For that reason, education is important so that everyone understands what grooming behavior looks like and why policies are what they are. One of the first warning signs a perpetrator exhibits is breaking the rules."

For example, a hospital might have a rule prohibiting an adult other than the parent being alone in a room with a child. If the staff members do not understand the reason for that rule, they might be lax in reporting violations, Logan says. "This person is not going to seem like a creep. They're going to have the best intentions, and everyone thinks they're the best person on the team," she explains. "So when they violate the rule about one-on-one contact, everybody thinks it's just a slip-up and not worth reporting. But there has to be zero tolerance for breaking the rules. You want an atmosphere in which people don't have to make a judgment call; if you break the rule, I have to report it, period."

Studies show that there are an estimated 42 million adult survivors of child sexual abuse. About 500,000 babies born in the United States each year will be sexually abused before they reach age 18. About 95% of abuse is perpetrated by someone the child knows and trusts; and 73% of children do not report the abuse until years afterward, if they report it at all.

The Bradley case, other healthcare cases, and The Pennsylvania State University scandal involving coach Jerry Sandusky are bringing more attention to the risk of sexual abuse, Logan says. "I definitely think the healthcare industry would be wise to get ahead of this instead of being the next Sandusky," she says.

Logan urges risk managers to visit the Darkness to Light web site at http://www.d2l.org for educational materials and other information.

"We are just starting to see some big hospital systems engage with us and be part of their prevention policies," she says. "That is either an indicator that everyone else is handling it really well, or hospitals are starting to say that they need to improve their prevention efforts. I suspect the latter." ✦

Independent review finds missed opportunities

Criticizes hospital for not acting on info

The investigative report of Earl Bradley, MD, by **Linda Ammons**, JD, associate provost and dean of the Widener University School of Law in Wilmington, DE, cites many instances in which his sexual abuse of children could have been stopped. It also alleges that Beebe Medical Center in Lewes, DE, failed to act properly when Bradley's behavior was questioned.

Sexual abuse in healthcare

Ammons' report cites these missed opportunities:

• The first known complaint against Bradley in Delaware occurred in 1996, when Joan Davis, a nurse who worked with Bradley at Beebe, complained to her supervisor about what she thought were too many catheterizations of female patients for urine samples by Bradley in his annexed office next to the hospital. Davis's allegations regarding Bradley also included allegations of excessive kissing of patients, inappropriate remarks about females, and that Bradley was taking pictures of patients without their parents' consent or knowledge and putting them on his computer. The hospital did conduct an internal investigation. After consulting with three independent doctors, it deemed that the catheterizations were medically appropriate and closed the investigation.

• Relying on Delaware's peer review statute, the procedures of their accreditation standards, federal statutes, and the fact that other experts in the field had cleared Bradley's actions as accepted medical practice, Beebe did not report Davis' allegations to law enforcement or the Board of Medical Practice. It does not appear that Beebe's internal investigation addressed Davis' other allegations.

• In 2005, **William J. Wenner**, MD, vice president of the medical staff at the hospital, had several discussions and written communications with Bradley concerning a possible law enforcement investigation of him. On Sept. 19, 2005, Wenner noted that he met with the CEO of the hospital, who informed Wenner about the allegations raised eight years previously concerning

Bradley. According to Wenner's notes, the CEO was also aware of a rumor of inappropriate behavior in Pennsylvania but believed it to be without substance. After the hospital was subpoenaed, Wenner informed Bradley that all patient contacts by hand must be in the presence of another witness. On Oct. 5, 2005, Wenner learned that the Milford Police Department investigation was closed and notified Bradley that chaperoning was no longer necessary.

• Beebe administrators did not notify the police department during the 2005 investigation that it had conducted its own investigation of Bradley in 1996.

Ammons concluded that "it is reasonable to conclude that if the Davis allegations were made known to law enforcement in 2005, it could have altered prosecutorial decisions such as whether to arrest, indict, or even seek a search warrant. Instead, it does not appear that the records of Beebe's investigation in 1996 were ever given to law enforcement until after Dr. Bradley was arrested, even after Bradley's records were subpoenaed by the Attorney General's Office in 2005."

For a summary of the Ammons report, go to http://tinyurl.com/bw5x2ow. For the entire report, go to http://tinyurl.com/bo4679d. ✦

Hospital develops chaperone policy

More changes made after abuse case

Following the arrest of pediatrician Earl Bradley, MD, for child sexual abuse, and allegations that Beebe Medical Center in Lewes, DE, did not adequately respond to concerns about Bradley, the hospital established a Special Investigative Commission to look at how Beebe might strengthen its internal procedures and practices.

Sexual abuse in healthcare

The following actions were implemented by the commission:

• A management "best practice" to follow up on safety concerns was adopted and implemented for use at Beebe. This practice is designed to investigate any safety issues that are identified internally and to determine whether or not the safety issue identified is a process breakdown or an avoidable and/or reckless act by an individual.

• A new chaperone policy identifies those situations when chaperones are needed, the roles and responsibilities of a chaperone, and the patient's rights to have a chaperone. A chaperone is required for pediatric patients and infirm adults of any age. Details on the chaperone policy can be found online at http://tinyurl.com/d9p9mcg.

• Signage and brochures have been developed to educate the public about Beebe Medical Center's revised Chaperone Policy.

• Beebe has created the brochure "Your Child's Doctor Visit" to advise parents on what they can/should expect during the examination of a pediatric patient.

• The medical staff took the initiative to make several constructive changes regarding peer review, even before the Special Investigative Commission was formed. The vice or assistant chief in each medical staff department is now responsible for the review of the performance of each practitioner within that department. Data is now collected, reviewed, and analyzed on a continuous basis to ensure that practitioner competency and performance is continually monitored.

• A multidisciplinary Peer Review Committee has been established by the medical staff to review any concerns or issues that have been identified by the clinical departments and the medical executive committee. The multidisciplinary peer review group has been formed to review practitioner performance to eliminate potential bias and conflicts of interest that could interfere with effective peer review.

A summary of the improvements, including the new chaperone policy, can be found online at http://tinyurl.com/8ysdku6. ✦

Secret recording raises question of peer review shield

As useful as peer review protection is in keeping potentially harmful information out of malpractice litigation, risk managers should keep in mind the limits and not become overly dependent on peer review privilege, attorneys say.

It is easy to rely on peer review protection too much because it is indeed a strong shield, says **James A. Hoover**, JD, partner in the Birmingham, AL, office of the law firm Burr & Forman.

"I have represented a ton of cases in which hospitals sought to quash the request for records, saying they were protected by peer review, and I've found that in both state and federal courts, the judges are very reluctant to release that information and say it's not protected," Hoover says. "There's no doubt that peer review protection is valuable and can be relied on in a lot of situations."

What confuses some providers

Executive Summary

The extent of peer review protection can depend on state law, but the shield always will have limits. Hospitals should be careful not to become overly dependent on peer review protection.

- ✦ Laws on secretly recording others will vary by state.
- ✦ Peer review does protect the underlying facts.
- ✦ Peer review protection can be waived if you do not act in confidence.

is whether peer review protects the underlying facts of the case. It does not, Hoover explains. "It protects the correspondence, the opinions, the exchange of information between people, but not the underlying facts of the case," he says. "State laws will phrase it differently, but in Alabama it is called the original source. The facts themselves often are discoverable."

So if, for example, a nurse overhears a physician admitting guilt and is then called to relate that experience during peer review, the nurse's statement will be protected by peer review, Hoover explains. But the plaintiff's attorney can ask the nurse what she heard, and that underlying fact is not protected. The nurse would have to provide that information, as long it was not heard in a protected situation such a credentialing committee meeting, he says.

The issue was raised by a recent Ohio case in which a patient's family secretly tape-recorded a meeting in which a hospital official stated that the patient's death was the result of an error. The hospital tried to bar the plaintiffs from using the recording in their case against the hospital, and it cited peer review protection. The recorded statement was protected by peer review privilege, the hospital argued, because the error had been discussed in peer review, and the hospital official was conveying part of that review, a root cause analysis, to the family.

Ohio trial and appellate courts refused to bar the evidence. They said the hospital failed to prove the statement about a lab error was connected to peer review. The case is still in litigation.

As for the legality of secretly recording another party, state laws will vary on whether the other person must be informed that you are recording. Hoover advises healthcare providers to always assume they are being recorded and act accordingly.

Peer review protection is analogous to the attorney-client privilege, Hoover says. If you tell your attorney you ran a red light, that statement is protected and cannot be used against you in court, he says. The fact that you ran the red light, if that can be proven otherwise, is not protected just because you told your attorney.

"What trips up a lot of people is that you have to act in such a way that you intend for it to be confidential," Hoover explains. "You can waive the peer review protection if you do not act in confidence, just like if you yelled across a crowded restaurant that you ran the red light, that would not be a protected communication with my client."

SOURCE

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Risk goes up when pharmacy closes, but what is solution?

The risk of a medication error rises sharply when a hospital's pharmacy is closed, according to a report by **Michael J. Gaunt**, PharmD, senior patient safety analyst with the Pennsylvania Patient Safety Authority in Harrisburg. His recent study found that the incorrect drug was retrieved from an automated dispensing cabinet or night cabinet in 82.3% of wrong-drug events.[1]

Between June 2004 and September 2010, Pennsylvania hospitals submitted to the Pennsylvania Patient Safety Authority 519 medication error reports that implied an event occurred while the pharmacy department was closed, the report says. The most common types of medication errors reported included wrong-drug events, drug omissions, and prescription or refill delays. The predominant medications associated with these reports were warfarin sodium, hydration solutions, insulin, guaifenesin, and vancomycin.

In 28.7% of drug omission events, the medication was not available to the nurse to administer, which led to an omission. Gaunt's report suggests strategies to prevent errors when the pharmacy is closed, such as:

- providing a limited supply of medications to be used for urgent medication orders;
- standardizing processes for accessing medications when the pharmacy is closed to reduce variability and opportunity for error;
- establishing a forcing function error reduction strategy to make the allergy reaction selection a mandatory entry in the organization's order entry

Executive Summary

A new report shows that the risk of medication errors rises significantly when a hospital's pharmacy is closed. Of all the medication errors in the study, 82% involved an automated dispensing unit or night cabinet.

- ✦ Some patients do not receive needed medications because they cannot be obtained after hours.
- ✦ Solutions include providing access to some medications for urgent orders.
- ✦ Warfarin sodium and hydration solutions were among those most commonly involved in errors.

systems for prescribers and pharmacists.

A 24-hour pharmacy is always preferable, but not always economically possible, says **Marianne F. Ivey**, PharmD, MPH, FASHP, associate professor at the University of Cincinnati (OH) in the Pharmacy Practice and Administrative Sciences. She has worked as vice president of pharmacy services at a system of eight hospitals, some of which smaller and could not afford a 24-hour pharmacy. In those cases, she says, one solution was to have the 24-hour pharmacy at a larger facility act as the after-hours review for a smaller facility where the pharmacy was closed.

"They were connected electronically, so there could be prospective review of orders," Ivey says. "Today's patients are sicker than ever, which means more complicated therapies. All of our nurses wanted the assurance that a pharmacist was checking those orders at night."

Other hospitals have restricted off-hours cabinet access to nurses with special training in medication safety, or nurses at a certain level of training such as a registered nurse, Ivey notes.

Technology also is cited as the potential solution by **David Kile**, director of continuing education and professional development at Albany (NY) College of Pharmacy and Health Sciences and longtime director of pharmacy at a New York hospital. With modern technology, hospitals can improve on the older solution of having a pharmacist on call to address difficult prescription orders. "It's now possible that a pharmacist could log into the hospital's information system, look at the patient, see the order, and process that order from home," Kile says. "This is a step above calling the pharmacist and waking him or her up several times a night. You can have a pharmacist on duty, in effect, at home to review these orders as they come in."

Another option, Kile says, is to contract with a company that will provide after-hours pharmacy review, which can be pricey but still less expensive than a 24-hour pharmacy.

"The break point is about 200 to 300 beds," Kile says. "Those hospitals should be seriously considering a 24-hour pharmacy."

Reference

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SOURCES

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Texas cap on pain, suffering passes court

A Texas law that caps pain and suffering awards in healthcare lawsuits was ruled constitutional by a federal judge recently. U.S. District Judge **Rodney Gilstrap** issued a brief one-page ruling stating "all claims by plaintiffs in this matter are denied," which left the state's 2003 cap on non-economic damages standing.

In 2003, Texas joined 26 other states in limiting awards in medical lawsuits for hard-to-quantify injuries such as mental anguish, emotional distress, or loss of companionship. The capped amount varies from $250,000 to $750,000, depending upon the variety of defendants in the suit. Past, present, and future medical costs, as well as lost wages, remain uncapped, explains **Michael Hull**, JD, general counsel of Texas Alliance for Patient Access, the statewide healthcare coalition that defended the cap.

Executive summary

A state law limiting non-economic damages in malpractice cases has passed constitutional muster. The court determined that the Texas limits did not deny patients their constitutional right to seek restitution.

- ✦ The law appears to have drawn more physicians to Texas.
- ✦ Voters in the state had approved the law after it was implemented by the legislature.
- ✦ Malpractice insurance rates for Texas physicians have been cut in half.

"The court's decision removes any lingering uncertainty about the voter-approved cap on non-economic damages," Hull says. "A trial lawyer victory would have gutted the benefits of reform and been a big blow to the delivery of healthcare."

The Texas Hospital Association is pleased with the court's decision because it upholds one of the key 2003 medical liability reforms that has improved access to healthcare in Texas, says President and CEO **Dan Stultz**, MD. "Since implementation of these reforms, hospitals have invested savings from reduced liability insurance coverage back into hospital operations, including new technology that saves lives and improves patient safety," Stultz says "Hospitals also have been able attract new physicians to their community and offer new or expanded services to patients."

Doctors see liability costs drop 46%

In 2008, 10 plaintiffs filed a federal lawsuit in Marshall claiming the state's non-economic cap violates the U.S. Constitution. Among the plaintiffs was the family of the late Dallas Cowboy Ron Springs, who died after a four-year coma. The suit argued the cap had a direct impact on an injured patient's potential jury award and whether the cost of proving up the damages was worth pursuing the case. Named as defendants were healthcare providers who sought to enforce the damage cap and more than 600 Texas trial court judges who are required to enforce the damage limits. The judge subsequently removed those parties from the suit.

Gilstrap recently dismissed the remaining two claims: that a cap on damages unconstitutionally takes private property and that the cap bars access to the courts.

Hull explains that Texas lawmakers passed the cap in 2003 in response to a medical lawsuit crisis. Later that year, Texas voters affirmed the legislature's authority to set caps on non-economic damages in healthcare lawsuits. Unlike most cap challenges, the federal suit in Marshall did not claim the non-economic cap violated the state's constitution, Hull says. Rather, the plaintiffs claimed the cap violated the U.S. Constitution. This argument gave them the right to have the issue resolved in federal court, they contended.

Prior to the passage of the cap, most Texas doctors had seen their insurance costs double, Hull says. Many had stopped taking emergency calls or restricted their practice out of fear it would make them vulnerable to a career-threatening lawsuit, he says.

Proponents argued that emergency department services for head injuries, childbirth, and trauma involving small children were in shorter supply due to the prospects of an over-sized award. Since the passage of reforms, Texas doctors have seen their liability rates cut in half, Hull says.

Consequently, Texas doctors have seen their liability costs cut, on average, 46%, Hull says. Thirty-four rate cuts have occurred in Texas since the passage of the 2003 landmark reforms. The combined premium reduction for doctors has been $1.9 billion, he says. Premium reductions include rate cuts and dividends.

Physician growth has outpaced population growth every year since 2007 and the ranks of high-risk specialists have grown twice as fast as the state's population.

"As a result of the liability limits, new doctors have flocked to the state in record numbers," Hull says. "Counties that lacked an orthopedic surgeon, an emergency medicine physician, or a cardiologist now have one."

SOURCES

- Michael Hull, JD, General Counsel, Texas Alliance for Patient Access, Austin. Telephone: (512) 494-8089. Email: mhull@hhm-llp.com. ✦
- Dan Stultz, President and CEO, Texas Hospital Association, Austin. Telephone: (512) 465-1000. Email: dstultz@tha.org. ✦

Alert fatigue often related to uncertainty of purpose

A study by Regenstrief Institute in Indianapolis and U.S. Department of Veterans Affairs investigators provides the first in-depth look at how healthcare providers react to medication alerts generated by electronic medical record systems.[1] They found that clinicians often ignore alarms because they are uncertain what they mean.

The authors identified nine factors that influence prescribers as they encounter alerts, and they provided a detailed description of 44 components that contribute to these factors. The researchers found that prescribers sometimes were unsure why an alert was appearing, and they also determined that alert designs were more pharmacist-oriented than physician- or nurse practitioner-oriented, in spite of the fact that doctors and nurse practitioners were the principal prescribers.

The researchers plan to use this information to improve the design of medication alerts and diminish the phenomenon known as alert fatigue, where providers can become desensitized and might start unintentionally ignoring some important warnings, says Regenstrief Institute investigator **Alissa Russ**, PhD, a research scientist with the Center of Excellence on Implementing Evidence-Based Practice at the Richard L. Roudebush VA Medical Center in Indianapolis. She is first author of the study and is an adjunct assistant professor of pharmacy practice at Purdue University in West Lafayette, IN.

The researchers observed providers

as they treated patients to learn about the strengths and weaknesses of medication alerts, Russ says. Medication alerts provide the healthcare team with computer-generated information on a variety of drug-related issues. Among the most common medication alerts are warnings about patient allergies, drug interactions, and duplicate prescriptions. The alerts, critical to patient safety, can be triggered by many factors including the prescription of a new medication or a change in a patient's laboratory test results.

However, healthcare providers might experience alert fatigue and unintentionally overlook important alerts if the electronic medical record system generates too many medication alerts, Russ explains. Common example are alerts that don't apply to the patient , such a warning about a drug the patient already has been taking without problems or an alert that provides too much extra information. The goal is to develop alerts that aid healthcare providers more effectively and enhance patient safety, Russ says.

"As a human factors research scientist, I am interested in learning how to improve the usability of electronic medical records systems so doctors, nurses, and pharmacists can work more effectively," Russ says. "Too many alerts and overly detailed alerts are a common source of frustration across electronic medical record systems."

> *"Too many alerts and overly detailed alerts are a common source of frustration across electronic medical record systems."*

During the study, 320 medication alerts were generated by an electronic medical record system as 30 doctors, nurse practitioners, and pharmacists treated 146 patients in outpatient clinics. The study authors observed and analyzed factors that influenced how healthcare providers perceive, interpret, and respond to alerts.

"Unless we improve medication alerts so they contain information that users need to make decisions, the problem of alert fatigue will grow as EMR systems expand beyond single hospitals and share more data," Russ says.

Reference

1. Russ AL, Zillich AJ, McManus MS, et al. Prescribers' interactions with medication alerts at the point of prescribing: A multi-method, in situ investigation of the human-computer interaction. *Int J Med Inform* 2012; 81(4):232-43.

SOURCE

• **Alissa Russ**, PhD, Research Scientist, Center of Excellence on Implementing Evidence-Based Practice, Richard L. Roudebush VA Medical Center, Indianapolis. Telephone: (317) 274-7722. E-mail: Alissa.Russ@va.gov. ✦

Blue Cross to pay $1.5M for HIPAA violations

Blue Cross Blue Shield of Tennessee (BCBST) has agreed to pay the Department of Health and Human Services (HHS) $1.5 million to settle potential violations of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules. The enforcement action is the first resulting from a breach report required by the Health Information Technology for Economic and Clinical Health (HITECH) Act Breach Notification Rule.

BCBST also has agreed to a corrective action plan to address gaps in its HIPAA compliance program, according to **Leon Rodriguez**, director of the HHS Office for Civil Rights (OCR) in Washington, DC, who announced the settlement recently.

The investigation followed a notice submitted by BCBST to HHS reporting that 57 unencrypted computer hard drives were stolen from a leased facility in Tennessee. The drives contained the protected health information (PHI) of more than one million individuals, including member names, social security numbers, diagnosis codes, dates of birth, and health plan identification numbers.

OCR's investigation indicated BCBST failed to implement appropriate administrative safeguards to adequately protect information remaining at the leased facility by not performing the required security evaluation in response to operational changes. In addition, the investigation showed a failure to implement appropriate physical safeguards by not having adequate facility access controls; both of these safeguards are required by the HIPAA Security Rule.

"This settlement sends an important message that OCR expects health plans and healthcare providers to have in place a carefully designed, delivered, and monitored HIPAA compliance program," Rodriguez said. "The HITECH Breach Notification Rule is an important enforcement tool, and OCR will continue to vigorously protect patients' right to private and secure health information."

In addition to the $1.5 million settlement, the agreement requires BCBST to review, revise, and maintain its privacy and security policies and procedures, to conduct regular and robust trainings for all BCBST employees covering employee responsibilities under HIPAA, and to perform monitor reviews to ensure BCBST compliance with the corrective action plan. ✦

EMTALA physician protections pass U.S. House

Medical liability reforms that include specific protections for physicians who provide services to fulfill the requirements of the Emergency Treatment and Labor Act (EMTALA) has passed the U.S. House of Representatives.

The protections were included as an amendment offered by Reps. Charlie Dent (R-PA) and Pete Sessions (R-TX) to comprehensive liability reform bill H.R. 5, the "Protecting Access to Healthcare (PATH) Act," which passed 223-181. Also included in H.R. 5 are liability protections for physicians working in disaster situations and repeal of the Independent Payment Advisory Board (IPAB).

David Seaberg, MD, FACEP, president of the American College of Emergency Physicians (ACEP), calls the bill provisions "a critical step forward." "The legislation not only will provide liability protections for emergency physicians, but also for on-call specialists, which will help make sure they are available to emergency patients in their hour of need," he says.

H.R. 5 sets a $250,000 cap on non-economic damages in malpractice suits, limits attorney fees, and establishes other methods to rein in lawsuits. The sponsors say the bill would reduce health spending by $50 billion over 10 years. The amendment to H.R. 5, unanimously adopted, was language from H.R. 157, which is the "Health Care Safety Net Enhancement Act of 2011," introduced by Reps. Dent and Sessions. It provides limited liability protections to emergency and on-call physicians who perform the services mandated by the federal EMTALA law.

The legislation also includes another amendment offered by Rep. Cliff Stearns (R-FL) granting limited civil liability protections to health workers who volunteer at federally declared disaster sites. ✦

AHC Media launches *Hospital Report* blog

For further analysis and discussion of topics important to hospital professionals, check out Hospital Report, AHC Media's new free blog at http://hospitalreport.blogs.ahcmedia.com.

Healthcare Risk Management executive editor Joy Daughtery Dickinson contributes. ✦

COMING IN FUTURE MONTHS

- ✦ Worker's comp trends and tactics
- ✦ Telehealth brings new risks
- ✦ Patient dies after ED ejection
- ✦ What to expect from reform effort

CNE OBJECTIVES

Upon completion of this educational activity, participatns 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. In the case of child sexual abuse involving Earl B. Bradley, MD, what was the involvement of Beebe Medical Center?
   A. The convicted pedophile once worked as chief of pediatrics at the hospital, but the abuse is not alleged to have happened in the hospital. The abuse took place at the pediatrician's clinic, in an annex next door to the hospital.
   B. Bradley merely had privileges at the hospital and had no further connections.
   C. Bradley is alleged to have abused children under his care at the hospital, in patient rooms within the hospital.
   D. Bradley had no association with the hospital, but some of his victims were treated there.

2. During what time frame was Bradley suspected of sexual abuse of children?
   A. The first known compliant against Bradley occurred in medical school in 1985, and he was arrested in 2009.
   B. The first known complaint against Bradley in Delaware occurred in 1996, and he was arrested in 2009.
   C. The first known complaint against Bradley in Delaware occurred in 2005, and he was arrested in 2009.
   D. There were no reports of suspicious behavior until just prior to his arrest in 2009.

3. In a report by Michael J. Gaunt, PharmD, senior patient safety analyst with the Pennsylvania Patient Safety Authority, what was found to the most common type of wrong-drug event?
   A. The incorrect drug was retrieved from an automated dispensing cabinet or night cabinet in 82.3% of wrong-drug events.
   B. The incorrect dosage was retrieved from an automated dispensing cabinet or night cabinet in 82.3% of wrong-drug events.
   C. Double delivery of the correct dosage was obtained from an automated dispensing cabinet or night cabinet in 82.3% of wrong-drug events.
   D. Clinicians did not use an automated dispensing cabinet or night cabinet in 82.3% of wrong-drug events.

4. What was one result of the Texas law imposing limits on non-economic damages in malpractice lawsuits?
   A. Patients immediately filed more lawsuits than in previous years.
   B. Plaintiffs' attorneys focused their cases entirely on economic damages.
   C. More malpractice cases were settled through mediation.
   D. Texas doctors have seen their liability costs cut, on average, 46%.

HIPAA Regulatory Alert

Supplement to *Healthcare Risk Management* and *Hospital Access Management*

HIPAA compliance audits begin with a pilot program

You should prepare now — Documents are due 10 days after notice

As promised by the Department of Health and Human Services' Office for Civil Rights (OCR) and mandated by the HITECH Act, HIPAA compliance audits have begun, and 20 organizations were visited during the pilot phase of the program.

"Hospitals selected for the audit have to provide a lot of documentation in a short timeframe," explains **Adam Greene**, partner at the Washington, DC, law firm of Davis Wright Tremaine and a former OCR official. In addition to the expected policies and procedures related to privacy and security, auditors want to see current risk analyses and documentation related to improvement of data protection, he adds. *(See related story on documentation tips, p. 2.)* "Be aware that the audit's scope extends past electronic health records and covers privacy and security of data in clinical, research, and billing departments, as well as employee use of email and text messaging."

From the time of notification of an audit, you have 10 calendar days to provide all of the documents requested, says **Mac McMillan**, chief executive officer of CynergisTek, an information technology security consulting company. McMillan advised a Texas hospital included in the initial audit.

Because initial documents requested also include non-HIPAA specific items such as demographic information about a hospital's market and patient population, and an organizational chart, prepare ahead of time by knowing where these documents are located, he suggests.

The audit is scheduled between 30 and 90 days from the date of the notice, but OCR does give five days' notice before auditors arrive, says McMillan. "Actually, my client got eight days' notice, which helped us make sure everyone who was likely to be interviewed by auditors, or involved in the audit, was onsite during those days." OCR estimates audits to take 3-10 days, depending on the organization being audited. McMillan says his hospital client's audit was one week long. *(Learn what to expect during an audit, p. 3.)*

Because you do not have a lot of time to educate people who may be involved in the onsite audit, set up your audit team now, suggests **Chris Apgar**, CISSP, president of Apgar & Associates, a Portland, OR-based consulting firm. "This will make preparation for the audit easier because everyone will understand their role." *(See how to set up an audit team, p. 3.)*

Results of the 20 audits conducted during the pilot program will be used to evaluate the audit tool as well as the audit process, and to make changes if needed before the remaining 130 audits scheduled for 2012 are conducted after the pilot program's completion in the spring, says Apgar. Although larger organizations such as health plans, claims clearinghouses, and larger hospitals expected to be audited earlier rather than later in the process, the pilot program included a dental office, a long-term care facility, and a pharmacy. "I am sure these smaller organizations were surprised at their inclusion, but it is important to smaller providers that the pilot included them," he says.

EXECUTIVE SUMMARY

At press time, results of the HIPAA compliance audit pilot program and any resulting changes in the process or the audit tool were expected to be finalized in the spring. Lessons learned by organizations in the pilot phase of the program include:

- Identify and locate key HIPAA policies, procedures, and documentation. Develop a system that ensures quick access before you receive the 10-day notice to provide information.
- Have an up-to-date risk analysis related to privacy and security rules.
- Evaluate your business associate program to ensure you have documented your management of those relationships.
- Establish your HIPAA compliance audit team, and assign specific responsibilities before your receive an audit notice.

OCR auditors and staff members will be able to ensure that the audit tool is practical for smaller as well as larger organizations, which will help small hospitals, specialty hospitals, and freestanding surgery centers, he adds.

Prepare now

Although there is no way to know if your organization will be one of the 130 additional audits conducted in 2012 or in upcoming years, you can take steps now to prepare, suggests McMillan.

"Even if you don't know exactly what documents will be requested in your initial notice, there are a number of items that can be expected," he says. "Ten calendar days is not a lot of time to gather documents, so the first step is to know where everything is located."

Apgar says, "You don't have to centralize all policies and documentation related to HIPAA privacy and security issues, but you do need to have a way to quickly access them."

Assigning the responsibility to one or two people and creating an index of all documents that might be requested is a good start, he says. Identify the documents, their location, and contact information for the people who can access them easily.

Be sure you have a current risk analysis, says Apgar. "The rule does not specify how often a provider must conduct a risk analysis, but a good guideline is annually or whenever there is a change that might affect security risk levels," he points out. Adding a new business associate or introduction of a new system such as electronic health records are points at which a risk analysis should be done, he says.

Along with the documentation of the risk analysis, auditors will want to see corrective action plans and data to show progress in remediation of areas that were identified as non-compliant, says Greene. "This is very important if the hospital is aware of a potential weakness in compliance," he says. "Demonstrate to auditors that you are aware of the issue, have identified steps to correct it, and are making progress."

McMillan says, "Pay close attention to how you manage your business associate relationships, and document your efforts to carefully control information released to them. This requires more than showing a copy of an agreement. Document due diligence related to flow of information, procedure for termination, and process to jointly handle breaches." *(For information about business associates and HIPAA, see "Data breaches attributed to business associates increase,"* HIPAA Regulatory Alert, *February 2012, p. 1.)*

Set up an audit team

"OCR has hinted that there will be no hesitance to levy fines on non-compliant organizations identified in the audits," says Apgar. These fines will be used to support the audit program, so although it was originally described as a non-punitive program, it is important to take the process seriously to avoid potential fines, he adds.

Because the HITECH Act has given OCR the ability to assess significant financial fines, this is not the time to play the odds, warns Greene. "Although your chance of being one of the 130 organizations audited this year is small, look at this as a way to get your house in order," he says. "Perform a thorough assessment, make sure your HIPAA training programs are effective, and even if you prepare for an audit that doesn't happen, your hospital and your patients benefit."

SOURCES

For more information about preparation for HIPAA compliance audits, contact:

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Get these documents ready for an audit

Although there is no way to know exactly what documents you will be asked to provide in the initial HIPAA compliance audit notice from the Department of Health and Human Services' Office for Civil Rights (OCR) there are some items you can expect to see on the list, according to experts interviewed by HIPAA Regulatory Alert:

• all policies related to compliance with HITECH privacy and security requirements;

• documentation of risk analysis for the organizations;

• business associate agreements and documentation of provider management;

• HIPAA training program for employees;

• names of compliance officers along with organizational chart for the provider;

• demographic information about the hospital, the patient population, and the medical staff.

Some of the documents you should also be prepared to provide include:

• List of terminated employees as well as new hires.

"This list will be used by the auditors to see how well you disable access for terminated employees and control access to protected health information for new employees," explains **Mac McMillan**, chief executive officer of CynergisTek, an information technology security consulting company, who advised a Texas hospital included in the initial audits. Although you might have a policy that describes the process, this list will give auditors an opportunity to see if your actual practice follows the policy.

• Proof of employee training on privacy and security requirements.

Having a HIPAA training program and proving that employees receive the training are different things, points out **Adam Greene**, partner at the Washington, DC, law firm of Davis Wright Tremaine. Your documentation should describe the content of the training program, who provides the training, and how you ensure that all employees are trained, he adds.

• List of complaints related to privacy.

Be prepared to share a list of complaints you've received from patients, family members, or employees about data privacy or security issues, says Greene. Documentation should include the complaint, who handled it, how it was handled, and how it was resolved.

There are also some documents you should choose to include, suggests Greene.

• Description of your best practices.

"The audit contract calls for identification of best practices, so if you know you have an effective poster campaign or HIPAA hotline, provide documentation of the program's success," suggests Greene.

• Improvement plans related to privacy and security.

Almost all risk analyses result in identification of areas that can be improved, points out Greene. "If you know you have a weakness, don't try to hide it and hope the auditors don't notice," he says. "Provide documentation of a plan to address a non-compliant area, show that you have prioritized the issues, and provide the results of evaluations of your efforts to come into compliance." ■

What can you expect when auditors arrive?

The initial notice of audit from the Department of Health and Human Services' Office for Civil Rights (OCR) asks for a significant amount of documentation and information to be submitted within 10 days of the notice date, but that will not be the end of information for which you'll be asked, says **Mac McMillan**, chief executive officer of CynergisTek, an information technology security consulting company, who advised a Texas hospital included in the initial audits.

"A pre-audit conference call is made a minimum of five days before the visit," explains McMillan. His client's audit occurred six weeks after the initial notice, but it could have been scheduled anytime during a 30-90 day period from the date of the notice, he says. During the conference call, additional documentation and a list of people with whom the auditors want to meet is provided. "The call is helpful because you can make sure your key people are onsite when the auditors arrive and prepared to meet with them," McMillan adds.

His client provided a conference room for the auditors to use during the visit and gave them guest privileges on the hospital's wireless network, he says. "The privacy and security officers cleared their schedules so they were available to the audit team the entire week," he explains. In addition to the privacy and security officers, make sure other administrative and medical staff leaders are aware of the audit and are prepared to meet with auditors, he suggests.

Auditors did walk around the facility, says McMillan. "Let your entire staff know the auditors will be onsite and that they may talk with employees at any time," he says. The walking tour and talks with employees are two ways the auditors can check to see if the hospital policies are communicated and understood by all employees.

Remember that an auditor's job is to uncover weaknesses, points out McMillan. "After you submit your initial documentation, you don't know if the auditors are going to audit your entire program or focus on specific areas," he says. They have the option of conducting the audit either way, he adds.

Immediately following the onsite visit, the hospital received an outline of audit results along with specific areas in the privacy and security rules in which the hospital was deficient, says McMillan. "This outline gives hospital leaders a good idea of what the final report will include," he says. "The hospital had 10 days to respond to the final report and provide any additional documentation that demonstrated compliance." ■

Do now: Set up in-house audit team

A well-prepared team that understands roles and responsibilities when a notice of a HIPAA compliance audit is received is essential for every

organization and should be established long before a notice is received, suggests **Chris Apgar**, CISSP, president of Apgar & Associates, a Portland, OR-based consulting firm. Educate them about the purpose of the audit, and give each person specific responsibilities, he says.

"Define who the caretakers of the auditors will be when they are onsite, and make sure they understand their role in the audit," Apgar says.

One way to test your documentation index and the effects of your audit team's education is to conduct a "fire drill," recommends **Adam Greene**, partner at Davis Wright Tremaine, Washington, DC. Deliver a mock audit notice to the administrative offices. If plans go well, the chief executive officer is immediately notified that the letter has arrived and requests for information are disseminated quickly. "Making sure the letter doesn't sit unopened on someone's desk is important," Greene points out.

Set a deadline of gathering all requested documents in 6-7 days from the date of the notice so you have time to identify missing items.

In addition to testing your ability to respond to the audit notice in 10 days, conduct a mock HIPAA compliance audit throughout your organization, suggests Apgar. Don't focus only on policies and procedures, or the information technology department, he says. "Auditors are likely to walk throughout your facility, in multiple departments, so take your own walk through the hospital," he says. "Look for shared computers that have passwords on notes taped to the monitor or screens that can be easily read by members of the public," he says.

Mac McMillan, chief executive officer of CynergisTek, an information technology security consulting company, says, "Make sure all employees understand your privacy and security policies and the purpose of the audit. The greatest risk in a HIPAA compliance audit is not your information technology staff; it is other employees." ■

Proposed rules published for stage 2 meaningful use

Comment period ends May 7, 2012

The Office of the National Coordinator for Health Information Technology (ONC) and the Centers for Medicare and Medicaid Services (CMS) have issue Notices of Proposed Rulemaking that are open for comment until May 7, 2012.

The CMS proposed rule applies to stage two of the "Meaningful Use" rule and new requirements that participants in the Electronic Health Record (EHR) Incentive Programs will have to meet to demonstrate meaningful use in the program. The companion ONC rule discusses the certification capabilities and standards and tests that Certified EHR Technology (CEHRT) would have to do. Although the two rules overlap some, they are different.

A few of the items included in the proposed rule include:

- Nearly all of the Stage 1 meaningful use core and menu objectives would be retained for Stage 2 meaningful use.
- "Provide patients with an electronic copy of their health information" objective would be removed because it would be replaced by an electronic/online access" core objective.
- For eligible hospitals and CAHs, the set of CQMs beginning in 2014 would align with the Hospital Inpatient Quality Reporting (HIQR) and The Joint Commission's hospital quality measures.

The proposed rule for Stage 2 Meaningful Use also includes a minor delay of the implementation of the onset of Stage 2 criteria from the current 2013 implementation date to 2014.

To access the CMS proposed rule, "Medicare and Medicaid Programs: Electronic Health Record Incentive Program-Stage 2 Meaningful Use," go to federalregister.gov/a/2012-4443.

To access the ONC proposed rule, "Health Information Technology; Implementation Specifications, and Certification Criteria: Electronic Health Record Technology, 2014 Edition," go to federalregister.gov/a/2012-4430. ■

Consumer privacy is subject of FTC report

The Federal Trade Commission (FTC) has issued a final report outlining best practices for businesses to protect the privacy of American consumers and give them greater control over the collection and use of their personal data.

The report proposes a privacy framework that would have no legal effect on HIPAA-covered entities. However, some of the practices proposed in the report, such as automated mechanisms to track access of information and restoration of patient consent to sharing information, might be considered as the Department of Health and Human Services updates the HIPAA privacy rule to incorporate more stringent privacy protections.

To see a copy of the report, go to http://1.usa.gov/H3LgcC. ■

Legal Review & Commentary

A Monthly Supplement to HEALTHCARE RISK MANAGEMENT

Failure to detect latex allergy leads to death, $4.7M verdict

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News: A woman underwent a hysterectomy at a local hospital. After surgery, the woman woke up complaining of itching and nausea, and she had blisters on her lips. She was given over-the-counter drugs to assist with these symptoms. The woman later had trouble breathing and developed ventricular tachycardia. Four days after surgery, the woman died. A Mississippi jury returned a verdict in favor of the plaintiff in the amount of $4.7 million.

Background: A 29-year-old mother of two young sons received a hysterectomy and partial vulvectomy at the recommendation of her gynecologist. The surgery was performed by the woman's OB/GYN and his partner. The woman regained consciousness after surgery but complained of itching and nausea. She also had blisters on her lips and redness of the face. The woman was provided with Benadryl for the itching and another drug for her itching.

The night of the surgery, the woman's husband heard the woman gasping and making gurgling sounds. When she was unable to respond to him, the husband contacted the nurse who found the woman having trouble breathing. An emergency department (ED) physician immediately intubated the woman. Due to the intubation, the woman was unable to breathe on her own and was placed on a ventilator and transferred to the intensive care unit. Despite this intervention, the woman exhibited no neurological function following the cardiac arrest and was taken off the ventilator. She died four days later.

Despite this intervention, the woman exhibited no neurological function following the cardiac arrest and was taken off the ventilator.

The woman's husband brought a wrongful death action against the hospital and alleged that the hospital and physicians were negligent in failing to discover that the woman was allergic to the latex gloves used by the surgeon. He asserted that the woman died as a result of the latex allergy, which caused her cardiac arrest.

At trial, the husband introduced the hospital's latex allergy policies and procedures which provided, in part, that "all patients should be assessed for [a] latex allergy." The policy also provided that patients should be questioned about certain items, including apple, banana, and chestnut allergies (ABC food allergies), which would indicate a patient was at high risk for such an allergy. The woman's allergy list included sulfa, Lorcet, dairy products, seafood, and adhesive tape. On the nursing admission history, prepared a week before surgery, the same allergies were listed. The form also included a section titled "Latex Allergy Alert" which did not appear to be adequately completed by the nurse despite the woman

FINANCIAL DISCLOSURE: Author **Greg Freeman**, 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. **Radha V. Bachman**, co-author, and **Leilani Kicklighter**, co-author, have no relationships to disclose.

admitting to having an allergy to chestnuts (one of the ABC food allergies' foods). The doctor never was informed that the woman had several of the ABC food allergies.

Had an allergy been noted on the woman's chart, the hospital's policy would have required an allergy sticker on the chart, signage on the patient's door, notification to central supply and purchasing regarding any special supplies or products needed, and notification to food and nutrition to ensure servers not wear latex gloves when serving the patient's food. The nurse maintained during her testimony that the patient did not give her any information regarding being allergic to latex and that based on her understanding of the policy, notification was only required if the patient had affirmatively acknowledged a known allergy to latex.

Experts for the parties disagreed on whether the woman had a latex allergy. Ultimately, however, the jury returned a verdict in favor of the woman's husband in the amount of $4.7 million. The award was split such that $516,000 was paid to the wrongful death beneficiaries and $4.2 million to the woman's estate.

The hospital appealed the finding. The court of appeal rejected the hospital's contention that the verdict was inconsistent as a result of finding that the hospital was found to be at fault while the physician was not at fault. In its holding, the appellate court found that the nurses had a separate duty to assess the woman for a latex allergy or sensitivity and to notify the physician of any such allergy or sensitivity.

Additional information was provided which showed that the duties related to assessing for latex allergy were generally required and were not solely required by the hospital's policies. Evidence was shown that the nurses did not follow the policies. There was also no evidence to provide that had the nurses acted within the standard of care, the doctors would have heeded their warnings.

At trial, the husband introduced the hospital's latex allergy policies and procedures which provided, in part, that "all patients should be assessed for [a] latex allergy."

What this means to you: Latex comes from the rubber plant sap. Historically, all medical gloves were made of rubber. After each use, healthcare providers filled them with water to test for leaks. If a leak was found, the glove was discarded; if not, it was washed, inside and out, packaged in a surgical towel, and sterilized for reuse. Washing apparently reduced the latex concentration, as we recognized latex reactions were dramatically low.

Latex is a component of many household and office materials and tools, such as garden hoses, automobile hoses and connections, elastic bands in clothes, and elastic bands used to hold hair and papers. Many of the medical supplies and equipment used in hospitals and other healthcare facilities also contain latex including, for example, gloves, urinary catheters, facemasks, tourniquets, bandages, wound drains, injection ports, rubber syringe stoppers, bulb syringes, mattresses on stretchers, dental devices, and stethoscopes.

The powder in latex gloves also has latex, which a problem when the gloves are removed and the powder is disbursed into the air and into the air conditioning system. Powder containing latex has been found in the hair and beards of members of surgical teams in operating rooms that are supposed to be sterile environments. As a result, experts agree that facilities should attempt to schedule latex-sensitive patients undergoing surgery as the first case of the day, when aerosolized latex particles in the operating room and elsewhere are at their lowest. Generally speaking, however, latex allergies do not have a significant public presence.

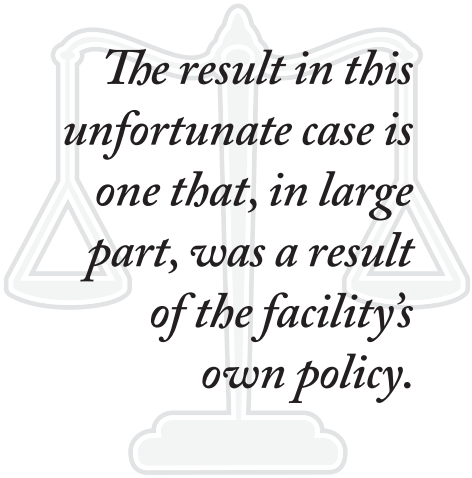
Nevertheless, allergies are funny things. A person can eat tomatoes and ketchup every day and have no problem until one day the person develop hives, a rash, or an allergic reaction. Usually this reaction would not be attributed to tomatoes since tomatoes were consumed by the person regularly prior to the reaction. Often, individuals live with these allergy symptoms by taking an antihistamine until a significant reaction occurs and the person is forced to seek medical attention. Other times, these symptoms dissipate on their own, though they can suddenly exacerbate as well.

Latex allergies can play the same game, such as this patient who had an allergy to tape. The symptoms of this allergy probably were localized where the tape was placed and dismissed on that basis. From the facts

provided here, there is no indication as to whether there was any further questions regarding the signs and symptoms of the tape reaction. Many people forget to mention food allergies unless it is known to be significant from the point of causing life-threatening issues such as respiratory difficulties.

Nurses and physicians/surgeons must be more cognizant of this failure to be forthcoming and specifically query about food, make-up, and other common non-medical type allergies. For example, in today's widespread use of propofol, an anesthetic agent that has a soy base, in surgical settings, it is particularly important to solicit if a patient has a sensitivity or allergy to soy or soy products. Should a patient in respond that they have or have had sensitivity or allergy to a substance, drug, or food, further discussion should be undertaken. This information is specifically brought to the attention of the physician/surgeon/nurse practitioner and, in the case of surgery, to the anesthesiologist as well. Documentation of such information sharing should be done as well. The affixing of the allergy sticker on the front of the chart — and with the implementation of the electronic medical record (EMR), we soon will have no front of the chart — is a policy and standard of practice. However, it is possible that it often is ignored and not addressed in the medical record.

In a healthcare setting, the two major strategies for management are one, prevention and treatment of occupational latex allergy in employees, and two, the safe care of the latex-allergic patient. The cornerstone of latex allergy treatment is avoidance. As a result of recognition of risk of latex allergy and the potential for anaphylaxis, there was a significant focus on the use of latex gloves and other medical equipment and supplies containing latex. In the late '90s and early 2000s many healthcare facilities went latex free and/or powder free. During the initial employment health screen, many facilities have a latex allergy screen that all employees must complete. This screen is updated annually as sensitivities can evolve as mentioned above. In many facilities, this screen is a component of the nursing intake history. Many facilities have pointedly made it a policy to purchase only latex-free equipment and supplies, and manufacturers have bowed to that pressure. Again, many facilities have a surgical latex allergy protocol for those patients with a known latex allergy. In 1998, the American Academy of Dermatology's Committee on Latex Allergy made suggestions in its position paper with respect to the use of latex. *(See list, p. 4.)*



The result in this unfortunate case is one that, in large part, was a result of the facility's own policy.

The result in this unfortunate case is one that, in large part, was a result of the facility's own policy. Risk managers preach "policy must follow practice" and "practice must follow policy," and of course both must follow accepted standards. However, department staff don't always validate that statement is the case. One exception is the failure modes and effects analysis (FMEA) process — a very involved but valuable evaluation tool — which is not undertaken for each policy and procedure.

In addition to conducting a root cause analysis (RCA) of this event, the risk manager should review in detail the current policy and procedure(s) relating to latex allergies including the latex/powder-free program status. Based on these finding, the risk manager should undertake to convene a small group of frontline nursing staff members and a small group of physicians and surgeons to discuss the issues and how it can be addressed more effectively. Both groups can come together to collaborate on how best to address the issue in the best interests of the patient's safety in the facility. Changes identified then should be implemented and an educational program provided to all physicians and employees relating to latex allergies, signs and symptoms, and equipment and supplies that might contain latex. This issue is one that cannot be addressed once and then put on the shelf until a subsequent adverse incident occurs. The population in general, which includes the medical and facility staff, can be latex allergy-free one day and subsequently have a significant allergic reaction up to and including anaphylaxis. Emphasize the signs and symptoms of allergy. The physician from the ED who responded to the breathing difficulties apparently did not consider latex allergy reaction and anaphylaxis, even with face redness, lip blis-

ters, itching, nausea, and difficult breathing after surgery. If he had, perhaps appropriate treatment could have been initiated. One wonders if the endotracheal (ET) tube placed by the ED physician was latex-free.

A part of the educational program to physicians/surgeons and nurses should include an emphasis on recognition of signs and symptoms of an allergic reaction and particularly those that show up after a surgical procedure. In this situation, one would question whether this was a latex-free facility and if staff members were using latex-free ET tubes throughout the facilities. With documentation of an allergy to tape, one would question if that allergy were taken into consideration when dressing the post-op wound, when taping the ET, or taping the Foley or intravenous line?

Another relevant question is what social and medical history was noted in this surgeon's office record. Did the surgeon review the patient's medical record in detail before commencing the surgical procedure? One wonders if the allergy to tape were noted as a part of the timeout process.

One very distressing comment in this scenario is the last one before the end of the fact pattern: "There was also no evidence to provide that had the nurses acted within the standard of care, the doctors would have heeded their warnings." This statement presents a significant challenge for risk managers, nursing, administrators, and members of healthcare facility boards. Specifically, the challenge is how to bridge this apparent disconnect, especially in the facility context. Is it possible that this disconnect might be more widespread throughout healthcare than recognized? This potential disconnect is a significant impediment to providing safe, trusted healthcare in each and every healthcare environment.

Reference

Mississippi, Court of Appeals, Case No. 2009-CA-01796-COA. ✦

American Academy of Dermatology's Committee on Latex Allergy

Position Paper: Use of Latex (Excerpt)

• Physicians should take careful histories before exposing patients to latex-containing devices. They also should indicate patients' allergy status in their charts and at their bedsides.

• Physicians should offer a latex-safe environment, no one should wear powdered latex gloves, only non-latex gloves should be used to directly examine the patient, and all latex-containing devices they regularly come in contact with should be removed or covered.

• All patients who have had type I allergic reaction to latex should be briefed about avoiding latex-containing products and potentially cross-reacting foods, such as avocado or banana. These patients also should carry an Epi-Pen and wear medical alert bracelets indicating their status.

• All medical and dental facilities should use only powder-free gloves with low latex-antigen levels.

• All emergency medical facilities, including trauma surgery rooms, should be latex safe because proper screening of these patients is not usually feasible.

• All medical facilities should use non-latex gloves for general physical exams, especially for those in which mucosal tissues such as the mouth, vagina, or rectum are inspected.

• All food workers at restaurants, hospitals, and food plants should use only non-latex gloves.

• All medical offices should educate employees about latex allergy and have a policy to manage latex-sensitive patients.

Source: Cohen DE, Scheman A, Stewart L et al. *J Amer Acad Dermatol* 1998; 39(1):98-106. ✦

Healthcare Risk Management

2012 Reader Survey

In an effort to learn more about the professionals who read *HRM*, we are conducting this reader survey. The results will be used to enhance the content and format of *HRM*.

Instructions: Fill in the appropriate answers. Please write in answers to the open-ended questions in the space provided. Return the questionnaire in the enclosed postage-paid envelope by **July 1, 2012.**

1. Please fill in all the areas for which you are responsible for risk management in your facility or system.

- O A. acute care
- O B. outpatient services
- O C. same-day surgery
- O D. home health services
- O E. rehabilitation services
- O F. extended care facility
- O G. hospice

In future issues of *HRM*, would you like to see more less coverage of the following topics?

	A. more coverage	B. less coverage	C. about the same amount
2. compliance	O A	O B	O C
3. malpractice	O A	O B	O C
4. patient safety	O A	O B	O C
5. patient restraints	O A	O B	O C
6. informed consent	O A	O B	O C
7. patient confidentiality/privacy	O A	O B	O C
8. patient falls	O A	O B	O C
9. medical errors	O A	O B	O C
10. root-cause analysis	O A	O B	O C
11. sentinel event reporting	O A	O B	O C
12. accreditation issues/audits	O A	O B	O C

13. Do you find the *Legal Review & Commentary* insert in *HRM* helpful?

O A. yes O B. no

14. Including *HRM*, which publication or information source do you find most useful, and why?

_____

_____

15. Do you plan to renew your subscription to *HRM*?

- O A. yes
- O B. no If no, why not?_____

_____

16. Are the articles in *HRM* written about issues of importance and concern to you?

- O A. always
- O B. most of the time
- O C. some of the time
- O D. rarely
- O E. never

17. How would you describe your satisfaction with your subscription to *Healthcare Risk Management* newsletter?

- O A. very satisfied
- O B. somewhat satisfied
- O C. somewhat dissatisfied
- O D. very dissatisfied

18. Which best describes your title?

- O A. risk manager or risk management director
- O B. VP or assistant administrator
- O C. director/manager of quality
- O D. medical director or director of nursing
- O E. other_____

19. Please indicate all of the activities for which you have primary management responsibility.

- O A. risk management
- O B. compliance
- O C. legal
- O D. quality or utilization review
- O E. other_____

20. Which area at your facility triggered the most incident reports in 2011?

- O A. emergency department
- O B. medical
- O C. obstetrics
- O D. operating room
- O E. other _____

21. *HRM* has been approved for 15 nursing contact hours using a 60-minute contact hour by the American Nurses Credentialing Center's Commission on Accreditation. If you participate in this CNE activity, how many hours do you spend in the activity each year?_____

Please rate your level of satisfaction with the following items.
A. excellent B. good C. fair D. poor

22. Quality of newsletter	○ A	○ B	○ C	○ D
23. Article selections	○ A	○ B	○ C	○ D
24. Timeliness	○ A	○ B	○ C	○ D
25. Length of newsletter	○ A	○ B	○ C	○ D
26. Overall value	○ A	○ B	○ C	○ D
27. Customer service	○ A	○ B	○ C	○ D

28. On average, how many people read your copy of *HRM*?

○ A. 1
○ B. 2
○ C. 3
○ D. 4
○ E. 5 or more

29. What is the bed size of your facility/system?

○ A. fewer than 200 beds
○ B. 200 to 400 beds
○ C. 401 to 600 beds
○ D. 601 to 800 beds
○ E. more than 800 beds

30. On average, how many articles in *HRM* do you find useful?

○ A. none
○ B. 1-2
○ C. 3-4
○ D. 5-6
○ E. 7 or more

31. What do you like most about *HRM* newsletter?

32. What do you like least about *HRM* newsletter?

33. Please list the top three challenges you face in your job today.

34. What issues would you like to see addressed in *HRM* newsletter?

Contact information _____